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ORIGINAL RESEARCH ARTICLE

Traction force profile in children with severe perinatal outcomes delivered with a digital vacuum extraction handle: A case–control study

Stefhanie Romero[1,2] | Kristina Pettersson[1,2] | Khurram Yousaf[3] | Magnus Westgren[1,2] | Gunilla Ajne[1,2]

[1]Pregnancy Care & Delivery, Karolinska University Hospital, Stockholm, Sweden

[2]Division of Obstetrics and Gynecology, CLINTEC, Karolinska Institutet, Stockholm, Sweden

[3]School of Technology and Health, Royal Institute of Technology, Stockholm, Sweden

Correspondence
Stefhanie Romero, Pregnancy Care & Delivery, B76, Karolinska University Hospital, Stockholm, 141 86, Sweden.
Email: stefhanie.romero@regionstockholm.se

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Abstract

Introduction: During the second stage of labor, vacuum-assisted delivery is an alternative to forceps delivery and emergency cesarean section. Extensive research concerning perinatal outcomes has indicated that the risk of complications, although rare, is higher than with a spontaneous vaginal delivery. An important factor related to perinatal outcomes is the traction force applied. Our research group previously developed a digital extraction handle, the Vacuum Intelligent Handle-3 (VIH3), that measures and records traction force. The objective of this study was to compare traction force profiles in children with and without severe perinatal outcomes delivered with the digital handle. A secondary aim was to establish a safe force limit.

Material and Methods: This was an observational case–control study at the delivery ward at Karolinska University Hospital, Sweden. In total, 573 children delivered with the digital handle between 2012 and 2018 were included. Cases were defined as a composite of severe perinatal outcomes, including subgaleal hematoma, intracranial hemorrhage, hypoxic ischemic encephalopathy 1–3, seizures or death. The cases in the cohort were matched 1:3 based on five matching variables. Traction profiles were analyzed using the MATLAB® software and conditional logistic regression.

Results: The incidence of severe perinatal outcomes was 2.3%. The 13 cases were matched with three controls each (n = 39). A statistically significant increased odds for higher total traction forces was seen in the case group (odds ratio [OR] 1.004; 95% confidence interval [CI] 1.001–1.007) and for the peak force (OR 1.022; 95% CI 1.004–1.041). Several procedure-related parameters were significantly increased in the case group. As expected, some neonatal characteristics also differed significantly. An upper force limit of 343 Newton minutes (Nmin) revealed an 86% reduction in severe perinatal outcomes (adjusted OR 0.14; 95% CI 0.04–0.5).

Abbreviations: HIE, hypoxic ischemic encephalopathy; NICU, neonatal intensive care unit; VAD, vacuum assisted delivery; VIH3, Vacuum Intelligent Handle-3.

Conclusions: Children with severe perinatal outcomes had traction force profiles with significantly higher forces. The odds for severe perinatal outcomes increased for every increase in Nmin and Newton used during the extraction procedure. A calculated total force level of 343 Nmin is suggested as an upper safety limit, but this must be tested prospectively to provide validity.

KEYWORDS
matched case–control study, perinatal outcome, traction force, traction force profile, vacuum assisted delivery

1 | INTRODUCTION

The most common indications for vacuum-assisted delivery (VAD) is failure of progress in the second stage of labor or fetal distress. It is an alternative to forceps or emergency cesarean delivery when prompt delivery is required. The use of VAD varies worldwide and in Scandinavian countries is used in 6%–9% of all deliveries.[1] Similar to the international guidelines, the Swedish guideline for VAD limits factors such as the number of pulls and the duration of the procedure.[2–4]

Perinatal outcomes after VAD have been extensively studied.[5,6] The incidence of VAD is low but carries an increased risk of complications such as subgaleal hematoma[7,8] and hypoxic ischemic encephalopathy (HIE)[9] compared with spontaneous vaginal delivery. Additionally, the fetal head station, cup detachment and sequential instrumental method have been shown to adversely impact neonatal outcomes.[10–13] When comparing VAD to forceps or emergency cesarean deliveries, these associations are less obvious.[14–17]

