

Moxibustion for Correction of Breech Presentation

A Randomized Controlled Trial

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Context.—Traditional Chinese medicine uses moxibustion (burning herbs to stimulate acupuncture points) of acupoint BL 67 (Zhiyin, located beside the outer corner of the fifth toenail), to promote version of fetuses in breech presentation. Its effect may be through increasing fetal activity. However, no randomized controlled trial has evaluated the efficacy of this therapy.

Objective.—To evaluate the efficacy and safety of moxibustion on acupoint BL 67 to increase fetal activity and correct breech presentation.

Design.—Randomized, controlled, open clinical trial.

Setting.—Outpatient departments of the Women's Hospital of Jiangxi Province, Nanchang, and Jiujiang Women's and Children's Hospital in the People's Republic of China.

Patients.—Primigravidas in the 33rd week of gestation with normal pregnancy and an ultrasound diagnosis of breech presentation.

Interventions.—The 130 subjects randomized to the intervention group received stimulation of acupoint BL 67 by *moxa* (Japanese term for *Artemisia vulgaris*) rolls for 7 days, with treatment for an additional 7 days if the fetus persisted in the breech presentation. The 130 subjects randomized to the control group received routine care but no interventions for breech presentation. Subjects with persistent breech presentation after 2 weeks of treatment could undergo external cephalic version anytime between 35 weeks' gestation and delivery.

Main Outcome Measures.—Fetal movements counted by the mother during 1 hour each day for 1 week; number of cephalic presentations during the 35th week and at delivery.

Results.—The intervention group experienced a mean of 48.45 fetal movements vs 35.35 in the control group ($P < .001$; 95% confidence interval [CI] for difference, 10.56-15.60). During the 35th week of gestation, 98 (75.4%) of 130 fetuses in the intervention group were cephalic vs 62 (47.7%) of 130 fetuses in the control group ($P < .001$; relative risk [RR], 1.58; 95% CI, 1.29-1.94). Despite the fact that 24 subjects in the control group and 1 subject in the intervention group underwent external cephalic version, 98 (75.4%) of the 130 fetuses in the intervention group were cephalic at birth vs 81 (62.3%) of the 130 fetuses in the control group ($P = .02$; RR, 1.21; 95% CI, 1.02-1.43).

Conclusion.—Among primigravidas with breech presentation during the 33rd week of gestation, moxibustion for 1 to 2 weeks increased fetal activity during the treatment period and cephalic presentation after the treatment period and at delivery.

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IN CASES OF BREECH presentation at the onset of labor, delivery is associated with additional risks: for the mother, cesarean delivery and for the neonate, physical injury. Breech presentation is common in the midtrimester

pregnancy and the incidence decreases as the pregnancy approaches term because of spontaneous version.¹⁻⁴ It is reasonable to assume (although not firmly established) that fetal activity plays an important role in spontaneous version.⁵⁻⁹ The incidence of breech presentation at delivery can be reduced, but not eliminated, by the use of external cephalic version (ECV).¹⁰

Since ancient times, traditional Chinese medicine has proposed moxibustion of acupoint BL 67 (Zhiyin) to promote

version of fetuses in breech presentation. Moxibustion is a traditional Chinese method that uses the heat generated by burning herbal preparations containing *Artemisia vulgaris* (mugwort) (the Japanese name is *moxa*) to stimulate acupuncture points. Acupoint BL 67 is beside the outer corner of the fifth toenail.

At present, there are no randomized, controlled clinical trials to evaluate the efficacy of this therapy. The 2 published Chinese studies^{11,12} are not randomized and are based on a mixed population of primipara and multipara subjects stimulated at varying times between the 28th and 38th weeks of pregnancy. Although both studies give encouraging results and stimulate reflection regarding possible mechanisms of action, they do not allow definitive conclusions regarding efficacy because they are not randomized, little information is provided about the population sample, and the times at which stimulation is applied are wide ranging.

Cardini et al¹³ identified the stage of pregnancy at which stimulation should commence and the parity status of the groups studied as primary factors to ensure the reliability of a clinical trial concerning spontaneous or induced correction of breech presentation.

