


ORIGINAL RESEARCH

Vaginal breech delivery in all-fours position—Hands off instead of intervention: A prospective observational study

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Abstract

Introduction: Vaginal delivery in cases of breech presentation is considered potentially stressful for the newborn. The maternal upright position may represent a more physiological approach to facilitating birth. We compare the safety and efficacy of two maternal positions in vaginal breech delivery.

Material and Methods: A prospective, single-center, observational cohort study from October 2006 to January 2021 in a high-level obstetric center, in Salzburg, Austria. Vaginal breech deliveries in maternal all-fours position ($n=140$) were compared with those in assisted supine position ($n=92$). The primary outcome measures for neonatal morbidity included Apgar scores, pH levels, and the rate of transfer to the Neonatal Intensive Care Unit (NICU) postdelivery.

Results: In the all-fours position, 51.4% ($n=72$) of deliveries occurred without obstetric intervention. The second stage of labor was significantly shorter in the supine position (39.5 min [95% CI 28–47] versus all fours position 52 min [95% CI 42–63], $p=0.042$). Umbilical artery pH levels did not differ significantly (7.21 [95% CI 7.19–7.23] versus 7.19 [95% CI 7.17–7.21] vs. $p=0.06$). Nor did the APGAR scores at 5 and 10 min below eight ($p=0.697$; $p=0.760$). Maternal and neonatal morbidity also did not significantly differ. Transfer of neonates to NICU $n=12$ (13%) versus $n=11$ (7.9%), $p=0.097$, transfer birth-related $n=6$ (6.5%) versus $n=8$ (5.7%), $p=0.803$. The number of postpartum umbilical artery pH < 7.10 were $n=9$ (9.8%) versus $n=28$ (20%), $p=0.065$. There was one reported neonatal death due to intracerebral hemorrhage in the supine position group.

Conclusions: Our results indicate that vaginal breech delivery in the all-fours position seems to be comparable to supine position regarding neonatal safety. Additionally, the all-fours position shows potential for emergency management for unplanned breech deliveries by inexperienced attendants.

Abbreviation: NICU, neonatal intensive care unit

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KEYWORDS

first-aid management, maternal position, second stage of labor, term breech presentation, vaginal delivery

1 | INTRODUCTION

Approximately 4.5% of fetuses present in breech position at term.¹ Following the publication of the Term Breech Trial² a global shift toward performing cesarean sections for breech births was observed.³ A follow-up study of the Term Breech Trial found no significant difference in the risk of death or neurodevelopmental delay at 2 years of age between infants who underwent planned vaginal birth and those who had planned cesarean sections.^{4–6} Despite this controversy about the short- and long-term neonatal outcomes due to vaginal birth,^{4,7–10} many obstetric centers adhere to the concept of vaginal birth. They were able to show that under optimal conditions, good perinatal outcomes of vaginal birth in breech position are feasible.^{4,11–17} Most of these deliveries have been traditionally managed with women in supine position.

In the search for a safer approach to vaginal breech delivery, some researchers have focused on the impact of maternal positioning. This led to the validation of the upright maternal position as a viable option during delivery. Royal College of Obstetricians and Gynecologists (RCOG) guideline suggests choosing all-fours in this situation.⁸ However, this is based on limited evidence by two small studies.^{18,19} Serious fetal and neonatal morbidity related to the mode of delivery was relatively low overall, with no significant differences observed between upright vaginal births and cesarean sections.

A panel consisting of obstetricians and midwives experienced in vaginal breech birth “strongly agreed that the purpose of upright positioning was to optimize physiology, facilitating the mother's ability to birth her baby with maximum efficiency, and that optimizing this physiological process could increase the safety of vaginal breech birth for both mother and baby.”²⁰ A possible explanation for this perceived facilitation might be that the transverse diameter in pregnant and nonpregnant women significantly widens in a kneeling squat position compared to a supine position according to an MRI pelvimetry study.²¹ Moreover, gravity and the wider range of motion in the maternal pelvis will improve the mechanisms of breech birth in an all-fours position. A recent study with simulation models has shown that delivery in all-fours leads to less mechanical stress on the fetal neck.²²

A structured video analysis of upright breech deliveries examined the process leading to the birth of the infant. New maneuvers were introduced in managing breech delivery.²³ Breech birth in an upright position often enables deliveries without maneuvers to manipulate the baby. However, former studies have shown differences in the rate of completely spontaneous births in this position, reporting rates of 56%¹⁹ and 70.7%¹⁸ of deliveries without any maneuvers used.