The pathophysiology behind the effects of the forces on the fetal head during delivery is unclear,[18,19] and measurements taken during spontaneous vaginal delivery and VAD indicate an increased pressure during the latter.[20–22] The negative pressure in the cup (commonly 0.8 kg/cm^2) and the traction force exerted when pulling the handle are two extra forces added to those in the delivery tract. Clinical guidelines suggest avoiding excessive traction force, but "excessive" is not defined. The previous suggested peak force limits of 216–220 Newtons for cup detachment,[23–25] as well as the force used by the operator during traction, are often underestimated.[26] According to Pettersson et al.,[27] a high level of total traction force is associated with an increased risk of admission to the neonatal intensive care unit (NICU).

We have previously described in detail the digital vacuum extraction handle, the Vacuum Intelligent Handle-3 (VIH3), developed in collaboration with the Royal Institute of Technology, Stockholm.[26] It monitors the traction force exerted in real time and provides objective documentation.[28,29] The aim of this project was to use data from this handle to study the traction force profile in children with and without severe perinatal outcomes. A secondary aim was to calculate a safe traction force limit.

Key message

Neonatal outcomes after vacuum assisted deliveries are affected by traction force. In this study, children with severe perinatal outcomes were delivered with significantly higher traction forces than children without. Keeping the total traction force below 343 Newton minutes could reduce this outcome by 86%.

2 | MATERIAL AND METHODS

2.1 | Study population

This was an observational matched case–control study. The study population consisted of children born at term after a VAD at the two delivery wards within Karolinska University Hospital (Sweden) between 2012 and 2018, using the VIH3 (n = 573). All pregnancies were singleton pregnancies of ≥37 gestational weeks with the fetal head at a low or mid station in the birth canal. Swedish national guidelines were followed for the extraction procedure;[2] these are similar to international guidelines,[3,4] allowing a maximum of six pulls, two cup detachments and a duration of 15–20 min. The cases were defined as children with severe perinatal outcomes. This constitutes a composite outcome of subgaleal hematoma, HIE 1–3, intracranial hemorrhage, seizure or death. Selection was non-computerized and based on matching variables. The first patient who met the matching variables was chosen as a control. Cases were individually matched with three controls each by maternal age (<30, 30–39, ≥40 years), maternal body mass index (BMI) at first trimester (<18.5, 18.5–25, >25 kg/cm^2), parity (primipara or multipara), fetal weight at birth (≤3000 g, >3000 to <4000 g, ≥4000 g) and fetal head station (low or mid).

2.2 | Digital vacuum extraction procedure and calculation of primary outcome

The VIH3 was implemented as part of two prospective clinical studies[27,29] and used by obstetricians (Supporting Information Figure S1). It

is hooked to a Bird metal cup (only the 50 mm cup was used) applied to the fetal scalp with 80 kPa negative pressure and contains a force sensor that is connected via Bluetooth® to a tablet computer. The tablet computer collects the forces registered and transfers them to MATLAB® software, which visualizes, analyzes and performs calculations on these recordings. For each infant, a traction force profile was created during the vacuum extraction procedure. These profiles were visualized using MATLAB®, and the data were analyzed as the primary outcome (Figure 1). Data include a peak force (Newton) and a total force (Newton minutes [Nmin]) for the entire procedure, and a peak force and a total force for each pull. In accordance with Swedish national guidelines, all vacuum extractions were documented with a specific clinical protocol, and pull forces were subjectively evaluated as easy, medium or heavy.

Authors S.R. and K.P. collected maternal, obstetric and neonatal characteristics from the hospital's electronic medical record system (Obstetrix®). Missing data included pH <7.00 and pH <7.10 for three of the controls.

2.3 | Secondary outcome

As a secondary aim, we intended to search for a traction force safety limit using the total traction force. The 10th, 25th, 75th and 90th percentiles for total traction force within the whole cohort without the cases and within the case cohort were predefined for analyses of sensitivity, specificity and area under receiver operating characteristic (ROC) curve in relation to the outcome. The value of highest accuracy was then used as the exposure in a logistic regression analysis.