Data in the literature concerning the probability of spontaneous correction indicate that correcting breech presentation before the 32nd week is useless.¹⁴⁻¹⁶ There is also a sharp differentiation between multigravidas (high likelihood of spontaneous correction of breech presentation, even between the 32nd and 35th weeks) and primigravidas or multigravidas with a previous breech presentation at term (low probability of spontaneous version after the 32nd week).¹⁵⁻¹⁷

Gottlicher and Madjaric,^{15,16} by ultrasound examination of 4066 pregnant women, defined the likelihood of spontaneous correction of breech presentation from the 33rd week of pregnancy as 15.5% (95% confidence interval [CI], 2.8%-28.2%) for primigravidas and 57.5% (95% CI, 36.3%-78.7%) for multigravidas.

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Westgren et al,¹⁷ by ultrasound screening of 4600 women in the 32nd week of pregnancy, identified 310 cases (6.7%) of breech presentation, which were prospectively studied until birth. Rates of spontaneous cephalic version varied, according to whether subjects were primigravida (46%), multigravida with a previous breech presentation (32%), or multigravida with no previous breech presentation (78%). All the studies available report data relating to Western populations and we have been unable to retrieve any information regarding the spontaneous version rate from the 33rd week to term among Chinese pregnant women.

Given this background, Cardini and Marcolongo,¹⁸ in a retrospectively controlled clinical trial, compared 23 primigravidas treated for breech presentation by moxibustion in the 32nd and 33rd week with a retrospective, untreated group at the same stage of pregnancy. The difference in prevalence of breech presentation showed borderline statistical significance ($P = .05$). Thus, the subgroup of primigravidas with breech presentation at the 33rd week of pregnancy seemed to be the ideal population for a randomized, controlled clinical trial.

We undertook this study to evaluate the efficacy and safety of moxibustion on acupoint BL 67 in correcting breech presentation in a population of primigravidas treated since the 33rd week of pregnancy and to evaluate the efficacy of this technique in increasing active fetal movements (AFMs).

These 2 main objectives are consistent with the hypothesis that the use of moxibustion in women whose fetuses are breech in the 33rd week of pregnancy will (1) increase fetal activity; (2) reduce the proportion of fetuses that remain in a nonvertex presentation and, hence, decrease the need for ECV; and (3) decrease the incidence of breech presentation at birth. A secondary aim of the study was to assess the efficacy of 2 different dosages of moxibustion.

METHODS

This was a randomized, controlled, open clinical trial of subjects treated by moxibustion since the 33rd week of pregnancy (intervention group) vs untreated subjects (control group). Subjects with persistent breech presentation after 2 weeks' treatment (intervention group) or observation (control group) could undergo ECV. Moxibustion in the early third trimester and ECV in late pregnancy are the standard care for breech presentation in both the centers involved in the trial. Thus (and also for ethical reasons), the availability of ECV was maintained for all subjects recruited.

Subjects were included if they were primigravidas, in the 33rd week of gestation (from 32 weeks + 1 day to 33 complete weeks, based on the last menstruation date and ultrasound data), with breech presentation diagnosed by ultrasound within 24 hours of randomization, and with normal fetal biometry (biparietal diameter and abdominal circumference between the 10th and 90th percentiles). Subjects were excluded if they had pelvic defects, previous uterine surgery, uterine malformation or fibromyoma of diameter greater than 4 cm, fetal malformation, twin gestation, tocolytic therapy during pregnancy, risk of premature birth (uterine hypercontractility and/or initial shortening or dilatation of the neck, with a Bishop score ≥ 4), or pathological pregnancy (eg, intrauterine growth retardation, gestosis, serious infections, placenta previa, polyhydramnios, oligohydramnios) judged by the investigator to contraindicate inclusion in the study. Subjects refusing to undergo treatment were also excluded.