The aim of this study is to analyze differences in fetal and maternal outcome measures between vaginal breech deliveries, comparing

the all-fours maternal position with the supine position. We hypothesize that the all-fours position may represent a more physiological approach, potentially requiring fewer manual obstetric interventions. If our study confirms this, the all-fours position could offer an additional option for managing breech deliveries. Furthermore, this approach may be suitable for nonmedical professionals in emergency deliveries outside the hospital setting.

2 | MATERIAL AND METHODS

2.1 | Study design

This is a prospective, single-center observational study, utilizing data collected from October 2006 to January 2021 at an obstetric center equipped with a maximum-care-level neonatology unit. The center has an average of 2800 deliveries per year, including approximately 25 vaginal breech births annually.

2.2 | Study population

Vaginal breech births were recorded consecutively, chronologically, and prospectively between 2006 and January 2021. Given the relatively high rate of unplanned cesarean sections²⁴ and the lack of correlation with the mother's position at the end of the second stage, the intention-to-treat analysis was set to the end of the second stage of labor.

2.3 | Outcome measures

Primary outcome: rate of completion of delivery in all-fours. Composite outcome of severe perinatal outcomes (death, admission to Neonatal Intensive Care Unit [NICU]). Admission to NICU is surrogate marker for possible neonatal distress. Secondary outcome: Condition of the child postpartum was assessed based on the Apgar <8 at 5 min of age, umbilical artery mean, and rate of pH ≤7.10. Duration of birth, rate of obstetrics interventions (no vs. any obstetric intervention).

2.4 | Data collection

Women presenting with a fetus in breech position near term were provided with nondirective counseling about their options, including risks and alternatives to vaginal birth, and each signed informed consent. External cephalic version was routinely offered as the primary

approach. Each birth within the specified period was meticulously documented, with essential data reviewed and verified within 1-day postdelivery.

The study included all women who ultimately delivered vaginally. At the time, we decided to analyze by protocol, in which participants are compared based on the treatment they received. This shows what happens and shows what the treatment does when applied. Inclusion was determined at the point when the buttocks became visible without receding between contractions, a stage known as "rumping." This point marks the optimal time if not earlier, to transition to the all-fours position.

In general, inclusion criteria for this study of vaginal delivery were healthy singleton fetuses after the completed 35th week (35+0) with mothers, who requested vaginal breech delivery and finished vaginally. Exclusion criteria were preterm births before 35+0 weeks of gestation, estimated weight under 2500g or over 4000g, fetal position with hyperextended head or footling breech, growth restriction of the fetus under the 10th percentile (FGR), previous cesarean delivery, multiple pregnancy, and intrauterine fetal death. Due to the lack of consensus among national guidelines regarding contraindications for term vaginal breech delivery,²⁵ we referred our criteria to the guidelines of the Society of Obstetricians and Gynecologists of Canada.¹⁵

Radiologic pelvimetry was not performed. The choice of maternal position (all-fours or supine) was not predetermined at the time of deciding on a vaginal delivery attempt. Instead, this decision was guided by the experience and preference of the primary obstetrician (physician's choice) and the mother's preference, creating a quasi-randomization effect. Particularly in the early phase of the study, there was a lack of evidence regarding manual interventions. If the obstetrician felt uncertain or uncomfortable with the all-fours position, a transition to the supine position was mandatory.

