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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

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Moxa;
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Moxibustion;
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Summary
Objectives: To assess, using a modelling approach, the effectiveness and costs of breech version with acupuncture-type interventions on BL67 (BVA-T), including moxibustion, compared to expectant management for women with a foetal breech presentation at 33 weeks gestation.
Design: A decision tree was developed to predict the number of caesarean sections prevented by BVA-T compared to expectant management to rectify breech presentation. The model accounted for external cephalic versions (ECV), treatment compliance, and costs for 10,000 simulated breech presentations at 33 weeks gestational age. Event rates were taken from Dutch population data and the international literature, and the relative effectiveness of BVA-T was based on a specific meta-analysis. Sensitivity analyses were conducted to evaluate the robustness of the results.
Main outcome measures: We calculated percentages of breech presentations at term, caesarean sections, and costs from the third-party payer perspective. Odds ratios (OR) and cost differences of BVA-T versus expectant management were calculated. (Probabilistic) sensitivity analysis and expected value of perfect information analysis were performed.
Results: The simulated outcomes demonstrated 32% breech presentations after BVA-T versus 53% with expectant management (OR 0.61, 95% CI 0.43, 0.83). The percentage caesarean section was 37% after BVA-T versus 50% with expectant management (OR 0.73, 95% CI 0.59, 0.88). The mean cost-savings per woman was €451 (95% CI €109, €775; $p = 0.005$) using Moxibustion. Sensitivity analysis showed that if 16% or more of women offered moxibustion complied, it was more effective and less costly than expectant management. To prevent one caesarean section,

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7 women had to use BVA-T. The expected value of perfect information from further research was €0.32 per woman.
Conclusions: The results suggest that offering BVA-T to women with a breech foetus at 33 weeks gestation reduces the number of breech presentations at term, thus reducing the number of caesarean sections, and is cost-effective compared to expectant management, including external cephalic version.

Introduction

In pregnancies at term, about 3—5% of singleton foetuses present in breech position.[1] Caesarean section has become common practice for term breech deliveries in many Western countries,[2–6] but is not without disadvantages. Apart from the 1.29 relative risk (95% CI 1.03—1.61) of immediate severe maternal morbidity,[2,7] there is the risk of adverse effects on subsequent pregnancies.[4,8–11] Potential complications include deep-vein thrombosis, pulmonary thrombo-embolism, need for transfusion, puerperal infection, postpartum hemorrhage, neonatal respiratory distress, maternal urinary tract infection, wound infection, and scar dehiscence or uterine rupture during subsequent labor. Moreover, a higher number of caesarean sections could entail higher societal costs. Therefore, viewed from various perspectives, it would seem important to find ways to correct breech presentation before delivery.

One option is a procedure called external cephalic version (ECV), recommended by the American College of Obstetricians and Gynaecologists (ACOG) and the British Royal College of Obstetricians and Gynaecologists (RCOG).[12,13] This procedure is successful in 50 to 60% of cases and is usually performed by a gynaecologist starting at 36 weeks gestation.[14,15] On the other hand, serious complications, such as perinatal death, need for emergency caesarean deliveries and a spontaneous reversion rate of 3% have been reported.[15–19] In addition, ECVs generate costs.

Another, non-invasive, method to correct breech presentation comes from traditional Chinese medicine. Named Breech Version Acumoxa, the moxibustion of acupuncture-point Zhiyin, Bladder 67 (BL67, located beside the outer proximal corner of the toenail of the fifth toe), was first reported in 1980 as a safe and non-invasive way to correct breech presentation.[20] Since this Chinese study, various controlled studies in other countries have evaluated the merits of breech version by acupuncture-type interventions on BL 67 (BVA-T) including acupuncture-point-moxibustion, acupuncture, or electro-acupuncture.[21–26] Moxibustion is the burning of a roll of herbs (Artemisia Vulgaris = Moxa) to stimulate acupuncture points without needle insertion. The sticks are readily available, safe and user-friendly and can be applied by anyone following skilled instruction.[27–29]

A systematic review and meta-analysis of studies reporting the results of randomized controlled trials (RCTs) on acupuncture-type interventions on BL 67 versus expectant management showed that the pooled proportion of breech presentations was 34% (95% CI: 20—49%) in the treatment group versus 66% (95% CI: 55—77%) in the control group.[30] In this meta-analysis, three of the six studies used moxibustion, the other three used acupuncture, electro-acupuncture, and a mixture of moxibustion and acupuncture on BL 67.