2.4 | Statistical analyses

Descriptive statistics are presented as mean ± standard deviation, median (minimum–maximum) or number (%), as appropriate. Descriptive analyses used Cochrane's Q test for dichotomous data, repeated measurement analysis of variance for normally distributed continuous data and Friedman's test for non-normally distributed continuous data. For inference, we used conditional logistic regression for the primary outcome and logistic regression for the secondary outcome, with odds ratios (ORs) and 95% confidence intervals (CIs). A p-value <0.05 was considered statistically significant. We used the IBM® statistical software SPSS® Statistics (version 27).

2.5 | Ethics statement

This study was approved by the regional ethics review board, part of The Ethics Review Authority (Etikprövningsmyndigheten), Stockholm: DNR 2012/1553–31/1 on February 9, 2012, 2015/487–31/2 on April 8, 2015 and DNR 2016/211–32 on February 4, 2012.

3 | RESULTS

The incidence of children with severe perinatal outcomes in the study cohort was 2.3% (13/573) (Table 1). Each of the 13 cases was matched with three controls (n = 39) using the matching variables presented in Table 1.

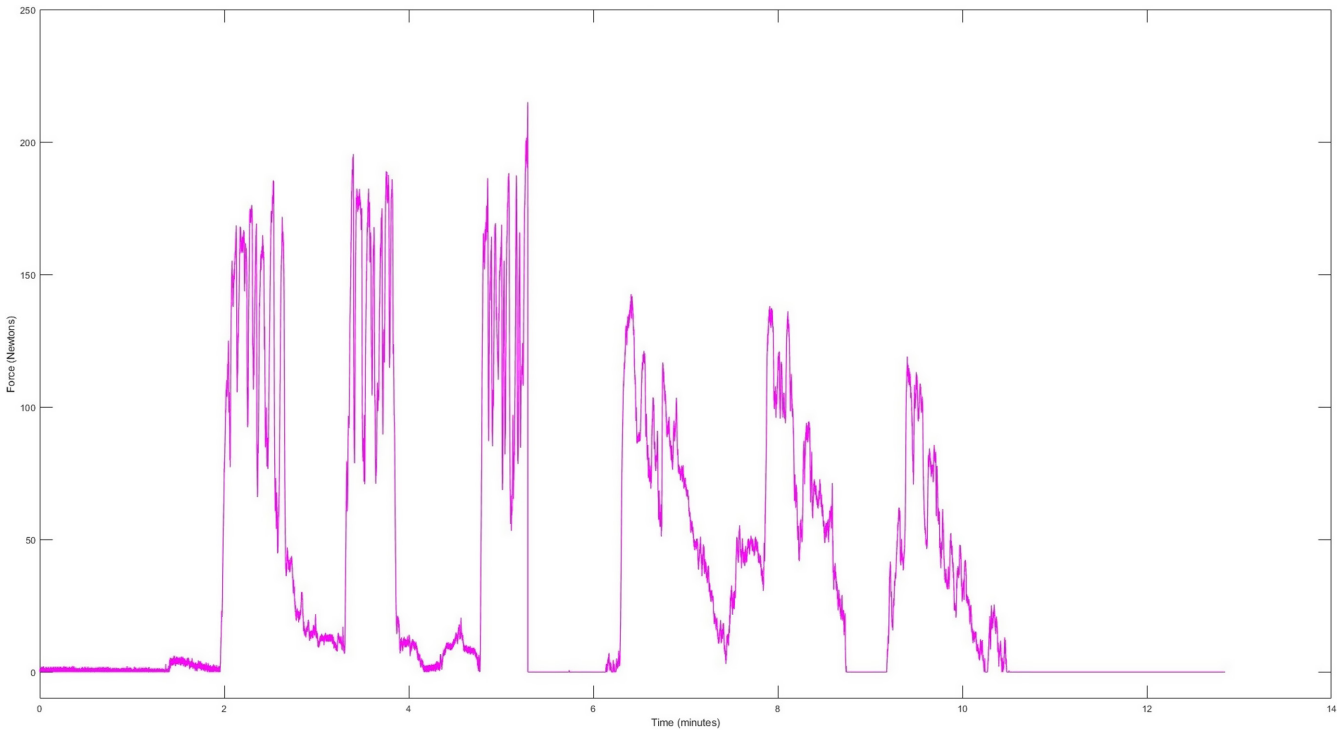

FIGURE 1 Traction force profile.