In our institution, vaginal breech birth is always performed in the presence of an experienced obstetrician (several years, at least 3 years' experience in vaginal breech births). The choice of birth maneuvers was determined by the primary obstetrician's decision, experience, and preference, considering fetal well-being and the clinical progression of labor. Routine use of maneuvers (supine and upright position) is not practiced at our institution. At the beginning of the study (2006–2012), there was no evidence or experience with the development of breech presentation in maternal upright position. Through observation, learning, and discussions with other study centers, valuable techniques emerged, which were later described and summarized in a subsequent publication.²³ The most common intervention was the shoulder press maneuver for delivering the baby's head. The study team received annual training and updates on new insights based on these findings. As standard of care, a pediatrician from the department of neonatology was always on stand-by during delivery.

For the acquisition and management of data ViewPoint, PIA Fetal Database was used to identify all breech births in the Department of Obstetrics and Gynecology, Paracelsus Medical University, Salzburg,

Austria from October 2006 to January 2021 as well as to extract the analyzed perinatal data for this study.

2.5 | Statistical analysis

The statistical significance level was set at $p < 0.05$. The Mann-Whitney U test was used for nonparametric data. For parametric data, the independent sample t -test was performed to determine statistical significance. Fisher's exact and chi-squared tests were used for testing if the distribution of variables is the same across different groups. Median and 95 CI are reported for nonparametric variables, mean and 95% CI are reported for normal distributed variables.

The statistical analysis was performed with R software (R Core Team, 2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria (<https://www.R-project.org/>).

The data of the two cohorts (all-fours and supine) were statistically examined for fundamental differences between groups as well as for clinical outcome parameters. Transfers to the NICU were further analyzed for "birth-associated transfers" defined as the following: birth trauma, neonatal metabolic acidosis, asphyxia, adaptation disorders, and respiratory distress, thereby excluding pre-existing fetal morbidities. Additionally, the all-fours position group was subdivided into two groups: with and without obstetric intervention, for statistical comparison. Data for aborted attempts in an upright position were kept and analyzed within the all-fours group.

3 | RESULTS

From October 2006 to January 2021, there were 325 vaginal breech births (Figure 1). We analyzed 232 vaginal singleton breech births, from which 140 were conducted in the all-fours position compared to 92 deliveries with assistance in a supine position. Eleven deliveries began in the all-fours but were converted to the supine position (7.8%). Reasons for terminating the all-fours position and switching to the supine position included difficulties in delivering the child ($n=5$), the prolonged second stage of labor (physician's choice, $n=5$), and obstetrician uncertainty regarding the method ($n=1$). These cases were still evaluated within the all-fours group. The two cohorts only differed significantly with regard to fetal weight and head circumference, with heavier and larger neonates being found in the all-fours group {fetal weight 3047.9 g [95% confidence interval (CI) 2972.48–3123.33] vs. 3239.39 g [95% CI 3175.75–3303.03], $p < 0.01$; head circumference 34.64 cm [95% CI 34.38–34.91] vs. 35.14 cm [95% CI 34.92–35.36], $p = 0.01$ } (Table 1). Other variables of categorical parameters (parity, types of breech, use of PDA) as well as numerical parameters (maternal age, gestational week) showed no significant differences.