In general, there is growing willingness of hospital departments and patients to adopt complementary care, provided it is safe.[31–33] More specifically in obstetrics, health-care providers are recognizing the favourable economic impact of low-cost, complementary therapies.[34] However, to decide whether BVA-T should be offered alongside the standard care of expectant management to correct breech presentation policymakers need more detailed information.

Our aim was to generate information by a decision-analytic approach about the projected effectiveness and costs of BVA-T compared with expected management including associated procedures such as external cephalic version, in order to reverse breech presentation after the 33rd-week gestation and reduce the number of caesarean sections at term.

Design and methods

Model structure

A decision tree was constructed to assess the effectiveness and costs of two strategies — ''BVA-T'' and ''expectant management'' (EM) — to facilitate spontaneous cephalic version of a foetus in breech position at 33 weeks gestation[35,36] (Fig. 1) Box 1 explains the terminology related to decision models in general. Outcome measures for effectiveness were percentage of breech presentations at term/delivery and percentage of caesarean sections. Costs were defined as third-party payer costs.

The model started at 33 weeks gestation and followed the time path until 1 week after delivery. At the starting point, breech presentation had been confirmed with ultrasonograph (US). In both strategies, a second US was performed at 36 weeks gestation. The model took into account events such as refusing BVA-T, lack of compliance to BVA-T, and spontaneous version. Both strategies included the option to have an ECV performed by a gynaecologist from 36 weeks gestation. Furthermore, in both strategies all births took place in hospital, assisted by a midwife or gynaecologist depending on the mother's and foetus's health status. BVA-T implied two instructional visits to an acupuncturist at 33 and 34 weeks gestation, with daily treatments performed at home, applied by the partner, during the intervening week. EM implied that the midwife would be in a ''wait and see mode'' until 36 weeks gestation. The model was consistent with the recommendation of the Dutch obstetric organization that healthy pregnant women are cared for by well-trained midwives whereas women with maternal and/or foetal complications are referred to a gynaecologist. Breech presentation at 36 weeks gestation is a reason for