Study Procedures

The trial was conducted from April 1995 through August 1996 in the Women's Hospital of Jiangxi Province, Nanchang, People's Republic of China. A few subjects (23) were recruited in the nearby Jiujiang Women's and Children's Hospital, also in Jiangxi Province. The subjects were recruited during the routine management of normal pregnancies in the outpatient department. All procedures were executed by midwives (with the supervision of physicians) except ultrasound examinations and ECVs. The protocol followed the ethical standards of the Declaration of Helsinki.

Pregnant women fulfilling all criteria of the study were asked to participate. Interested subjects gave oral informed consent. Subjects had an ultrasound scan at the 33rd week. On the day of the ultrasound scan by which breech presentation was confirmed, the selected subject was randomly assigned to 1 of the 2 groups. The sample was randomly allocated by numbered envelopes (randomized in groups of 10 by the computer program PACT, Version 2.0 [Glaxo-Wellcome, London, England], in Italy). Once randomized, subjects and investigators were aware of group assignment. All subjects recruited were advised to avoid or, at least, to ask the investigators about other interventions or therapies that could contaminate the results of the trial.

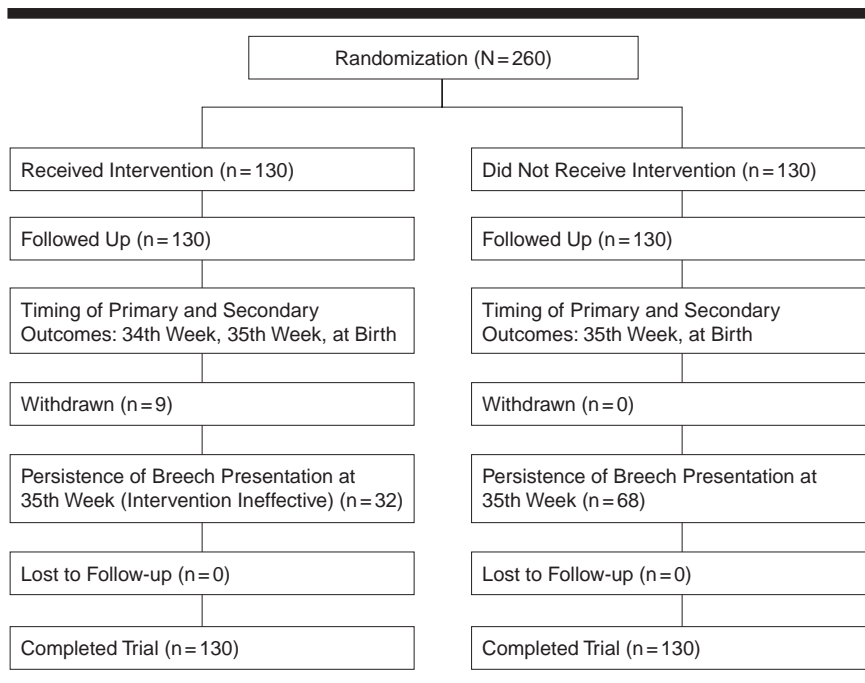
All subjects were asked to return after 2 weeks for an ultrasound check on presentation. If breech presentation persisted at this time, the subject (after giving informed consent) could undergo ECV in the following weeks.

All subjects were also asked to complete 2 record forms for AFMs, 1 for each of the 2 weeks subsequent to recruitment. These 2 forms were returned at the time of the ultrasound examination. Each record form had to be completed once daily for 7 days, reporting the number of AFMs counted in 1 hour (if possible, between 5 and 8 PM) and times of starting and finishing the count.

Finally, each subject was asked to report all significant details of her pregnancy and delivery during a personal or telephone appointment after she had given birth. The following specific information was collected: date of birth, place of birth, name and address of the obstetrician normally consulted, and name and address of the obstetrician present at birth. In this way, it was possible to consult other sources of information (obstetrician normally consulted, obstetrician present at birth, patient record forms) if the subject provided incomplete or unreliable information. Because almost all the enrolled subjects gave birth in the same hospital where they had been studied, information about delivery was reliable and easy to check.

