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Effectiveness of acupuncture-type interventions versus expectant management to correct breech presentation: A systematic review[☆]

Ineke van den Berg^{a,c,f,*}, Johanna L. Bosch^{a,c}, Ben Jacobs^b,
Irene Bouman^b, Johannes J. Duvekot^d, M.G. Myriam Hunink^{a,c,e}

^a Department of Epidemiology and Biostatistics, Erasmus University Medical Center Rotterdam, P.O. Box 2040, 3000 CA Rotterdam, The Netherlands

^b The Rotterdam Institution for Training Midwives, Rotterdam, The Netherlands

^c Department of Radiology, Erasmus University Medical Center Rotterdam, Rotterdam, The Netherlands

^d Department of Obstetrics and Gynaecology, Erasmus Medical Center Academic Hospital Rotterdam, Rotterdam, The Netherlands

^e Program in Health Decision Sciences, Department of Health Policy and Management, Harvard School of Public Health, Boston, United States

^f Clinic for Complementary Medicine, Praktijk Rodenrijs, Berkel Rodenrijs, The Netherlands

KEYWORDS

Acupuncture;
Breech presentation;
Moxibustion;
Systematic review;
Meta-analysis

Summary

Objective: A systematic review of studies assessing the effectiveness of acupuncture-type interventions (moxibustion, acupuncture, or electro-acupuncture) on acupuncture point BL 67 to correct breech presentation compared to expectant management, based on controlled trials.

Data sources: Articles published from 1980 to May 2007 in databases of Medline, EMBASE, the Cochrane Central Register of Controlled Trials, AMED, NCCAM, Midirs and reference lists.

Study selection: Studies included were original articles; randomised controlled trials (RCT) or controlled cohort studies; acupuncture-type intervention on BL 67 compared with expectant management; ultrasound confirmed breech presentation and position of the fetus after treatment confirmed with ultrasound, position at delivery, and/or the proportion of caesarean sections reported.

[☆] **Funding:** All authors and researchers involved state to be independent from the funding organisation, the Dutch Association for Acupuncture (NVA). The authors' work was independent of the funding organisation. The funding organisation had no involvement in the study design, data collection and analysis, writing of the manuscript, or in the decision to submit this article for publication.

* Corresponding author at: Department of Epidemiology and Biostatistics, Erasmus University Medical Center Rotterdam, P.O. Box 2040, 3000 CA Rotterdam, The Netherlands. Tel.: +31 10 4087399; fax: +31 10 4089382.

E-mail address: ineke.vandenbergh@erasmusmc.nl (I. van den Berg).

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doi:[10.1016/j.ctim.2008.01.001](https://doi.org/10.1016/j.ctim.2008.01.001)

Please cite this article in press as: van den Berg I, et al., Effectiveness of acupuncture-type interventions versus expectant management to correct breech presentation: A systematic review, *Complement Ther Med* (2008), doi:[10.1016/j.ctim.2008.01.001](https://doi.org/10.1016/j.ctim.2008.01.001)

Data extraction: Three reviewers independently extracted data. Disagreements were resolved by consensus.

Data synthesis: Of 65 retrieved citations, six RCT's and three cohort studies fulfilled the inclusion criteria. Data were pooled using random-effects models. In the RCT's the pooled proportion of breech presentations was 34% (95% CI: 20–49%) following treatment versus 66% (95% CI: 55–77%) in the control group (OR 0.25 95% CI: 0.11–0.58). The pooled proportion in the cohort studies was 15% (95% CI: 1–28%) versus 36% (95% CI: 14–58%), (OR 0.29, 95% CI: 0.19–0.43). Including all studies the pooled proportion was 28% (95% CI: 16–40%) versus 56% (95% CI: 43–70%) (OR 0.27, 95% CI: 0.15–0.46).

Conclusions: Our results suggest that acupuncture-type interventions on BL 67 are effective in correcting breech presentation compared to expectant management. Some studies were of inferior quality to others and further RCT's of improved quality are necessary to adequately answer the research question.