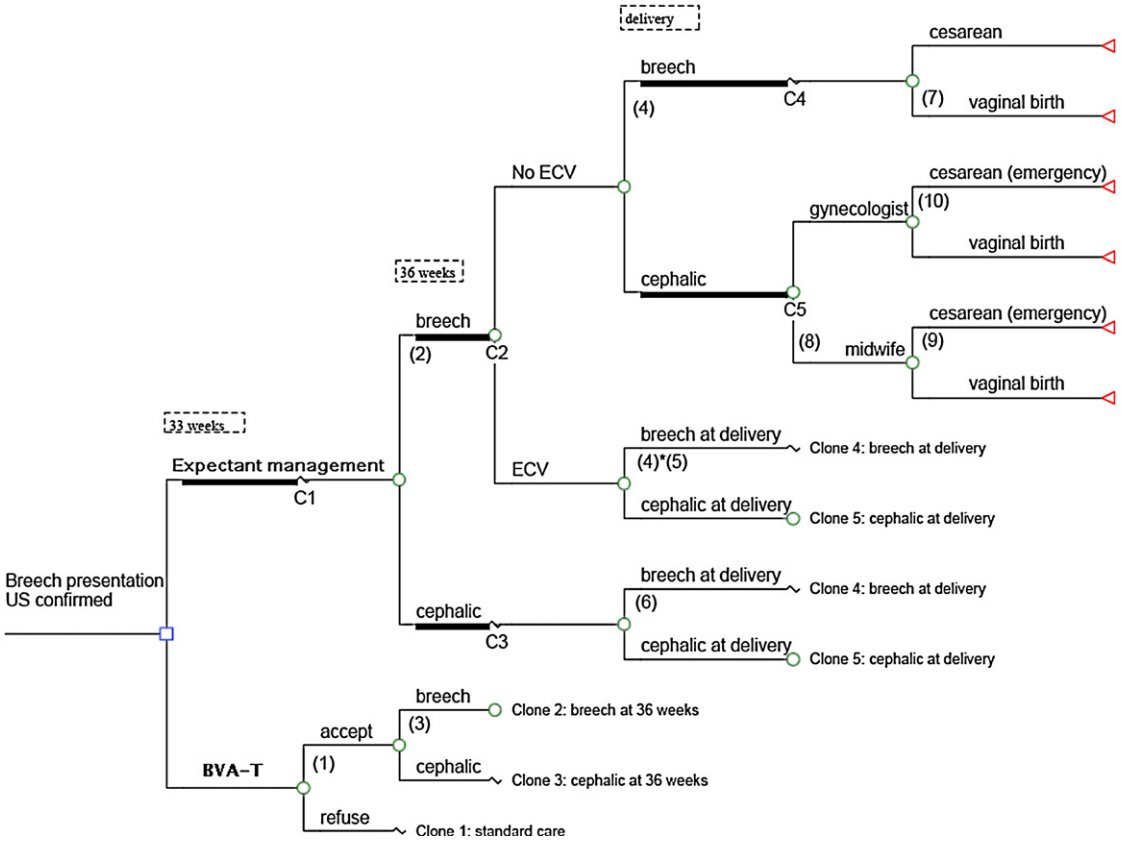

Figure 1 Decision tree for the decision of whether to add BVA-T to rectify breech presentation in generally healthy 33 weeks pregnant women with a breech baby. This decision model was also developed to predict the number of caesarean sections prevented by comparing BVA-T with expectant management (EM) to rectify breech presentation, including treatment compliance, and costs and associated event as external cephalic version (ECV). Shown is the generic framework of the model. The square node at the far left symbolizes the choice between BVA-T and EM. The tree is fully displayed only for the EM arm, but the BVA-T arm has the same detail. Generally healthy 33 weeks pregnant women with a breech baby cycle through the tree and are at risk for breech presentation at term and the risk of caesarean section at delivery. The square indicates the choice between BVA-T and EM, circles represent potential chance consequences, and triangles signify six different outcomes. The decision tree included five clones, after which it followed the branch indicated with C1 till C5. The numbers between brackets indicate the variables with their probabilities (Table 1).

referral, in which case responsibility of care shifts to the gynaecologist.

The decision model was constructed in TreeAge Pro 2006 (release 1.2, TreeAge Software, Inc. Williamstown, USA).

Input parameters

Clinical effectiveness

Box 2 explains the terminology related to effectiveness. Table 1 lists the mean probabilities, 95% confidence intervals, and distributions of the variables entered into the model. The data were retrieved from a PubMed literature search restricted to English-language reports, and confirmed by data from the Dutch Perinatal Database and from expert opinions. The probabilities of included events and interventions were based on clinical practice in maternal and neonatal maternity care in the Netherlands.[4,37–43] The probability that a woman would accept BVA-T and the probability of persistent breech presentation between weeks 33 and 36 following BVA-T or EM (Table 1) were retrieved from a systematic review and meta-analysis.[30]

Costs

Box 3 explains the terminology related to costs. Table 2 shows details of the cost items. Costs were assessed according to Dutch guidelines and from a third-party payer perspective. All costs related to the diagnosis and treatments of breech presentation were included.[44–46] In addition, both strategies included the costs of prenatal and postnatal care for 8 days after delivery, care provided by midwives and auxiliary maternity care.

Direct costs were assessed for BVA-T, ECV, caesarean section, breech vaginal birth, cephalic vaginal birth (gynaecologist) and cephalic vaginal birth (midwife).

In-hospital costs were retrieved from Diagnosis—Treatment-Combinations (DTCs) and from the financial department of the Bronovo Hospital in the Hague, which is a regional hospital, the type of institution

Box 1 Explanation of terminology related to decision models in general.
Decision analysis is a mathematical approach to making decisions based on weighing risks and benefits in an explicit quantitative manner.
Decision trees are visual representations of decision analytical models which depict all possible choices or strategies (at the *decision node*, depicted with a square), the consequences of these choices (at *chance nodes*, depicted with circles), and the outcomes of these consequences (at the *terminal nodes*, depicted with triangles or rectangles).
Cost-effectiveness analysis is an assessment of both the costs and effectiveness associated with different management strategies for a health-care problem.
Perspective is the viewpoint taken in performing the analysis which can be the patient, the physician, the department, the hospital, the third-party payer, the health-care system, or society.
Variables are the input parameters in the model that together determine the optimal decision, e.g. effectiveness of treatment, costs of treatment.