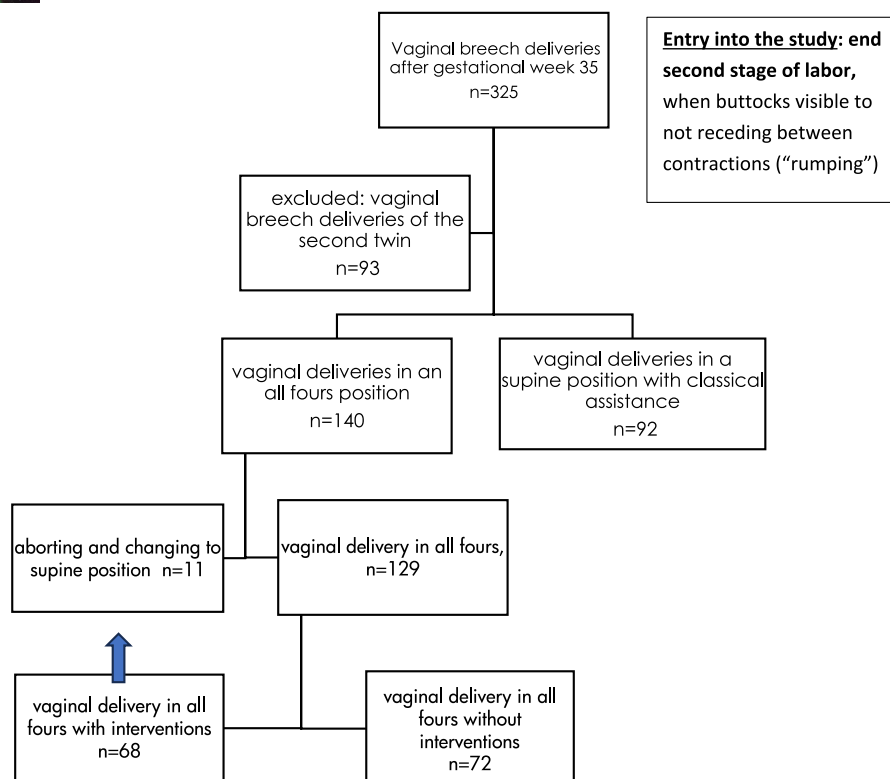


FIGURE 1 Flow diagram of included cases.

TABLE 1 Comparison of the groups regarding categorical parameters of pregnancy.

Variable	Supine position n = 92		All-fours position n = 140		p-value
	n	%	n	%	
First pregnancy	52	56.5%	71	50.7%	0.464
Primipara	56	60.9%	81	57.9%	0.749
Breech position					
Complete	14	15.2%	19	13.6%	0.898
Incomplete	3	3.3%	9	6.4%	
Frank	73	79.3%	109	77.9%	
Other	1	1.1%	2	1.4%	
NA	1	1.1%	1	0.7%	
Sex					
Male	31	33.7%	56	40.0%	0.406
Peridural					
Yes	11	12%	18	12.9%	1
	95% CI	Mean of central tendency	95% CI	Mean of central tendency	
Age of mother	29.68–31.93	30.8	31.02–32.46	31.7	0.166
Week of gestation	39–40	39*	39–40	39*	0.186
Weight (g)	2972.48–3123.33	3047.9	3175.75–3303.03	3239.4	<0.0001
Head circumference (cm)	34.5–35	35*	35–35.5	35*	0.005

Note: For nonnormal distributed data (labeled with *), the median as a measure of mean of central tendency is reported. For normal distributed data, the mean is reported. The corresponding CIs (mean or median) were calculated and are depicted above.

3.1 | Outcome of obstetric and maternal parameters

Obstetric parameters (Table 2) revealed significant differences in duration of the second stage of labor [supine position (39.5 min [95% CI 28–47] vs. all fours position 52 min [95% CI 42–63], $p=0.04$), and in the pushing phase of birth (10 min [95% CI 8–10] vs. 15 min [95% CI 10–15], $p<0.01$), respectively. The incidence of placental separation did not differ significantly between the two cohorts ($p=0.91$). Seventy-six mothers in the supine position experienced perineal injuries (48 episiotomies, 28 min or lesions) versus 66 in the all-fours

position (15 episiotomies, 51 min or lesions). There were no major perineal injuries documented in either cohort. Notably, two cases of cervical laceration were observed in the supine group, while none occurred in the all-fours position.

3.2 | Outcome of neonatal parameters

Analysis of the pH from the umbilical artery did not show significant differences between the all-fours group and the group with breech

TABLE 2 Comparison of obstetric parameters.