If the subject belonged to the intervention group, she was admitted to the hospital to attend an instruction session within 24 hours of randomization, alone or with her partner or the person who was actually going to help administer the treatment. Teaching the technique for applying moxibustion at home included presenting the moxibustion material (cigar-shaped rolls containing *Artemisia*), locating of acupoint BL 67, and explaining the technique for stimulation of acupoint BL 67. During the therapy the subject relaxed in the sitting or semisupine position, with the partner sitting comfortably. The therapy was executed for 30 minutes (15 minutes per side) daily for 7 days in the first 87 subjects, and twice daily in the last 43 subjects. The subjects were allowed to choose the time, ensuring no interruptions in the therapy (if possible, between 5 and 8 PM). The intensity of moxibustion was just below the individual tolerability threshold, causing hyperemia from local vasodilatation but not burn blisters.

Reasons for discontinuing stimulation and consulting the investigator (abdominal pain, other suspected adverse effects, sensation that version had occurred before completion of 7 days' treatment) were explained to the subject, together with symptoms suggesting that version had occurred (decreased pressure in the epigastrium or hypochondrium, increased pressure in the hypogastrium, pollakiuria, a "different feeling" in the abdomen). The first stimulation session was executed in the hospital and the neces-



Profile of the randomized controlled trial.

sary materials for the following 6 days' stimulation were dispensed, together with the AFM record forms.

Last, an examination after 1 week's treatment (visit 2) was scheduled. Visit 2 included a check on presentation and collection of the AFM record form. The presentation check was by localization of fetal heartbeats and abdominal palpation (Leopold maneuvers). Ultrasound examination was performed only in the event that the techniques described herein failed or yielded uncertain findings.¹⁹ This was to avoid an excess of ultrasound examinations, given that an ultrasound examination was scheduled for the 35th week in all subjects. If cephalic version had not occurred, another week's treatment was advised if there were no adverse effects and the subject agreed to continue. Further *moxa* rolls were therefore dispensed to the subject with a second AFM record form. The frequency of the treatment was the same as in the first week. Visit 3 was scheduled and executed after a further week; the procedure was the same for all treated and untreated subjects as described herein (Figure).

Outcomes Measured

The primary outcomes were number of cephalic presentations at the 35th week and at birth and fetal motor activity. Secondary outcomes were compliance with treatment, observation of possible adverse effects in the intervention group and adverse events in both groups, number of cephalic versions after 1 and 2 weeks of treatment (ie, 34th and 35th weeks' gestation), number of

cephalic versions with 2 different dosages of moxibustion (once or twice daily), number and causes of cesarean deliveries, spontaneous and induced vaginal deliveries, and Apgar score at 5 minutes.

Statistical Analysis

On the basis of the study by Cardini and Marcolongo,¹⁸ for primigravidas it seemed possible to identify a 30% difference in the number of cephalic presentations at the 35th week and at term between the intervention and control groups, with an α significance level of .05 and greater than 90% power if 60 subjects per group completed the study. Given that the reliability of the preliminary study was limited because it was based on retrospective data and that we decided to assess the efficacy of 2 different dosages of moxibustion, the number of enrolled subjects was increased to 130 per group.

Even if not attributable to 1 of the causes specified in the research protocol, discontinuation of treatment did not entail the subject's exclusion from the study. Outcomes of all subjects recruited were analyzed on the basis of intention to treat. Every possible effort was made to ascertain the reason for withdrawal.

The statistical processing was performed using Epi Info, Version 6.04 (Centers for Disease Control and Prevention, Atlanta, Ga). The χ^2 test (supplemented, where necessary, by the Fisher exact test) and the *t* test were used for comparing qualitative and continuous variables, respectively. The measurement of effects was also described in terms of relative risk (RR) with 95% confidence intervals (CIs).

Table 1.—Comparability Between Intervention and Control Groups*

	Intervention Group (n = 130)	Control Group (n = 130)
Maternal age, y	25.5 (2.5)	25.2 (3.0)
Maternal height, cm	159.8 (3.9)	158.8 (3.8)
Neonatal weight, g	3234 (347)	3252 (420)
Neonatal cranial circumference, cm	34.2 (1.3)	34.3 (1.3)
Male, No. (%)	62 (47.7)	56 (43.1)
Legs straight at 33rd week, No. (%)	79 (60.8)	68 (52.3)

*Unless noted otherwise, values are expressed as mean (SD).