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Introduction

In pregnancies at term, 3–4% of singleton fetuses present by the breech.^{1,2} Since the results of the Term Breech Trial in 2000 demonstrated a reduction in infant mortality and morbidity with planned caesarean sections compared with planned vaginal delivery in fetuses in breech presentation, caesarean sections have become common practice in many Western Countries for term breech deliveries.^{3–9} An increase in caesarean sections for breech position, however, has distinct disadvantages including an increased risk of maternal urinary tract infection, haemorrhage, wound infection, and scar dehiscence or uterine rupture during subsequent labour and higher costs.¹⁰

Another, non-invasive, method to correct breech presentation comes from traditional Chinese medicine (TCM), which involves the activation of acupuncture-point Zhiyin, Bladder 67 (BL 67)^{11–13}; BL 67 is located beside the outer proximal corner of the toenail of the fifth toe (Fig. 1). In 1984, a controlled cohort trial of the Co-operative Research Group in China, reported that the proportion of cephalic presentations following treatment was 81% in the intervention group ($n=241$) versus 49% in the control group ($n=264$).¹⁴ Since this Chinese study, various studies have been performed, using acupuncture-point-moxibustion, acupuncture, or electro-acupuncture, to correct breech presentation. In correcting breech position, acupuncture on point BL 67 is sometimes used in conjunction with heat through moxibustion, or electric stimulation.^{15–17}

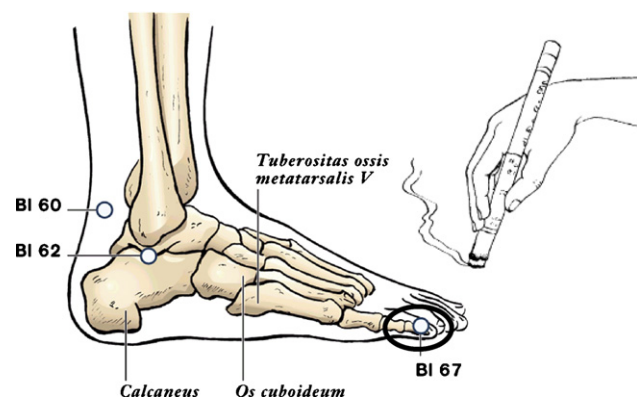


Figure 1 Moxibustion of ZhiYin, Bladder 67.

Moxibustion is the burning of a roll of specially prepared herbs containing *Artemisia vulgaris* or other *Artemisia* species ('mugwort'; the Japanese name for it is moxa) to stimulate acupuncture points without needling.^{18,19} The temperature intensity of the moxibustion is just below the individual tolerability threshold, causing hyperaemia from local vasodilatation.

The purpose of this study was to perform a systematic review of reported studies to evaluate the effectiveness of acupuncture-type interventions on BL 67 (moxibustion, acupuncture, and electro-acupuncture) compared to expectant management to correct breech presentation.

Methods

Data sources and data extraction

A literature search was performed in Medline (Pub Med), EMBASE, Cochrane Central Register of Controlled trials, AMED (Allied and Complementary Medicine), NCCAM (The National Centre for Complementary and Alternative Medicine), and Midirs (Midwifery Information Service).²⁰ The reference lists of the literature found were searched for more articles. We contacted the original authors for further information if necessary. Key words for the search were "moxibustion AND breech", "acupuncture AND breech", "pregnancy AND moxibustion". Articles were not masked for language, author or journal.^{21–23}

A study was included if the following criteria were met: (a) it was an original article; (b) published from 1980 to May 2007; (c) presenting results of an RCT or a cohort study including a control group; (d) of a traditional Chinese medicine acupuncture-type intervention of acupuncture point BL 67 in which (e) breech presentation was confirmed with ultrasound and (f) the authors reported one of the following outcome measures: position of the fetus after treatment confirmed with ultrasound, position of the baby at delivery, and/or number (and percentage) of caesarean sections. A study was excluded if sample size was not reported.