Variable	Supine position			All-fours position			p-value
	n	95% CI	Mean of central tendency	n	95% CI	Mean of central tendency	
Duration of delivery (h)	90	5.31–6.63	5.97	140	5–6	5*	0.959
Na pH (fetal)	84	7.19–7.23	7.21	129	7.17–7.21	7.19	0.065
Base excess fetal	81	–6.40 to –4.68	–5.54	132	–7.81 to –6.63	–7.22	0.002
Second stage of labor	88	28–47	39.5*	137	42–62	52*	0.042
Pushing birth phase	66	8–10	10*	126	10–15	15*	<0.001
	n		%	n		%	p-value
Apgar 5*							
<8	4		4.3%	10		7.1%	0.697
Apgar 10*							
<8	1		1.1%	3		2.1%	0.760
Transfer to neonatology*							
Yes	12		13%	11		7.9%	0.097
No	68		73.9%	129		92.1%	
NA	12		13.1%				
Birth associated transfer*							
Yes	6		6.5%	8		5.7%	0.803
Na pH							
≤7.10	9		9.8%	28		20%	0.0645
>7.10	75		81.5%	101		72.2%	
NA	8		8.7%	11		7.8%	
Base excess							
≤–12	5		5.4%	11		7.9%	0.002
>–12	76		82.6%	121		86.4%	
NA	11		12%	8		5.7%	
Perineal injury*							
Yes	76		81.1%	66		46.8%	0.636
No	15		16.1%	75		53.2%	
NA	2		2.2%				
Placental separation							
Yes	9		9.8%	12		8.6%	0.909
≥8	71		77.2%	100		71.4%	
≥8	12		13%	28		20%	

Note: For nonnormal distributed data (labeled with *), the median as a measure of mean of central tendency is reported. For normal distributed data, the mean is reported. The corresponding CIs (mean or median) were calculated and are depicted above. Bold values indicates p-values.

TABLE 3 Comparison of all-fours position with and without intervention.

Variable	Without intervention			With intervention			p-value
	n	95% CI	Mean of central tendency	n	95% CI	Mean of central tendency	
Duration of delivery (h)	72	3–5	4*	68	5–8	7*	0.001
Na pH (fetal)	67	7.18–7.23	7.2	62	7.15–7.20	7.17	0.120
Base excess fetal	66	–7.14 to –5.51	–6.33	66	–8.93 to –7.30	–8.11	0.002
Second stage of labor	71	25–54	41*	66	46–88	63*	0.002
Pushing birth phase	64	10–15	10*	62	15–20	15*	0.004

Note: For nonnormal distributed data (labeled with *), the median as a measure of mean of central tendency is reported. For normal distributed data, the mean is reported. The corresponding CIs (mean or median) were calculated and are depicted above.

birth in supine position (7.19 [95% CI 7.17–7.21] vs. 7.21 [95% CI 7.19–7.23], $p=0.06$). Furthermore, there were no significant differences in the number of neonates with a pH below 7.1 between groups (20% vs. 9.8%, $p=0.064$) as shown in Table 2. However, the fetal base excess differed significantly with lower values in the all-fours position (–7.22 [95% CI –7.81 to –6.63] vs. –5.54 [95% CI –7.81 to –6.63], $p<0.01$) (Table 2), which was also observed in categorical analysis of base excess values below –12 [5.4% vs. 7.9%, $p<0.002$]. The percentage of neonates with 5- and 10-min APGAR scores below eight showed no significant differences between groups ($p=0.697$, $p=0.760$), nor did the rate of transfers to neonatology ($p=0.097$).

One neonatal death was reported in the group of standard breech deliveries on the third-day postbirth, attributed to a postnatal intracerebral hematoma. This case involved an uncomplicated birth in a multiparous mother, without intervention or the use of obstetric maneuvers.

3.3 | Comparison of all-fours births with and without intervention

Overall, 51.4% of births in the all-fours position progressed spontaneously without any obstetric intervention ($n=72$ out of 140). As shown in Table 3, the deliveries with intervention generally took significantly longer, with a prolonged active second stage of labor and newborn had significant lower base excess.