RESULTS

The total number of subjects was 260 (130 subjects per group), recruited, randomized, observed, or treated and followed up to delivery. No significant differences emerged between the intervention group and the control group (Table 1). Neither the placental localization and grading nor the amount of amniotic fluid at the 33rd week showed significant differences between the 2 groups.

The main results of the trial are summarized in Table 2. At the ultrasound check at the 35th week of gestation (2 weeks after the first visit), 98 (75.4%) of 130 fetuses in the intervention group were cephalic compared with 62 (47.7%) of 130 in the control group ($P < .001$; RR, 1.58; 95% CI, 1.29-1.94).

After 35 weeks of pregnancy, only 1 subject in the intervention group agreed to undergo ECV, but version was not obtained. Twenty-four subjects in the control group agreed to undergo ECV and in 19 subjects cephalic version was obtained. Despite this, the number of cephalic presentations at birth was still significantly different in the 2 groups: 98 (75.4%) of 130 in the intervention group compared with 81 (62.3%) of 130 in the control group ($P = .02$; RR, 1.21; 95% CI, 1.02-1.43). The results obtained excluding subjects treated with ECV are shown in Table 2.

Of the 98 cephalic versions obtained in the intervention group, 82 occurred during the first week and 16 during the second week of treatment. The cephalic or breech presentations observed at the second visit (35th week of pregnancy) remained unchanged up to term in all subjects treated and observed, except for those successfully treated with ECV.

Compliance and Adverse Effects and Events

The only intervention allowed for the subjects in the control group was ECV during the last 5 weeks of pregnancy. They were specifically questioned at the 35th week and after delivery and none reported having been treated with moxibustion or other therapies.

Among the intervention group only 1 subject failed to comply with the treatment schedule prescribed and discontinued the therapy. At the end of the first week of treatment 8 subjects withdrew from therapy, 3 on the advice of the obstetrician (for Braxton Hicks contractions, breech engagement, and maternal tachycardia and atrial sinus arrhythmia, respectively) and 5 subjects for unspecified reasons. All 9 subjects maintained the breech presentations of their fetuses to term and none of them were excluded from the statistical analysis.

The form of discomfort most frequently reported by both groups was a sense of tenderness and pressure in the epigastric region or in one of the hypochondria (epigastric crushing) attributable to the head of the breech fetus pressing against the maternal organs.

No adverse events occurred in the intervention group during treatment. After treatment, 2 premature births occurred (both at 37 weeks), 1 of which was preceded by premature rupture of the membranes (PROM). There were 4 PROMs in the intervention group.

Adverse events occurring in the control group included 3 premature births at 34, 35, and 37 weeks (the third was preceded by placental detachment with fetal distress) and 1 intrauterine fetal death (intrauterine growth retardation and oligohydramnios, spontaneous delivery at 38 weeks; growth was within normal limits at ultrasound examination at 35 weeks). The total number of PROMs in the control group was 12.

Active Fetal Movements

Regarding the efficacy of the moxibustion treatment in producing an increase in fetal motility, comparison between the 2 groups proved possible for only the first week of treatment (or observation) because all the subjects in the intervention group who achieved cephalic version in the first week of treatment filled in only the first of the 2 record forms used for the weekly AFM counts. The mean value for fetal movements recorded during a 1-hour observation period for 7 days was 48.45 for the subjects in the intervention group and 35.35 for the subjects in the control group (difference, 13.08; 95% CI, 10.56-15.60; *t* test, 10.215; *P* < .001).