Box 2 Explanation of terminology related to effectiveness.
Effectiveness is the expected benefit of a treatment.
The *odds ratio (OR)* is a measure of association of exposure and outcome (event) and equals the odds of risk in the exposed group divided by the odds of risk in the control group. The OR equals the cross product in a 2×2 table of exposure versus outcome. In the context of treatment the OR is a measure of the effectiveness of the treatment and equals the odds of the risk of the outcome in the treated group divided by the odds of the risk of the outcome in the control group. An $OR < 1$ indicates an effective treatment, $OR = 1$ an ineffective treatment, and $OR > 1$ a harmful treatment.
The *risk difference (RD)* is a measure of association of exposure and outcome (event) and equals the risk in the exposed group minus the risk in the control group. In the context of treatment the RD is a measure of the effectiveness of the treatment and equals the risk of the outcome in the treated group minus the risk of the outcome in the control group. A $RD < 0$ indicates an effective treatment, $RD = 0$ an ineffective treatment, and $RD > 0$ a harmful treatment.
The *number-needed-to-treat (NNT)* is the number of patients that need to be treated to avoid one event in a defined time period and is the inverse of the absolute risk reduction. In formula form: $NNT = -1/RD$

where babies in the Netherlands are usually delivered. DTCs come with fixed prices for treatment of patients with specific diagnoses and cover the complete process from the first specialist consultation to the final outpatient visit.[47] The DTCs applicable here do not differentiate between the different types of caesarean sections, but rather give weighted averages. Out-of-hospital costs were retrieved from the Dutch Association of Acupuncture (NVA), the Royal Dutch Organization of Midwives (KNOV), and ''Maatzorg Pregnancy and Baby Care'' — an organization specialized in postnatal care at home.

Indirect costs and costs of subsequent pregnancies were not taken into account. Costs are reported in 2006 Euros.

Table 1 Overview of all parameters included in the model with their references. The numbers before the parameters correspond with the numbers after the chance nodes in Fig. 1.

Parameters	Reference	Mean (prob.)	95% CI	Distribution
(1) Acceptance BVA-T	Cardini et al.	0.84	(0.77,0.89)	Beta(123, 24)
(2) Stay breech between week 33—36 EM	van den Berg et al.[a]	0.66	(0.54,0.77)	Beta(45.38, 23.48)
(3) Stay breech between week 33—36 BVA-T	van den Berg et al.[a]	0.34	(0.21,0.5)	Beta(13.73, 26.22)
(4) Stay breech between week 36—+ EM	Hofmeyr et al.[b]	0.80	(0.74,0.85)	Beta(175, 44)
(5) RR stay breech between week 36—+ BVA-T	Hofmeyr et al.[b]	0.38	(0.18,0.8)	Log-Normal(−1.31, 0.83)
(6) Spontaneous breech at term	Janssen et al.[c]	0.01	(0.00,0.02)	Beta(7, 855)
(7) Vaginal breech delivery	Rietberg et al.[c]	0.20	(0.19,0.21)	Beta(2835, 11423)
(8) Cephalic delivery by midwife (hospital)	Janssen et al.	0.57	(0.54,0.59)	Beta(743, 571)
(9) Emergency cephalic caesarean by midwife (hospital)	Janssen et al.	0.18	(0.15,0.21)	Beta(135, 608)
(10) Emergency cephalic caesarean by gynaecologist	Janssen et al.	0.12	(0.09,0.15)	Beta(68, 503)
(11) Emergency cephalic caesarean by midwife (home)	Janssen et al.	0.06	(0.05,0.08)	Beta(55, 807)
(12) Maternal factors and the probability of a planned home birth	Anthony et al.[d]			1/3 home-births

[a] Pooled result of RCTs[21—24,26].
[b] Cochrane Database Systematic Review.
[c] Confirmed by data from the Dutch Perinatal Database.
[d] Only used in sensitivity analysis for homebirth in the Netherlands.

Box 3 Explanation of terminology related to costs.
Direct health-care costs are costs associated with medical procedures, hospital admissions, outpatient visits, medication, therapeutic interventions, patient care, and overhead.
Overhead costs are costs for the building and administration.
Indirect health-care costs are future costs and costs induced by the chosen strategy.

Data analysis

Box 4 explains the terminology related to decision models in general. Two main analyses were performed, namely without (0%) and with (100%) implementation of ECV. We calculated proportions of breech presentations at term and caesarean sections, and third-party payer costs for each strategy. Next, we calculated the odds ratios (OR) of BVA-T versus EM for the proportion of breech presentation and caesarean sections and we calculated the difference in third-party payer costs between the strategies.