Three authors (IvdB, BJ, and IB) independently selected and reviewed the articles and evaluated all reports for inclusion and exclusion criteria. Next, the same reviewers independently extracted the data concerning study design, patient characteristics, intervention, and outcomes. Disagreements were resolved by consensus.

Statistical analysis of the data

The primary outcome of our analysis was the proportion of breech presentations following the period of the acupuncture-type intervention. In addition, we assessed and explored each relevant methodological aspect individually.²⁴ We also analysed possible treatment side effects.

To detect the presence of publication bias, we constructed a funnel plot in which we plotted the sample size of the study population as a function of the natural logarithm of the odds of a fetus in breech presentation.²⁵

The results within the intervention group and the expectant management group were tested for heterogeneity using the χ^2 -test ($p=0.05$) and the Higgins I^2 test.²⁶ Random-effects models take into account the variation within a study, but also variation between the various studies. Using random-effects models, we pooled the proportion breech presentations following the treatment-period of the intervention groups and of the expectant management groups.²⁷

Furthermore, we calculated the pooled OR with the 95% CI of breech presentations following the period of treatment of the intervention groups and of the expectant management groups.²⁸ The data of the RCT's and the observational cohorts with a control group were pooled separately and jointly.

All analyses were performed in SAS (Proc Mixed for Windows 8.2 1999–2001, SAS Institute Inc., Cary, NC, USA) and Excel (Microsoft Windows Excel 2000 professional, Microsoft Corporation, Phoenix USA), using the formulas described by Laird and Mosteller.²⁷

Results

Literature search

Our search identified 65 studies, of which we excluded 15 on the basis of the abstract and 43 studies on the basis of the full text (Fig. 2). In total seven articles met the