TABLE 1 Basic characteristics of cases according to the matching variables

Case ID	Maternal age (year)	Maternal BMI (kg/cm^2)	Nulliparous	Fetal head station	Fetal birth weight (g)	Perinatal diagnosis
1	31	24	Yes	Mid	4268	HIE 2, seizure
2	33	23	No	Mid	3755	Subgaleal hematoma
3	34	21	Yes	Mid	3325	Seizure, intracranial hemorrhage
4	34	31	No	Mid	3932	Subgaleal hematoma
5	31	20	Yes	Mid	3345	Subgaleal hematoma
6	47	26	Yes	Mid	3750	HIE 2, subgaleal hematoma, seizure
7	26	23	Yes	Low	4185	HIE 1
8	38	31	Yes	Low	4600	HIE 1
9	39	26	Yes	Mid	3705	HIE 1
10	26	23	Yes	Mid	3575	HIE 1
11	30	25	Yes	Mid	3117	HIE 1
12	23	19	Yes	Mid	4138	HIE 1
13	22	19	Yes	Mid	3105	Subgaleal hematoma

Abbreviations: BMI, body mass index; HIE, hypoxic ischemic encephalopathy.

TABLE 2 Crude comparison of traction force profiles in cases vs controls

Traction force	Case (n = 13)	Control (n = 39)	OR (CI 95%)	p-value
Total force, Nmin	472 (209–1380)	233 (16–842)	1.004 (1.001–1.007)	0.01
Peak force, N	215 (157–377)	194 (119–296)	1.022 (1.004–1.041)	0.02
Total force pull 1, Nmin	93 (21–156)	74 (3–139)	1.009 (0.990–1.029)	0.36
Peak force pull 1, N	203 (142–299)	173 (110–306)	1.010 (0.999–1.027)	0.07
Total force pull 2, Nmin	76 (51–191)	66 (6–138)[a]	1.022 (0.998–1.046)	0.07
Peak force pull 2, N	210 (86–311)	163 (48–290)[a]	1.024 (1.004–1.044)	0.02
Total force pull 3, Nmin	75 (51–180)[b]	39 (5–89)[c]	1.111 (1.003–1.231)	0.04
Peak force pull 3, N	200 (75–332)[b]	155 (53–245)[c]	1.017 (1.001–1.032)	0.03

Note: Data are presented as *n* (%) or median (min-max). Statistical analysis: Conditional logistic regression test.

[a]Missing: 3.

[b]Missing: 1.

[c]Missing: 13.

A conditional logistic regression analysis comparing the traction force profiles between the matched case and control groups is presented in Table 2. Statistically significant higher odds for severe perinatal outcome was seen with each increase in Newton minute used in total force (OR 1.004; 95% CI 1.001–1.007) and each increase in Newton used in peak force (OR 1.022; 95% CI 1.007–1.041) in cases vs controls for the whole extraction procedure.

Results for achieved total force during pull three were similar in the case group (OR 1.11; 95% CI 1.003–1.231) but not at pull one or two. For peak force, there was a significant difference in forces at pull two and three but not at pull one.

There were more extraction procedures in the case group with more than three pulls (OR 12; 95% CI 1.43–99).

We conducted a descriptive analysis between the groups comparing maternal, obstetric and perinatal characteristics (Table 3). It showed a statistically significant longer extraction procedure, an increased number of pulls and cup detachments, and more subjectively heavy extractions in the case group. The case group had a greater need for neonatal intensive care and lower Apgar scores at 5 minutes.

Epidural was used in 85% of the deliveries and oxytocin infusion in close to 100%. Five deliveries (39%) in the case group and six (12%) in the control group were converted to a cesarean (one after a previous attempt with forceps). In this last group, two children were delivered with forceps after the vacuum extraction attempt.