We took the inverse of the absolute risk difference (RD) to calculate the number of women — needed-to-treat with BVA-T to prevent one caesarean section.

Sensitivity analysis

Our initial analyses were based on 100% hospital births, which were assisted by a gynaecologist or midwife. Cultural differences in birth settings, however, do exist. For example, in the Netherlands, many home-births take place and midwives provide basic care to pregnant women and serve as an arbitrator for the admission of more complex pregnancies to gynaecologists.[48] To specifically evaluate the effect of these cultural differences, we performed sensitivity analyses in which we extended our original decision tree and added the proportions of home-births (i.e., 33.3%) versus hospital-births (66.7%) (Fig. 2).

In our initial analyses, breech presentation at 33 weeks gestation was always confirmed by US. In practice, however, this is not always done. In additional sensitivity analyses, therefore, we adopted a 20 to 100% range of confirmed breech presentations rather than 100%. In addition, the acceptance rate of BVA-T was varied from 0 to 100% to demonstrate the impact on total costs

Table 2 The included costs per procedure in the model.

		Description	Source	Cost (€)
Interventions	BVA-T	Office visit acupuncturist, Moxa-sticks and echo by midwife	NVA, KNOV, NatuurApotheek®	158.50
	ECV	Admission, honorarium gynaecologist	DTC	885.45
Prenatal	Gynaecologist		DTC	518.26
	Midwife		KNOV	343.00
Delivery	Caesarean section	Hospital, salaries gynaecologist, paediatrician and anaesthesiologist, admission and overhead costs, *incl. stay mother and child in hospital**	DTC + overhead regional hospital	5075.67
	Assisted breech vaginal birth	Hospital, salaries gynaecologist, paediatrician and anaesthesiologist, admission, nurse and overhead costs	DTC + overhead regional hospital	1916.49
	Assisted cephalic vaginal birth (gynaecologist)	Hospital, salaries gynaecologist and anaesthesiologist, admission, nurse and overhead costs	DTC + overhead regional hospital	1827.93
	Assisted cephalic vaginal birth (midwife)	hospital, salaries midwife, admission, nurse and overhead costs	DTC	721.50
Postnatal	Caesarean	Midwife/gynaecologist, maternity nursing (to add with *)	DTC/KNOV, www.progeria.nl	637.20
	Vaginal birth	Midwife, maternity nursing (8 days at home)	KNOV, www.progeria.nl	1564.70

Box 4 Explanation of terminology related to analyzing decision models.
A *dominant strategy* is a strategy that is less expensive and more effective than the alternative strategy and is thus superior to the alternative. If dominance exists, the cost-effectiveness ratio is meaningless.
The *incremental cost-effectiveness ratio* is the incremental cost divided by the gain in effectiveness compared to the next best strategy and should be calculated in the setting of non-dominance to determine whether more money is justified by the gain in effect.
Sensitivity analysis is a ''what-if'' analysis. By varying the value of variables in the decision model we can explore the effect on the outcome and evaluate whether alternative assumptions would change the decision.
In *probabilistic sensitivity analysis* all variable values are modelled with distributions instead of deterministic values. Variable values are picked at random from the distributions for each variable and the outcomes are calculated. This is repeated multiple (e.g. 10,000) times which yields distributions of the outcomes and from which we can determine the probability that one strategy is preferred over another.
Value of information analysis determines the potential benefit of further research.
Expected value of perfect information (EVPI) is the expected incremental benefit of the optimal strategy based on accurate estimates of all the variables should these become available through further research compared to the benefit of the optimal strategy based on current information.

Probabilistic sensitivity analysis and value of information analysis

All probabilities were modelled with beta or lognormal distributions (Table 1). Probabilistic sensitivity analysis, using 10,000 second-order Monte Carlo simulations, was performed and provided the 95% confidence intervals around the estimates. In addition, this analysis provided the probability that EM rather than BVA-T would be the optimal strategy.