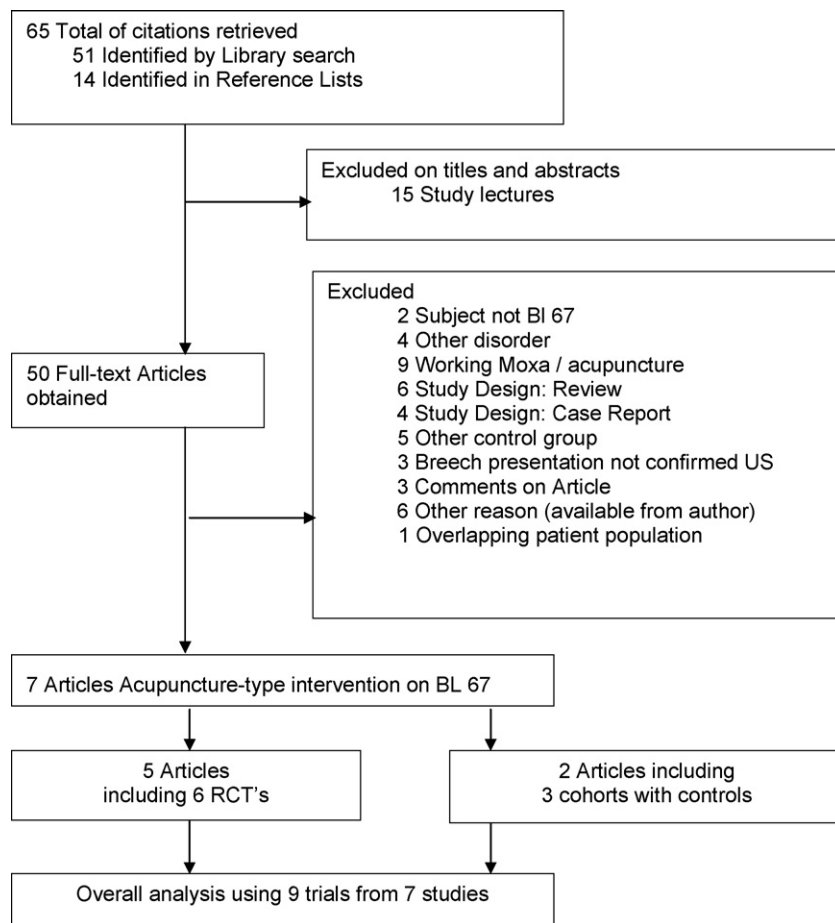


Figure 2 Flowchart of the reviewed literature. From the initial search, a total of 65 abstracts were retrieved. Of these 65 abstracts, 15 were study lectures.^{12,13,34,46–57} Of the remaining 50 abstracts, the full papers were retrieved and evaluated for the additional selection criteria. The following articles were excluded: in two studies the intervention was not performed on BL 67^{58,59}; in four studies no acupuncture-type intervention was used for other disorders^{60–63}; nine articles were about the mechanism of Moxa^{18,19,33,36,64–68}; six articles were reviews^{43,69–73}; four articles were case reports^{51,74–76}; two articles were cohort studies with controls retrospectively assessed from the Chinese literature^{77,78}; three articles had no comparable control group.^{79–81} In three studies the breech presentation was not confirmed with US.^{11,14,82} Three were opinion papers^{83–85} and six articles were excluded for other reasons.^{7,13,86–89} Two articles reported on overlapping patient populations of which we included only the most recent study.^{32,38}

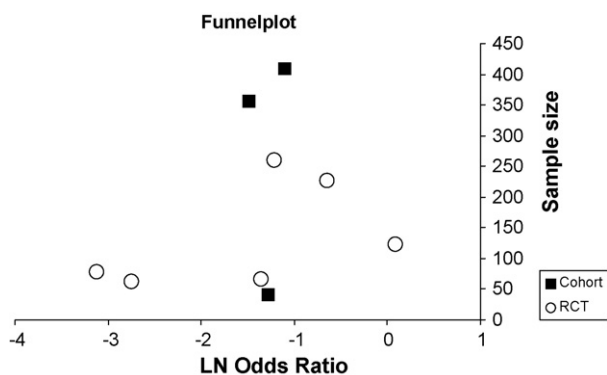


Figure 3 Funnel plot. The funnel plot shows the number of patients included in the study versus the natural logarithm of the odds ratio of breech presentation after treatment. The data points are symmetrically distributed in an inverted funnel shape indicating that the presence of publication bias is unlikely.

inclusion criteria and were included in our study (Table 1). Six RCT's were described in five articles,^{15,17,29–31} that is, one paper reported on two RCT's.¹⁷ In two articles the results of three cohort studies with control groups were described,^{16,32} that is, one article reported on two patient cohorts.¹⁶ The research findings from studies reported in the same source, applied the treatments in different randomly selected group of subjects and therefore we believe the independent assumption is reasonable.^{16,17}

Funnel plot

To detect publication bias, we constructed funnel plots (Fig. 3). The data points for the included studies are symmetrically distributed in an inverted funnel shape suggesting the absence of publication bias.

Study characteristics

The characteristics of the included studies are shown in Table 1. Six of the nine studies used moxibustion,^{15–17,29,30,32} among which one study performed combined moxibustion with needling.¹⁵ One study used acupuncture,³¹ and two studies electro-acupuncture stimulation of BL 67.^{16,17} RCT's were computer randomised and written informed consent was obtained in all studies. In one study the evaluator was blinded to the participant's group allocation.²⁹

Heterogeneity was found between all the studies ($\chi^2 = 9.3$ (p -value=0.001); the estimated natural logarithm of the odds ration (ln OR) and the approximate 95% confidence intervals (CI) varied between the nine studies (Fig. 4). The Higgins I^2 value (=96.2%) is close to 100% implies that there is high heterogeneity across the studies. Therefore, we use a random-effects approach to take into account this variability.²⁶ The random-effects model was used to pool the outcomes.²⁷

Harms of the interventions

No significant harmful effects of moxibustion on women or their infants were reported during or immediately after per-