Effects of 1 or 2 Moxibustion Sessions per Day

In the intervention group, the first 87 subjects received 1 stimulation per day, lasting 30 minutes, for 7 or 14 days (QD [*quaque die*] group). The last 47 subjects received 2 30-minute stimulations per day for 7 or 14 days (BID [*bis in die*] group). The 2 subgroups showed no significant

Table 2.—Main Results of the Trial

	No. (%)		<i>P</i>	RR (95% CI)*
	Intervention Group	Control Group		
Cephalic presentation at 35 wk	98/130 (75.4)	62/130 (47.7)	<.001	1.58 (1.29-1.94)
Cephalic presentation at birth	98/130 (75.4)	81/130 (62.3)	.02	1.21 (1.02-1.43)
Cephalic presentation at birth†	98/129 (76.0)	62/106 (58.5)	.004	1.30 (1.08-1.57)

*RR indicates relative risk; CI, confidence interval.

†Data exclude subjects treated with external cephalic version.

differences in amount of amniotic fluid during the 33rd week, frequency of straight or bent leg position during the 33rd week, placental localization, neonatal sex, treatment compliance, or adverse effects attributable to the treatment.

At the end of the first week of treatment in the BID group, 34 (79.1%) of 43 cephalic versions were obtained compared with 48 (55.2%) of 87 in the QD group (*P* = .007; RR, 1.43; 95% CI, 1.12-1.83).

During the second week of treatment, 15 additional cephalic versions were obtained in the QD group and only 1 additional version in the BID group. Thus, the following cephalic presentation results were observed on ultrasound examination at the end of the second week of treatment: 63 (72.4%) of 87 in the QD group and 35 (81.4%) of 43 in the BID group (nonsignificant difference). The same percentages were maintained to term.

Cesarean and Vaginal Deliveries

No statistically significant differences were found in the number of cesarean deliveries performed. In the intervention group, 46 cesarean deliveries (35.4% of births) were performed, 20 of which were with cephalic presentations and 26 of which were with breech presentations. The 20 cesarean deliveries in the cephalic presentations were performed for fetopelvic disproportion (14 cases), postterm pregnancy (3 cases), or fetal distress (3 cases). The 26 cesarean deliveries in the breech presentations were performed for PROM after week 37 (10 cases), large fetus (2 cases), fetal distress (1 case), oligohydramnios (2 cases), and unspecified causes (11 cases).

In the control group, 47 cesarean deliveries (36.2%) were performed, 21 of which were with cephalic presentations and 26 of which were with breech presentations. Indications for cesarean delivery in the subjects with cephalic fetuses included fetopelvic disproportion (11 cases, 1 of which was with oligohydramnios), fetal distress (4 cases, 1 of which was in a subject with toxemia of pregnancy), sacral rotation of the occiput (2 cases), placental insufficiency (1 case), toxemia of pregnancy (1 case), PROM (1 case), and deep transverse arrest (1 case). Cesarean deliveries in the breech presentations were performed

for PROM after 37 weeks (8 cases, 1 of which was with prolapse of the cord), oligohydramnios (3 cases), fetal distress (2 cases), large fetus (1 case), and unspecified causes (12 cases).

In both the intervention and control groups, cesarean delivery revealed 1 case of previously undiagnosed bicornuate uterus. In both cases, the presentation at birth was breech. Because they had been randomized, both cases were included in the statistical analysis of the data despite uterine malformations being exclusion criterion.

In regard to vaginal deliveries, the only significant difference between the 2 groups relates to the use of oxytocin, given to 7 (8.6%) of 81 subjects in the intervention group vs 25 (31.3%) of 80 in the control group (RR, 1.33 [95% CI, 1.13-1.56]; *P* < .001) before or during labor. In the intervention group, 2 vacuum-extractor and 1 forceps deliveries were performed and in the control group, 2 vacuum-extractor and 3 forceps deliveries were performed.

Apgar Scores

No neonates in the intervention group, but 7 in the control group, had Apgar scores of less than 7 at 5 minutes (Fisher exact test, *P* = .006). On grouping Apgar scores in the traditional manner, in the intervention group no neonates had Apgar scores less than 4 and 4 had scores 4 to 7; in the control group, 2 neonates had Apgar scores less than 4 and 12 had scores 4 to 7.

COMMENT

Moxibustion is a popular and much appreciated therapy for breech presentation in the People's Republic of China; thus, it would have been impossible to propose a "sham moxibustion" as a placebo for the control group.