Value of information analysis was performed to determine the potential benefit of further research. We calculated the expected value of perfect information (EVPI), which is the expected incremental benefit of the optimal strategy based on exact accurate estimates of all the variables compared to the benefit of the optimal strategy based on current information. Since obtaining exact accurate estimates of parameter values is impossible (it needs a study with an infinite sample size evaluating all parameters), EVPI is the upper limit of the expected benefit of further research.[49–51]

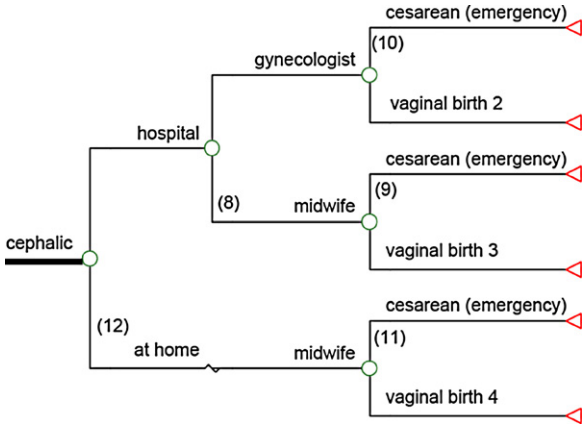

Figure 2 Extension of the decision tree in which home-births were included. The numbers between brackets indicate the probabilities corresponding with Table 1.

Results

Table 3 shows the main simulated outcomes of the initial analyses. Without the option of ECV at 36 weeks gestation, the proportion of breech presentation at term after BVA-T was 32%; that after EM 53%. The corresponding figures for the analysis in which ECV was performed were 12% and 19%.

Without the option of ECV, the proportion of caesarean sections after BVA-T was 37%; that after EM 50%. The corresponding figures for the analysis in which ECV was performed were 23% and 28%, respectively. To prevent one caesarean section, seven women with a foetus in breech presentation at 33 weeks gestation would need to be treated with BVA-T.

Substantial differences in costs were observed between vaginal births and caesarean births.

In both analyses, the mean direct costs for BVA-T were somewhat lower than those for EM. The difference mainly resulted from the lower proportion of caesarean births associated with the BVA-T-strategy.

Sensitivity analysis

Sensitivity analyses were performed to evaluate the effect of the probability of a planned home birth and by varying the input parameters over the acceptance rate of BVA-T. Sensitivity analyses, in which 33.3% of all hospital births were altered to home-births and care given by the midwife, demonstrated similar percentages of breech presentations compared to the main analyses and a decrease in the percentages of caesarean sections and a decrease in total costs (both with and without ECV). The percentage caesarean section was 35% after BVA-T versus 49% after EM without the option of ECV (OR 0.71, 95% CI 0.56, 0.88); whereas this was 20% versus 25% respectively, if ECV was performed (OR 0.80, 95% CI, 0.64, 0.97).

The mean direct costs were €4369 after BVA-T versus €4890 after EM without ECV (cost difference €520; 95% CI, €135, €883); whereas this was €4230 versus €4658, if ECV was performed (cost difference €428, 95% CI €79, €941).

The results of sensitivity analyses performed on the percentage US-confirmed breech presentations at 33 weeks and the acceptance rate of BVA-T on the expected total costs are demonstrated in Fig. 3a and b, for the strategies without and with ECV respectively. If 100% of breech presentations are US-confirmed and the BVA-T compliance rate is 16.0% or

Table 3 Simulated outcomes (mean of 10,000 subjects) of BVA-T and expectant management strategies for women at 33 weeks gestation with a foetus in breech presentation.

Percentage breech presentation at delivery				
		Mean (%)	OR (95% CI)	Probability EM preferred
Analysis — no ECV performed				
BVA-T		32.0	0.61 (0.43, 0.83)	0.0008
Expectant management		52.9		
Analysis — ECV performed				
BVA-T		11.6	0.62 (0.45, 0.84)	0.001
Expectant management		18.8		
Percentage caesarean section				
	Mean (%)	OR (95% CI)	Probability EM preferred	Number-to-treat to prevent one caesarean
Analysis — no ECV performed				
BVA-T	36.6	0.73 (0.59, 0.88)	0.0008	7.3
Expectant management	50.3			
Analysis — ECV performed				
BVA-T	23.1	0.83 (0.67, 0.98)	0.001	21.0
Expectant management	27.8			
Total costs (2006 Euros)				
		Mean (€)	Cost difference (95% CI)	Probability EM preferred
Analysis — no ECV performed				
BVA-T		4595	451 (109,775)	0.0052
Expectant management		5046		
Analysis — ECV performed				
BVA-T		4523	404 (72,864)	0.0073
Expectant management		4927		

BVA-T = breech version by acupuncture-type interventions on BL 67; EM = expectant management; ECV = external cephalic version; CS = caesarean section.

more without ECV, or 17.6% or more with ECV, BVA-T was less costly than EM. If 20% of breech presentations are US-confirmed, the BVA-T strategy was less costly compared with EM at a BVA-T compliance rate of 37.7% and 41.5% for the strategy without and with ECV, respectively.