Table 1 Study characteristics and TCM-type interventions on BL 67

Study	Year	Race	N intervention group	N control group	Mean age intervention group (S.D.)	Mean age control group (S.D.)	N withdrawal	Mean gestational age (weeks)	Intervention BL 67	Tx time	Tx freq	Tx period
RCT												
Cardini ²⁹	2005	Caucasian	65	58	31	31	14+ ^{2a}	33	Moxa	15	1	1–2
Neri ¹⁵	2004	Caucasian	112	114	30.1 (3.6)	31.7 (14.7)	8+6	33.7 ^b	Acupuncture+Moxa	10	2 ^c	1–2
Habek ³¹	2003	Caucasian	34	33	22 (3.1)	23 (1.3)	n/r	34	Acupuncture	30	1	1–3
Cardini ³⁰	1998	Chinese	130	130	25.2	25.5	9+0	33	Moxa	15	1–2	1–2
Li ¹⁷	1996	Chinese	32	31	22–36	22–36	n/r	28 ^d	Moxa	20	n/r	1–6 ^e
Li ¹⁷	1996	Chinese	48	31	22–36	22–36	n/r	28 ^d	Electro-acupuncture	30	n/r	1–6 ^e
Cohort with control group												
Kanakura ¹⁶	2001	Japanese	133	224	28.4	n/r	n/r	28 ^d	Moxa ^f	5	1	Until correction
Kanakura ¹⁶	2001	Japanese	191	217	n/r	n/r	n/r	28 ^d	Electro-acupuncture	5	n/r	n/r
Cardini ³²	1993	Chinese	23	18 ^e	20–37	22–31	n/r	33	Moxa	15	1	5–40 days

n/r, not reported; EP, expectant policy; n/r, not reported; ^a Retrospective controls are presented in the Cardini study of 1993.
^b 22% of Italian participants temporarily or definitively interrupted the treatment because of uncomfortableness due to moxa.
^c S.D. 0.7.
^d Per week.
^e Minimal gestational age.
^f Sessions.
^f BL 67 used in combination with 5 other acupuncture points.

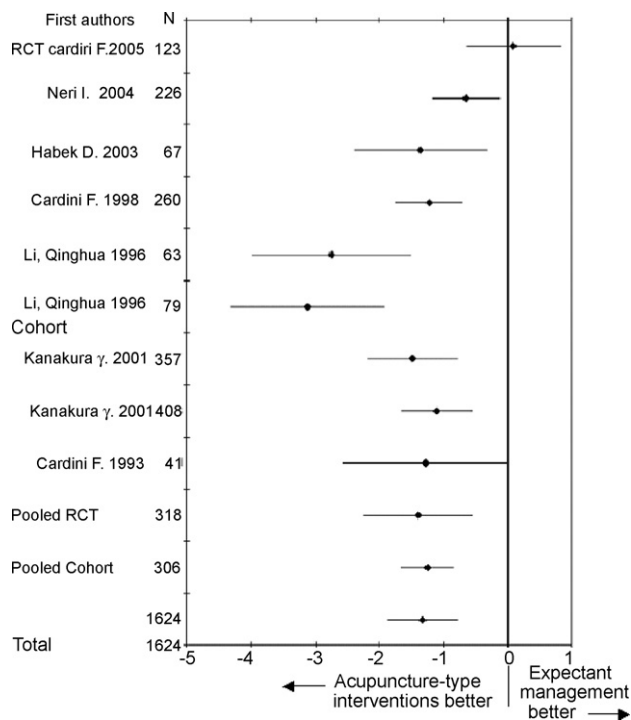


Figure 4 Odds ratio's (log scale) and 95% confidence intervals of breech presentations. Odds ratio's (log scale) and 95% confidence intervals of breech presentations following the period of treatment of the intervention groups and of the expectative policy groups for acupuncture-type intervention for individual studies and the pooled results. N =total of subjects. The plot shows substantial heterogeneity in the estimated effects among the studies.