Furthermore, moxibustion is a typical cheap, self-administered home therapy. This made blinding practically impossible. It was very difficult for investigators to persuade subjects to accept randomization and the consequent risk of having to do without the therapy. Consent was often obtained because of the availability of ECV later in pregnancy, but this is a much less popular and somewhat feared therapy; thus, only a few subjects, mostly belonging to the control group, opted for this solution.

Because the main results of the trial are of a qualitative type and were measured objectively (ultrasound), we believe that the lack of blinding and a placebo does not undermine the validity of the results. This is not entirely the case when considering fetal movement count, which was subjectively assessed.

The choice of sample (primigravidas at the 33rd week of gestation) appears to have been appropriate because the presentation did not change after the 35th week in any of the subjects (except for those undergoing ECV). This confirms the rarity of spontaneous fetal version (to either breech or cephalic presentation) among primigravidas after the 35th week.¹⁶

Two half-hour stimulations per day proved more effective in producing cephalic version than a single stimulation. On prolonging the therapy by 1 week in those cases in which cephalic version was not achieved, this difference in efficacy was partly, although not entirely, annulled. Of the 2 dosages, then, twice-daily stimulation is recommended because it did not reduce treatment compliance and had no adverse effects. Compliance with the treatment was by and large good.

In 2 cases, disorders serious enough to prompt discontinuation were observed during treatment. It was not clear whether these were adverse effects of the treatment.

No severe adverse events attributable to the treatment were observed and, in particular, there were no cases of intrauterine death or placental detachment. No cases of severe fetal anemia attributable to fetomaternal transfusion²⁰ were reported. The number of

PROMs was similar in both groups and the number of premature births was lower in the intervention group.

Moxibustion treatment did not reduce the rate of cesarean deliveries in a population in which elective cesarean delivery is not envisaged for breech presentations. On the other hand, it is possible that the significantly higher number of breech presentations at birth in the control group may have been a factor in bringing about worse Apgar scores.

The mechanism of action of moxibustion appears to be through increased AFMs, which proved significantly stronger in the treated subjects. Although a number of studies in China^{11,12,21} have investigated the neurologic path of stimulation by moxibustion and have shown evidence of its effect on maternal plasma cortisol and prostaglandins, we think that the mechanism of action of moxibustion is not entirely clear and warrants further research.

Further studies²² are needed to establish the efficacy and safety of moxibustion at more advanced gestational ages than those considered in this trial, as well as in second pregnancies or multigravidas and populations other than Chinese. Moreover, it is not clear whether moxibustion is more or less efficacious than ECV at term for obtaining cephalic presentation given the small number of subjects (nearly all belonging to the control group) who underwent ECV. Furthermore, since moxibustion and ECV must be performed at different gestational ages, we may regard them as complementary therapies to be used in succession. As we see it, if the results of this

trial are confirmed, moxibustion should be extensively used on account of its noninvasiveness, low cost, and ease of execution. In fact, it is easy to train expectant mothers (either alone or with their partners) to administer the therapy at home. Further studies are also necessary to establish whether moxibustion treatment can reduce the rate of cesarean deliveries where these are used electively for breech presentation at birth.

Additional results regarding the effects of family history, fetal sex, cranial circumference, and leg position on the likelihood of cephalic version will be presented in a subsequent article.

On the basis of the results of the trial, moxibustion, when performed in primigravidas for 1 or 2 weeks starting in the 33rd week of pregnancy, has proved to be an effective therapy for inducing a significant increase in cephalic versions within 2 weeks of the start of therapy and in cephalic presentations at birth.