Probabilistic sensitivity analysis and value of information analysis

In all scenarios and for all outcomes the probability that EM was preferred (i.e. the probability that BVA-T would not be favourable compared to EM) was less than 1% (Table 3). Assuming BVA-T was implemented instead of EM, the EVPI without and with ECV was €0.32 and €0.37 per woman, respectively.

Discussion

This modelling exercise aimed at evaluating the effectiveness and costs of BVA-T compared with EM for women with a foetus in breech position at 33 weeks gestation. Our analyses are consistent with a significant decrease in breech presentation after treatment with BVA-T, both with and without the option of ECV, when compared with EM. Consequently, BVA-T is associated with significantly fewer caesarean sections and therefore notably decreases the third-party payer costs. Although additional costs were attributed to BVA-T, its effectiveness corresponded with lower total costs. The results were robust in sensitivity analyses in which we varied the percentage of breech presentations confirmed by US and the BVA-T compliance rate, and considered the Dutch situation in which 33% of births take place at home. In the Netherlands, midwifery-led care is only permitted when the foetus is in cephalic presentation. Our analysis showed that with BVA-T, without ECV, there is a 21% decrease in foetuses in breech presentation at term. These mothers with foetuses in cephalic presentation at 36-week gestation stay with or may return to midwifery-led care. Some authors showed that midwifery-led care does not lead to higher maternal or neonatal risk associated with planned home birth.[52,53]

In addition, the value of information analysis showed that, compared to implementing BVA-T based on the currently available evidence, perfect information on the probabilities in the model obtained from further effectiveness and cost research would result in a minimal gain in expected benefit. We showed in our model with 10,000 second-order Monte Carlo simulations, that if BVA-T was implemented instead of EM, with the currently available evidence, the low EVPI makes further research of the cost

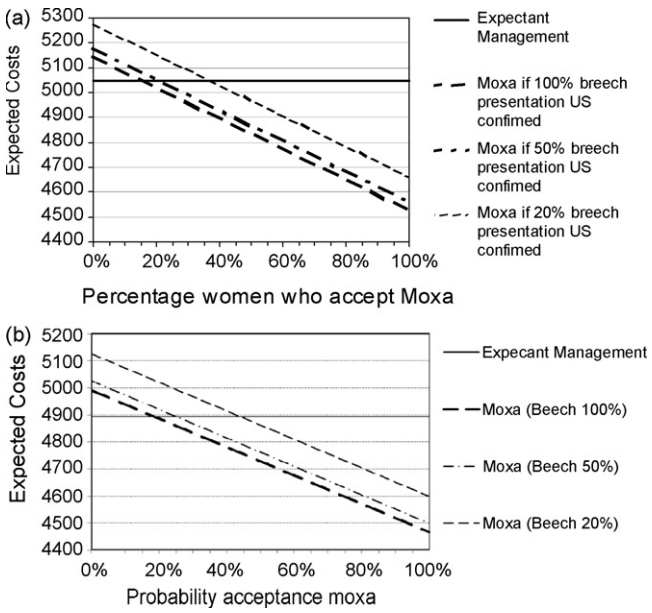

Figure 3 (a and b) Two-way sensitivity analysis in which the percentage of women who accept BVA-T and the percentage of breech presentations that were confirmed by ultrasound (US) were varied. The different discontinuous lines show the impact of these variables on the total costs of BVA-T. There is no influence of change in these variables on the total costs of expectant management. (a) Shows the strategies without ECV. The intersections of BVA-T with expectant management are at 16.0, 21.4 and 37.7%. (b) The strategies with ECV. The intersections of BVA-T with expectant management are at 17.6, 23.6 and 41.5%.

effect of implementing BVA-T unnecessary. Nevertheless, we do recommend performing a well-designed RCT in a Western setting, with special attention to the safety of the Moxa technique, in line with an ongoing study in Spain.[54] To our knowledge, no other study has evaluated both the effectiveness and costs of BVA-T compared with EM. The results of this study, however, could guide informed decision making on the implementation of BVA-T for women with a diagnosed foetus in breech presentation after 33 weeks of gestation.