forming the treatment; that is, no signs of fetal distress, preterm uterine contractions or maternal cardiovascular changes occurred.³³ In the two RCT's of Cardini, however, cases of preterm premature rupture of the membrane (PPROM) were reported in the intervention groups.^{29,30} In the Italian study, two cases of preterm deliveries were described, one certain, due to PPRM, one suspected which occurred at 34 weeks of gestation, and no PPRM was recorded in the control group.²⁹ After delivery of the described cases by caesarean section, there were no consequences for the neonates described. In the Chinese study, no adverse events occurred during treatment. Preterm rupture of the membrane (PRM) occurred in three cases at 37 weeks gestation, which was at least 2 weeks after completion of treatment.³⁰

In some studies withdrawal from the study was reported.^{29,30,34} The main reported reasons were the aggravation of respiratory symptoms and uncomfotableness on exposure to the moxa smoke. Other reasons were uterine contractility, mild hypertension, and reluctance to comply.^{29,30,34}

Benefits of the interventions

Eight of the nine studies demonstrated that treatment on BL 67 was effective in correcting breech presentation whereas in one study poor compliance of the clients led to inter-

ruption of the study and no effect could be demonstrated²⁹ (Table 2). In the pooled RCT's, 421 women were included in the intervention group and 397 women in the expectant management (control) group (Table 2). The pooled RCT's demonstrated a significant effect of the intervention: the proportion of breech presentations in the intervention group was 34% versus 66% in the control group (OR 0.25, 95% CI: 0.11–0.58) (Table 2, Fig. 4).

In the pooled controlled cohort series, the proportion of breech presentations in the intervention group was 15% ($n=347$) versus 36% in the control group ($n=459$) (OR 0.29, 95% CI: 0.19–0.43) (Table 2, Fig. 4).

Combining all studies, the proportion of breech presentations in the intervention group was 28% ($n=768$) versus 56% in the control group ($n=856$) (OR 0.27, 95% CI: 0.15–0.46) (Table 2, Fig. 4).

Discussion

In this systematic review, we found a beneficial effect of acupuncture-type interventions stimulating BL 67 to induce a version to cephalic presentation compared to expectant management. Whereas the effect was more pronounced absolutely in the RCT's, the effect was more pronounced in a relative sense in the cohort studies. In the cohort series, the percentage of breech presentations was halved with intervention, but this was not statistically significant, which may have been due to the limited sample size. The pooled result of the RCT's and that of all studies combined demonstrated a clinically and statistically significant reduction in breech presentations.

As a rule, cohort series generally demonstrate a larger effect than RCT's and are more likely to reach statistical significance. In contrast, we found that the pooled RCT's demonstrated a larger absolute effect than the cohort studies and the effect was significant in the pooled RCT's whereas in the pooled cohort studies it was not. A possible explanation for these findings is that the gestational age at the time of inclusion in two cohort studies was lower than in the RCT's.¹⁶ Prior to 32 weeks gestational age, spontaneous version occurs more often than after 32 weeks (11.5% versus 6.3% to a nadir of 1.7% after 40 weeks).^{1,13,32} This will have an effect in both the intervention group and the expectant management group resulting in lower proportions of breech presentation and a smaller absolute effect of the intervention in the cohort studies compared to the RCT's. It has been suggested that also patient age and condition, female babies, fetal motor activity and room temperature during treatment could play a role in the effectiveness of acupuncture-type interventions on correcting breech presentations.^{14,35} Overall there are few well designed studies exploring the role of these covariates in relation to different treatment designs. The decision was made not to conduct a meta-analysis including these covariates due to the significant differences in the intervention type. Further studies are necessary to establish the related results.