The highest value of accuracy for the secondary outcome, safety limit of total traction force, was reached with the 75th percentile in the full cohort without the cases (345 Nmin [n = 558, two with missing force data]) and the 25th percentile in the case group (341 Nmin [n = 13]). A safety total force limit of 343 Nmin gave a sensitivity of 77%, a specificity of 74%, a positive predictive value of 7% and a negative predictive value of 99% for severe perinatal outcome. A ROC curve was generated with an area under the curve of 0.83 for the total force of 343 Nmin (Supporting Information Figure S2).

The logistic regression analysis showed an adjusted OR (aOR) of 0.14 (95% CI 0.04–0.5) for the safety force limit (Table 4), indicating an 86% decreased risk for a severe perinatal outcome with a total traction force of <343 Nmin.

4 | DISCUSSION

In this case–control study, each case was matched to three controls based on five matching variables of importance to a VAD (Table 1). Cases were defined as a perinatal outcome of subgaleal hematoma, intracranial hemorrhage, HIE (1–3), seizure or death; subgaleal hematoma and HIE were the most common outcomes (no case of death was registered). The traction force profiles were analyzed in cases and controls, all delivered with the VIH3 handle. Cases experienced significantly higher total and peak forces. The calculated OR for the total traction force showed 0.4% increased odds for the composite severe perinatal outcome for each Newton-minute. The same was true for the peak force, with an increased odds of 2.2% for each increase in Newton.

The amount of force used in the succeeding pulls in relation to pull one also differed between the groups. For each subsequent pull, cases were exposed to almost constant levels of forces in contrast to the decreasing levels in the control group, showing a significant difference in both total and peak force at pull three.

Looking at the procedure-related characteristics, the case group had longer VAD durations, more pulls, subjectively heavier extractions and more cup detachments. This was also true for neonatal characteristics such as lower Apgar score at 5 min and increased admissions to the NICU. Although not statistically significant, the case group had a tendency towards more shoulder dystocia.

Selection bias can occur in a case–control study when controls are selected from the same risk set. We tried to approach the risk of confounding by matching our cases and using appropriate statistical analyses. The case group was well defined, which made it easier to choose cases from the study population. Our study population was limited to 573 term deliveries, where 13 were classified as cases. We matched the remaining 558 (two were missing force data) by five variables: age, maternal BMI in the first trimester, fetal birthweight, fetal head station and parity. Some might question whether these variables are sufficient. However, they were chosen in accordance with the assumed association with prolonged second stage of labor and the probability of an operative vaginal delivery.

Our ability to match all cases with three controls is considered a strength. Studies indicate that the statistical power can be increased by matching by more than one control per case but that an additional gain after a matching of 1:4 is small.[30] Another strength is the small amount of missing data in the population.

The small number of cases ($n = 13$) may be considered a limitation since a small sample size can hide differences that are not readily apparent. Nevertheless, sizes are often small when studying rare events. However, it is positive from the clinical point of view that so few cases have been reported over such a long period (2012–2018).

Statistical analyses on matched data are argued to require specific analytical methods, specifically when the strata are small. We

TABLE 3 Maternal, obstetric and perinatal characteristics in cases vs controls

Characteristics	Cases ($n = 13$)	Controls ($n = 39$)	p-value
Maternal characteristics			
First stage of labor, hours	12 ± 4	10 ± 5	0.21
Second stage of labor, hours	3 ± 1	3 ± 2	0.55
Gestational length, days	284 ± 6	283 ± 8	0.59
Obstetric characteristics			
OFHR	7 (54%)	16 (41%)	0.23
Shoulder dystocia	3 (23%)	1 (3%)	0.07
Position OAP	5 (39%)	26 (67%)	0.12
VAD duration, min	10(2–23)	6 (1–19)	<0.01
Number of pulls	5 (2–10)	3 (1–7)	<0.01
Failed VAD	5 (39%)	8 (21%)	0.36
Subjective heavy VAD	12 (92%)	12 (31%)	<0.01
Cup detachment	7 (54%)	3 (8%)	<0.01
Perinatal characteristics			
Sex, male	10 (77%)	19 (49%)	0.25
pH a. umbilicalis <7.00	1 (8%)	0	0.39
Apgar <7 at 5 min	8 (62%)	0	<0.001
NICU admission	11 (85%)	2 (5%)	<0.001

Note: Data are presented as *n* (%), mean ± standard deviation or median (min-max).