Some limitations of our study and the intervention itself should be mentioned. For one, the effectiveness data in the model had been retrieved from a meta-analysis of six RCTs in which we demonstrated positive effects of acupuncture-type interventions on BL 67, where moxibustion was used in four of the six RCT's.[30] Since heterogeneity was found between these studies, the random-effects model of DerSimonian and Laird[55] was used to pool the outcomes, thereby allowing heterogeneity in the true treatment effects. The random-effects model takes into account the variability across the studies and results in wider confidence intervals than does the fixed-effects model, which ignores the between-study heterogeneity. Part of the heterogeneity might perhaps be explained by specific study characteristics such as patients' mean age or ethnicity. In a meta-regression the study characteristics are put as covariates in a regression analysis with the estimated treatment effect of the study as dependent variable. Ideally, these covariates should be specified in advance to reduce the risk of post hoc conclusions prompted by inspecting the available data.[56] Especially when the number of studies is small, any covariate of which the value differs between the studies will be significantly related to the heterogeneity among the studies, and hence is a potential explanation of it. It is clear, however, that most of such 'explanations' will be entirely spurious.[57] In this regard, Lee concluded that none of the results of our meta-analysis of the six RCTs, according to ethnicity or the type of intervention, avoided heterogeneity.[58] However, as pointed out above, almost every study characteristic would be related to the heterogeneity between the studies and could therefore easily be based on spurious relationships. Also because the covariates proposed by Lee were not specified in advance, we think his conclusion should be interpreted with caution. However, we agree with Lee[58] that it would be interesting to explore the heterogeneity across studies as soon as a sufficient number of studies is available for a meta-regression. Furthermore, Vas et al. published a systematic review, which included Chinese studies.[59] In their analyses they evaluated in the pooled result two different treatments in the control group: expectant management and knee-to-chest-posture versus the combined effects of moxibustion with or without another technique. These results should be viewed with caution, and therefore, in this modelling exercise, we still stand for the use of the parameter-distribution of van den Berg et al, where the controls were treated with expectant management.

A second limitation of our analysis is that the follow up period was limited to 8 days postpartum and our study focused on the direct results of BVA-T on delivery mode. Therefore, indirect costs as well as effects and costs of subsequent pregnancies were not taken into account. Their inclusion, however, might well have given greater weight to the argument made.[60–63]

Third, costs of BVA-T may have been overestimated in our analysis, as these costs included two visits to a licensed acupuncturist and two confirmative US examinations. Costs could be reduced through the use of low-cost ''self-explanatory home Moxa kits'' which can be ordered through the Internet. However, as breech position may be associated with congenital malformations, placenta praevia, and malformations of the uterus, we recommend that pregnant women undergo an US before she and her foetus are exposed to Moxa.[64,65]

Finally, the working mechanism of moxibustion is not completely known. A systematic Cochrane review concludes that there is no consensus in the literature with respect to the best regimen[27] suggesting that the working mechanism remains unknown. The effect of moxibustion on version might be due to the odour, the temperature, or even the specific acupuncture location.[28,66–69] From the acupunctural point of view, BL 67 stimulates the activity of the foetus, which may be an important mechanism to induce spontaneous version. Moreover, it seems likely that the technique may be more successful in complete breech presentations than in frank or footling breech[15,21,70] suggesting that the foetus itself plays a role in inducing version. Further research on the specific working mechanism and side-effects of Moxa is therefore needed.

Thought provoking is the possible beneficial effect of BVA-T in low-income countries and in rural areas far removed from medical centres. Women in these settings are less likely

to undergo ECV or a caesarean section for breech presentation. The non-invasive and non-pharmaceutical BVA-T could therefore reduce infant and maternal morbidity, mortality, and medical costs in countries where poverty is an obstacle to obtaining medical care.

Conclusions

The results of this decision analysis suggested that for the rectification of a foetus in breech presentation in women at 33 weeks gestation, BVA-T reduced the number of breech presentations at term, the number of caesarean sections, and was less costly when compared to expectant management, including ECV.

Conflict of interest statement

No competing financial interests exist. This work was partly supported by the Dutch Association for Acupuncture (N.V.A.). All authors and researchers involved state to be independent from the funding organization (NVA). The authors' work was independent of the funding organization. The funding organization 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.

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