The mechanism of stimulation of BL 67 has, in part, been scientifically investigated. One study of the morphological basis and relationship between BL 67 and the viscera showed that seven segments (L2-S1) of the uterus

Table 2 Outcomes of the individual studies and pooled outcomes

Reference	N intervention group	N in breech during follow-up	Percentage breech	N control group	N in breech during follow-up	Percentage breech	OR breech presentation
Cardini ²⁹	65	43	66.2	58	37	63.8	1.09
Neri ¹⁵	112	52	46.4	114	71	62.3	0.52
Habek ³¹	34	8	23.6	33	18	54.6	0.26
Cardini ³⁰	130	32	24.4	130	68	52.3	0.29
Li ¹⁷	32	8	25.0	31	26	83.9	0.06
Li ¹⁷	48	9	18.7	31	26	83.9	0.04
Pooled results			34%			66%	0.25
RCTs (CI)	421	152	(20%, 49%)	397	197	(55%, 77%)	(0.11, 0.58)
Kanakura ¹⁶	133	10	7.5	224	59	26.3	0.23
Kanakura ¹⁶	191	21	10.5	217	57	26.1	0.33
Cardini ³²	23	7	30.4	18	11	61.1	0.28
Pooled results			15%			36%	0.29
Cohort studies (CI)	347	38	(1%, 28%)	459	127	(14%, 58%)	(0.19, 0.43)
Pooled results			28%			56%	0.27
Combined studies (CI)	768	190	(16%, 40%)	856	324	(43%, 70%)	(0.15, 0.46)

and the sensory innervation of BL 67 overlap.³⁶ Other authors suggested that the stimulation of BL 67 increases cortico-adrenal secretion, placental estrogens, and changes in prostaglandin levels, leading to raised basal tone of the uterus and enhanced movement of the fetus, thus making version more likely.^{11,16,33,37–40} The explanation that version of the fetus would be purely based on a reflex action of moxibustion mediated by a dermatome must be rejected, because stimulation of BL 67 performed in cases of intra-uterine fetal death failed to produce version.³⁸ According to the acupuncture point of view, one of the functions of BL 67 is to stimulate the activity of the fetus, which may be an important mechanism to induce spontaneous version. Furthermore, it seems likely that the technique may be more successful in complete breech presentation than in frank or footling breech presentation.^{29,41}

In this systematic review data from nine studies were extracted, reviewed, compared, and pooled odds ratios were reported. Many systematic reviews only consider randomised controlled trials (RCT's), which are generally considered the state-of-the-art study design for evaluation of interventions. Linde, however, suggested that non-randomised studies might also be useful in a systematic review to get a more comprehensive overview of current practice and to inform future research.⁴² Therefore, in our literature search, we also considered non-randomised studies.

A limitation of our systematic review, as with other reviews, was that the possibility of publication bias cannot be ruled out, even though our funnel plot did not demonstrated the presence of publication bias. We searched different sources to identify all RCT's and cohort studies with controls of TCM interventions on BL 67 for correction of breech presentation, but were not able to retrieve any unpublished studies. Although the use of acupuncture is widespread in China and Russia, our literature search retrieved only four eligible trials from China and none from Russia. Databases only partially cover literature from these countries and it is possible that unidentified eligible trials from these countries exist.

Another limitation of our study was that the sample sizes of RCTs included were relatively small and details of the study design and certain outcomes were sometimes not reported. For example, in three RCT's, the caesarean section rate was described.^{15,30,31} Some considers caesarean section an important outcome of the treatment effect. However it should be noted that the number of caesarean sections performed is not only determined by the effect of treatment but also by other factors such as many other medical indications as well as the women's own preferences. In the included studies elective caesarean deliveries for breech presentations were not studied.

Furthermore, among the included studies, a variety of acupuncture-type interventions (moxibustion, moxibustion combined with acupuncture, acupuncture alone, and electro-acupuncture) and protocols were used. Although of the included studies the most commonly used method was moxibustion, with a protocol of once a day for 15–20 min for as long as 1–2 weeks. The effect of these different interventions is unknown and beyond the scope of the current review. A Cochrane review on this topic, however, also concluded that there was no consensus in the literature with

respect to the best regimen.⁴³ In contrast to our study, the Cochrane review focused on the treatment of BL 67 with acumoxa only and concluded that moxibustion may help to correct breech presentation but that the number of studies was too small to demonstrate effectiveness with statistical significance.