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References

1. Hickok DE, Gordon DC, Milberg JA, Williams MA, Daling JR. The frequency of breech presentation by gestational age at birth. *Am J Obstet Gynecol.* 1992;166:851-852.
2. Hill LM. Prevalence of breech presentation by gestational age. *Am J Perinatol.* 1990;7:92-93.
3. Hughey MJ. Fetal position during pregnancy. *Am J Obstet Gynecol.* 1985;153:885-886.
4. Scheer K, Nubar J. Variation of fetal presentation with gestational age. *Am J Obstet Gynecol.* 1976;125:269-270.
5. Bartlett D, Okun N. Breech presentation: a random event or an explainable phenomenon? *Dev Med Child Neurol.* 1994;36:833-838.
6. Bartlett D, Piper M, Okun N, Byrne P, Watt J. Primitive reflexes and the determination of fetal presentation at birth. *Early Hum Dev.* 1997;48:261-273.
7. Babkin PS, Ermolenko NA. The motor adaptation syndrome in the human fetus and its dynamics in newborns. *Zh Nevrol Psikhiatr Im S S Korsakova.* 1994;94:19-21.
8. Rayl J, Gibson J, Hickok DE. A population-based case-untreated study of risk factors for breech presentation. *Am J Obstet Gynecol.* 1996;174:28-32.
9. Sival DA. Studies on fetal motor behaviour in normal and complicated pregnancies. *Early Hum Dev.* 1993;34:13-20.
10. Hofmeyr GJ. External cephalic version facilitation at term. In: Neilson JP, Crowther CA, Hodnett

- ED, Hofmeyr GJ, eds. The Cochrane Library: Pregnancy and Childbirth Module of the Cochrane Database of Systematic Reviews [database on disk and CD-ROM]. Oxford, England: Update Software; 1998.
11. Cooperative Research Group of Moxibustion Version of Jangxi Province. Studies of version by moxibustion on Zhiyin points. In: Xiangtong Z, ed. *Research on Acupuncture, Moxibustion and Acupuncture Anesthesia.* Beijing, China: Science Press; 1980:810-819.
12. Cooperative Research Group of Moxibustion Version of Jangxi Province. Further studies on the clinical effects and the mechanism of version by moxibustion. In: Abstracts of the Second National Symposium on Acupuncture, Moxibustion and Acupuncture Anesthesia; August 7-10, 1984; Beijing, China.
13. Cardini F, Basevi V, Valentini A, Martellato A. Moxibustion and breech presentation: preliminary results. *Am J Chin Med.* 1991;19:105-114.
14. Boos R, Hendrik HJ, Schmidt W. Das fetale Lageverhalten in der zweiten Schwangerschaftshälfte bei Geburten aus Beckenendlage und Schädellage. *Geburtsh Frauenheilkd.* 1987;47:341-345.
15. Gottlicher S, Madjaric J. Die Lage der menschlichen Frucht im Verlauf der Schwangerschaft und die Wahrscheinlichkeit einer spontanen Drehung in die Kopflage bei Erst und Mehrgeläbrenden. *Geburtsh Frauenheilkd.* 1985;45:534-538.

16. Gottlicher S, Madjaric J, Morgens KL, Mittags BEL. Ein Ammenmärschen? *Geburtsh Frauenheilkd.* 1989;49:363-366.
17. Westgren M, Edvall H, Nordstrom L, Svalenius E. Spontaneous cephalic version of breech presentation in the last trimester. *Br J Obstet Gynaecol.* 1985;92:19-22.
18. Cardini F, Marcolongo A. Moxibustion for correction of breech presentation. *Am J Chin Med.* 1993;21:133-138.
19. Thorp JM Jr, Jenkins T, Watson W. Utility of Leopold maneuvers in screening for malpresentation. *Obstet Gynecol.* 1991;78(3 pt 1):394-396.
20. Engel K, Gerke-Engel G, Gerhard I, Bastert G. Fetomaternal macrotransfusion after successful internal version from breech presentation by moxibustion [in German]. *Geburtsh Frauenheilkd.* 1992;52:241-243.
21. Weng J, Peng G, Yuang H, Mao S, Zhang H. The morphological investigation of the correcting abnormal fetus position by acupuncture, moxibustion and laser irradiation in the point Zhiyin. In: Abstracts of the Second National Symposium on Acupuncture and Moxibustion and Acupuncture Anesthesia; August 7-10, 1984; Beijing, China.
22. World Health Organization Regional Office for the Western Pacific. *Guidelines for Clinical Research on Acupuncture.* Manila, Philippines: World Health Organization Regional Publications; 1995. Western Pacific Series No. 15.