Abbreviations: NICU, neonatal intensive care unit; OAP, occipital-anterior position; OFHR, ominous fetal heart rate; VAD, vacuum-assisted delivery.

TABLE 4 Secondary outcome: total traction force safety limit (logistic regression analysis)

	Primary outcome in the cohort	Crude OR (95% CI)	p-value	aOR (95% CI)	p-value
<343 Nmin ($n = 418$)	3 (0.7%)	0.10 (0.03–0.4)	<0.001	0.14 (0.04–0.5)	0.004
≥343 Nmin ($n = 153$)	10 (7%)	1 (ref)		1 (ref)	

Note: aOR for maternal age, maternal BMI, parity, fetal weight at birth and fetal head station in a multivariate regression analysis.

Abbreviations: aOR, adjusted OR; CI, confidence interval; OR, odds ratio.

used conditional logistic regression analyses since the likelihood function is conditioned on the matching variables. These were then eliminated from further consideration to allow us to focus on covariates that, we believe, are not accurate to adjust for. Since we used 1:3 matching, the statistical methods used in the descriptive analyses are according to current recommendations.

Low- and particularly mid-station VAD are associated with an increased risk of perinatal complications.[13,17] To increase patient safety, most countries that practice instrument-assisted deliveries follow procedure-related clinical guidelines. This is mainly to limit fetal stress during the instrumental procedure. The guidelines limit the time of the procedure (usually to a maximum of 15–20 min), the number of pulls (maximum six pulls) and the number of cup or forceps detachments/sliding and recommend avoiding excessive force during pulls, with no further definition of "excessive." The incidence of severe perinatal outcomes after instrument-assisted delivery is generally low but is serious or fatal when it does occur, particularly if another mode of delivery might avoid the outcome. Results from both earlier studies[26] and the present study show that obstetricians underestimate and apply a higher level of force during VAD than earlier anticipated. The results also indicate that a high level of force is associated with unfavorable perinatal outcomes.

The point at which to convert a low- or mid-station VAD attempt to another mode of delivery, preferably to a cesarean section, is a subtle one. High numbers of cup detachments and sequential delivery modes increase the risk of severe perinatal outcomes.[10,11] If a feedback system could increase awareness and a possible safety force limit for the extraction procedure was in place, eg translated into total force, a deliberate conversion of a VAD attempt might increase perinatal safety. If not, mid-station VAD needs to be brought into question where it is practiced.

Is it possible, with current knowledge, to design a safety limit for total traction force during VAD? Pettersson et al.[27] studied a cohort of 331 VADs delivered with the VIH3. The prevalence of severe perinatal outcomes was 1.8% and admittance to the NICU was 7.2%. The 75th percentile of the total traction force during the first three pulls was used, with a level of 221 Nmin calculated as significant for the outcome of NICU admittance. In the present study, the prevalence of severe perinatal outcomes was 2.3%. Using the approach described, a total force limit for the whole extraction procedure <343 Nmin decreased the odds of severe perinatal outcomes by almost 90% (aOR 0.14; 95% CI 0.04–0.5). Prospective studies are needed to clarify whether the force limits discussed will lower the incidence of severe perinatal outcomes or admittance to NICU for a low- or mid-station VAD.

5 | CONCLUSION

The traction force profile is altered in children experiencing severe perinatal outcomes after a low- or mid-station VAD. Increased traction force is associated with this outcome, both in total traction force and in peak force. The odds for severe perinatal outcomes increased for every increase in Newton minute and Newton used during the extraction procedure. A calculated total force level of 343 Nmin is suggested as a safety limit but needs to be tested prospectively to provide validity.

Implementing supportive techniques that can strengthen skill, awareness and objective documentation, with little risk of harm, might increase the perinatal safety of VAD. Our observations could be one step towards such a development.

AUTHOR CONTRIBUTIONS

MW, SR and GA contributed to the conception and planning of the study. KP and SR collected the material. SR and KY conducted the study and the analyses. SR, MW and GA wrote the manuscript.

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CONFLICT OF INTERESTS

None.

ORCID

Stefhanie Romero https://orcid.org/0000-0001-9673-177X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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