Other limitations of our study are the poorly defined and reported characteristics of the women and fetuses, and outcomes of treatment in the original studies after treatment and at term and restricted our ability to adjust for differences in case mix and outcome measures (Table 1).

With the available data it was impossible to find a significant relation between acupuncture-type interventions of BL 67 and preterm birth due to PPRM. To assess the frequency of the possible relation, further studies are required.

Nevertheless, not only the method of stimulation and different protocols, but also ethnic, cultural and educational differences could account for the different results reported in the different studies.

Another limitation is that we could not adjust for parity because parity was often not reported, two studies were performed with only primigravid women.^{29,30} Among the included studies that considered parity, only one study demonstrated a significant difference between primi- and multiparae.¹⁵ The success rate of version to cephalic presentation may be related to the fact that the uterus of a multipara already reached the maximum length and so there is more room for version of the fetus. From the 37th week, spontaneously movement into cephalic presentation is no longer likely to occur, in either primiparae or multiparae.⁴⁴ In one study, parity was even found to be the only significant factor in predicting the success of external cephalic version.⁴⁵

Finally, the primary outcome measures of interest in RCTs that evaluate acupuncture-type interventions for correction of breech presentation would have been fetal presentation at the time of delivery, preferably adjusted for covariates. Secondary outcome measures of interest would be mode of delivery and neonatal outcome, including safety, morbidity and mortality. Relevant covariates would be parity, type of breech presentation, active-fetal-movements, location of the placenta, the amount of amniotic fluid, educational level, culturally defined expectations of therapy, previous caesarean sections, reason for performing previous caesarean section, and the women's viewpoint with respect to vaginal versus caesarean delivery.

In addition, the ideal study design may be placebo-controlled RCT, but due to the relative contraindication to the use of moxibustion during pregnancy in other locations than BL 67 it is not feasible to use a placebo moxa treatment. Besides that, a sham intervention would quickly be identifiable as sham by the patient and her partner through the informed consent procedure and through information about moxibustion on the Internet.

Based on the results of our study, the effect of using acupuncture-type interventions on BL 67 to correct breech presentation seems promising. Our results, however, are influenced by the variety of the included studies. Therefore, before making this adjuvant treatment to standard Western healthcare, we recommend to conduct a large-scale RCT in which moxibustion is compared to expectant management. We recommend moxibustion, as this method

is inexpensive, readily available, safe, client-friendly, and can be performed at home by the partner of the pregnant woman. In addition, more characteristics of the participants, such as parity, fetal position, both after treatment and at time of delivery, maternal and fetal complications, information of external cephalic version and its outcome, and the number of caesarean sections with the reasons for performing them, should be monitored. Also, women's preferences, the acceptance of the smell and warmth of the moxibustion treatment, quality of life of the women, and healthcare and non-healthcare costs should be assessed.

Conclusions

Our systematic review of the current literature shows a beneficial effect of using acupuncture-type interventions on BL 67 to induce correction of a breech presentation compared to expectant management. Our results, however, are influenced by the existing differences in design of the current studies and further RCT's of improved quality are necessary to adequately answer this question.

Conflict of interest statement

We have no conflict of interest to declare. All authors and researchers involved state to be independent from the funding organisation (NVA). The authors' work was independent of the funding organisation. The funding organisation had no involvement in the study design, data collection and analysis, writing of the manuscript, or in the decision to submit this article for publication.

Statements

Authorship contribution: The authors assure that all authors included in this paper fulfil the criteria of authorship and that there is no one else who fulfils the criteria but who has not been included as an author.

Guarantor: The corresponding author, Ineke van den Berg, states to accept full responsibility for the work and conduct of the study, to have had full access to the data and to have controlled the decision to publish.

Acknowledgements

The authors thank members of the ART group for their assistance in the data analyses and their helpful comments on the text.

We also thank the Dutch Association for Acupuncture (N.V.A.) who, in part, supported this study.

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