4 | DISCUSSION

This prospective observational study indicates that vaginal breech delivery with the mother in the upright position is not inferior to delivery in the supine position. Neonatal outcomes, as assessed by APGAR scores, umbilical cord pH, and postpartum NICU referral rates for obstetric issues were comparable between the two positions. Additionally, the incidence of perineal injuries was lower in deliveries conducted in the all-fours position.

Vaginal delivery in breech delivery puts greater stress on the newborn.^{8,9,15} Birth in the maternal upright position does not reduce

fetal and neonatal distress, as suggested in our hypothesis of the physiological approach, in the sense of no/few obstetric intervention.²⁰ The result is all the more interesting because our data show that the neonates in the all-fours group were found to be significantly heavier and with larger head circumference, which could potentially influence the outcomes.

In our center, 51.4% of breech deliveries in the all-fours position were completed spontaneously without any obstetric intervention. This contrasts with rates from previous studies analyzing all-fours and upright breech births, which reported spontaneous delivery rates of 56%,¹⁹ 70.7%,¹⁸ and 33%,²³ respectively. In comparison, only 11.9% of breech deliveries in our supine group were completed without obstetric assistance. Notably, in 7% of cases (11 instances) initially attempted in the all-fours position, the position was discontinued, and delivery was completed in the supine position.

The prospective study was designed for observation but without randomization. The lack of planned randomization was a limitation of our study. Real randomization was not possible in our unit for multiple reasons: the majority of the women after consultation opted for vaginal delivery on all-fours. Some of the obstetricians preferred obstetric support in the supine position. One obstetrician (the corresponding author and initiator of the study) consistently aimed for the all-fours method of birth.

This study was strengthened by the large number of participants in a single center as well as the interval of time in which data were collected. The number of births compared is large enough to show differences.

In the absence of randomization, matching of data in the sense of a propensity analysis is certainly a useful tool to imitate the effect of randomization. However, due to the matching process, the data would become significantly smaller. Since our study design corresponds to a prospective “quasi-randomization” approach, we decided against the propensity analysis.

Our study differs comparing to the result of previous studies on this topic. The evaluation of the study results from our earlier collective was adjusted by excluding the second twin in the breech presentation.¹⁹ The study collective of Louwen et al.¹⁸ was unequally distributed when comparing the groups (comparing 229 upright

deliveries to only 40 in the dorsal position). Due to differing inclusion criteria, the study concluded that offering vaginal birth in the upright position could reduce the cesarean section rate, though this rationale is not fully transparent. This retrospective study initially compared women intending to have a primary cesarean section with those attempting vaginal birth. Only afterward were the vaginal births analyzed by position, comparing upright with supine deliveries. Therefore, a direct comparison with our study is not feasible, as our research exclusively focused on women who successfully completed vaginal deliveries.

In our sample, there was no significant difference in umbilical artery pH levels indicating hypoxic stress; however, base excess values were significantly lower in the all-fours group (-7.22 vs. -5.54 , $p < 0.001$). Additionally, no significant differences were observed between cohorts in APGAR scores below 8 at 5 and 10 min or in the rate of NICU transfers. Additionally, our data revealed no significant differences in maternal morbidity. The lack of significant differences in neonatal and maternal morbidity outcomes aligns with findings published by Louwen et al.¹⁸ but shows more favorable results compared to a prior study by the same research group.¹⁹

At first glance, vaginal delivery in the all-fours position may appear inferior due to short-term outcomes such as lower pH, higher base excess, and lower 5-min Apgar scores; however, differences in pH and 5-min Apgar were not statistically significant, and statistical differences of higher base excess were clinically not meaningful. On the other hand, these indicators could suggest increased neonatal stress potentially linked to the longer duration of labor. This raises the question of whether early intervention may be warranted. Ultimately, the clinical condition of the newborns was not worse, as evidenced by a similar NICU transfer rate between groups.

The literature identifies various, sometimes conflicting, factors contributing to suboptimal peripartum outcomes. These factors include low birth weight, such as infants below the 10th percentile²⁶ or those weighing under 2.8 kg as noted by Su's 2003 study.²⁷ Additionally, a prolonged second stage of labor and the use of epidural anesthesia²⁸ have been linked to poorer peripartum outcomes. Limited experience among obstetricians also plays a role in suboptimal outcomes.^{26,27} A recent study demonstrated that an extended pushing phase is often associated with higher birth weights, and birth weight itself ($p = 0.011$) was independently associated with neonatal unit admissions.²⁹

Increased fetal weight may facilitate the mechanics of vaginal breech birth in the upright position by enhancing gravitational forces. However, it is noteworthy that one study found no significant difference in severe adverse outcomes for neonates or mothers in vaginal breech deliveries based on whether the baby weighed above or below 3800g.¹²

There was no evidence of neonatal impairment, supporting the hypothesis that physiological breech delivery (i.e., breech deliveries with minimal to no obstetrical intervention) is not only viable for skilled professionals but may also serve as a first-line, first-aid

method in unattended breech births. This approach could be particularly valuable in emergency, unplanned out-of-hospital deliveries occurring during the pushing phase.

In our study, the use of epidural anesthesia among participants was limited, reflecting a deliberate strategy to minimize medical interventions during childbirth. However, when participants requested epidural anesthesia, it was provided as needed.

Only a few large maternity units systematically offer vaginal birth in breech presentation in Austria and Germany. Both these units, as well as smaller units with sporadic vaginal births, have already begun to offer all-fours as a first-choice maneuver. While there is still a lack of clinical evidence, this change in clinical practice has occurred. It is our belief that this study has provided scientific support for this change in practice.

One neonatal death occurred in the supine breech delivery group on the third-day postbirth due to a postnatal intracerebral hematoma. No predisposing factors were identified, and there was no indication of a coagulation defect. The delivery was an uncomplicated birth for a multiparous woman, without intervention or the application of obstetrical maneuvers. This case of unexpected neonatal death, along with cases of severe clinical postpartum adjustment disorders, underscores that while catastrophic adverse events are rare,³⁰ they cannot be entirely ruled out. This consideration should always be addressed during informational consultations.

Our study was initially designed with a wait-and-see approach for deliveries in the all-fours position. Future research should focus on defining precise intervention thresholds to assist the newborn as needed. As a first step, a retrospectively reviewed maneuvers in video-recorded breech deliveries and developed an action algorithm based on this analysis.²³ The next phase should involve prospective testing of this algorithm, ideally through a multicenter study, which could provide valuable insights for breech delivery training and practice.³¹

5 | CONCLUSION

Vaginal breech birth in the all-fours position appears to be comparable to the supine position in terms of neonatal and maternal safety outcomes. Approximately half of the births completed in this position were successful without any interventions. Given its safety profile, the all-fours position should be routinely offered to mothers planning a vaginal breech delivery. We believe that this position also holds potential as a first-aid maneuver in emergency unplanned breech deliveries, particularly when managed by inexperienced attendants without obstetric supervision.

AUTHOR CONTRIBUTIONS

Gerhard Bogner: conception and design, planning, and conducting the study and wrote the draft. Johanna Schuller collected data and carried out analysis. Carina Gargitter made statistical analysis and together with Gerhard Bogner interpreted data. Eva Dölzl Müller,

Claudius Fazelnia, and Thorsten Fischer reviewed the draft. Gerhard Bogner, Eva Dölzlmüller, Claudius Fazelnia, and Thorsten Fischer predominantly attended most of the breech deliveries. All authors approved the submitted version.

CONFLICT OF INTEREST STATEMENT

The authors declare not conflicts of interest.

DATA AVAILABILITY STATEMENT

Only pseudonymized data were analyzed. The data that support the findings of this study are available upon request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

Approval for this study by the Ethics Committee of the Government of Salzburg was obtained on September 7, 2012 (proposition number 415-EP/73/145-2012). The learning phase, development, and take-over procedures for delivery in all-fours started in 2006 (few cases in all fours) and active prospective enrollment of women into the study commenced in 2012.

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