# Can We Predict Feto-Maternal Adverse Outcomes of Vacuum Extraction?

Lassen sich unerwünschte fetal-maternale Outcomes bei Vakuumextraktionen vorhersagen?

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## **Key words**

vacuum-assisted delivery, vacuum extraction, adverse outcomes of vacuum delivery, maternal complications of vacuum delivery, neonatal complications of vacuum delivery

#### Schlüsselwörter

Vakuumentbindung, Vakuumextraktion, vakuumbedingte unerwünschte Outcomes, vakuumbedingte mütterliche Komplikationen, vakuumbedingte neonatale Komplikationen

received 29.1.2022 accepted after revision 16.7.2022 published online 7.9.2022

#### **Bibliography**

Geburtsh Frauenheilk 2022; 82: 1274–1282 DOI 10.1055/a-1904-6025 ISSN 0016-5751

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## ABSTRACT

**Introduction** Vacuum extraction (VE) is an important modality in modern obstetrics, yet sometimes results in maternal or neonatal adverse outcomes, which can cause a lifetime disability. We aimed to characterize potential risk factors for adverse outcomes that in retrospect would have led the physician to avoid the procedure.

Materials and Methods Retrospective cohort of 3331 singleton pregnancies,  $\geq$  34 w delivered by VE. 263 deliveries (7.9%) incurred a VE-related feto-maternal adverse outcome, defined as one or more of the following: 3–4 th-degree perineal laceration, subgaleal hematoma, intracranial hemorrhage, shoulder dystocia, clavicular fracture, Erb's palsy or fracture of humerus. 3068 deliveries (92.1%) did not have VE-related adverse outcomes. Both groups were compared to determine potential risk factors for VE adverse outcomes.

**Results** Multivariable regression found seven independent risk factors for VE-related feto-maternal adverse outcomes: Nulliparity – with an odds ratio (OR) of 1.82 (95 % CI = 1.11–2.98, p = 0.018), epidural anesthesia (OR 1.99, CI = 1.42–2.80, p < 0.001), Ventouse-Mityvac (VM) cup (OR 1.86, CI = 1.35–2.54, p < 0.001), prolonged second stage as indication for VE (OR 1.54, CI = 1.11–2.15, p = 0.010), cup detachment (OR 1.66, CI = 1.18–2.34, p = 0.004), increasing procedure duration (OR 1.07 for every additional minute, CI = 1.03–1.11, p < 0.001) and increasing neonatal birthweight (OR 3.42 for every additional kg, CI = 2.33–5.02, p < 0.001). Occiput anterior (OA) position was a protective factor (OR 0.62, CI = 0.43–0.89, p = 0.010).

**Conclusions** VE-related adverse outcomes can be correlated to clinical characteristics, such as nulliparity, epidural anesthesia, VM cup, prolonged second stage as indication for VE, cup detachment, prolonged procedure duration and increasing neonatal weight. OA position was a protective factor. This information may assist medical staff to make an informed decision whether to choose VE or cesarean delivery (CD).

## ZUSAMMENFASSUNG

**Einleitung** Die Vakuumextraktion (VE), umgangssprachlich Saugglockenentbindung genannt, ist ein wichtiges Verfahren der modernen Geburtsheilkunde. Ihr Einsatz hat aber manchmal unerwünschte Folgen für Mutter und Kind, die mit lebenslangen Behinderungen einhergehen können. Ziel dieser Studie war es, die potenziellen Risikofaktoren für unerwünschte Outcomes zu beschreiben, die, retrospektiv gesehen, den Arzt/die Ärztin von einer VE-Entbindung abgehalten hätten.

Material und Methoden Untersucht wurde eine retrospektive Kohort von 3331 Einlingsschwangerschaften, die in der  $\geq$  34. SSW mithilfe der VE entbunden wurden. Bei 263 dieser Entbindungen (7,9%) kam es zu einem VE-bedingten unerwünschten Outcome für Mutter oder Kind, das als Auftreten von einem oder mehreren der nachfolgend aufgelisteten Ereignisse definiert wird: Dammriss 3.–4. Grades, subgaleatisches Hämatom, intrakraniale Blutung, Schulterdystokie, Schlüsselbeinbruch, kindliche Plexusparese oder Oberarmfraktur. Bei 3068 Entbindungen (92,1%) kam es zu keinen VE-bedingten unerwünschten Outcomes. Die 2 Gruppen wurden miteinander verglichen, um potenzielle Risikofaktoren für VEbedingte unerwünschte Folgen auszumachen. **Ergebnisse** Die multivariable Regressionsanalyse fand 7 unabhängige Risikofaktoren für VE-bedingte unerwünschte fetale oder maternale Outcomes: Nulliparität – mit einer Odds Ratio (OR) von 1,82 (95%-KI 1,11–2,98, p = 0,018), Epiduralanästhesie (OR 1,99, 95%-KI 1,42–2,80, p < 0,001), Mityvac-Ventouse-(MV-)Saugglocke (OR 1,86, 95%-KI 1,35–2,54, p < 0,001), ausgedehnte Austreibungsphase als Indikation für eine VE (OR 1,54, 95%-KI 1,11–2,15, p = 0,010), Ablösung der Saugglocke (OR 1,66, 95%-KI = 1,18–2,34, p = 0,004), lange VE-Entbindungsdauer (OR 1,07 für jede zusätzliche Minute, 95%-KI 1,03–1,11, p < 0,001) sowie ein hohes neonatales Geburtsgewicht (OR 3,42 für jedes zusätzliche Kg, 95%-KI 2,33–5,02, p < 0,001). Schutzfaktor bei der Geburt war eine vordere Hinterhauptslage des Kindes (VOHHL) (OR 0,62, 95%-KI 0,43–0,89, p = 0,010).

Schlussfolgerungen VE-bedingte unerwünschte Outcomes waren mit klinischen Merkmalen wie Nulliparität, Epiduralanästhesie, MV-Saugglocke, ausgedehnte Austreibungsphase als Indikation für eine VE, Ablösung der Saugglocke, langer VE-Entbindungsdauer sowie hohem neonatalen Geburtsgewicht korreliert. VoHHL des Kindes war ein Schutzfaktor. Diese Informationen sollten dem medizinischen Personal als Entscheidungshilfe dienen, wenn es um die Entscheidung für eine VE- oder eine Kaiserschnittentbindung geht.

## Introduction

Vacuum extraction (VE) is a common modality for delivery worldwide; used in 5.9% of the deliveries in Israel [1], and in up to 13% of the deliveries in the United Kingdom [2]. It is an important component of modern obstetric care and can be used to avoid cesarean delivery (CD) during the second stage of labor in times of fetal distress, arrest of descent or other maternal indications that require shortening the second stage [3].

Under the appropriate circumstances, VE is the preferred modality compared to CD, because it can often be accomplished more quickly. and CD is also associated with short- and long-term maternal morbidities, such as extensive hemorrhage, infection, prolonged healing, repeat CD, uterine rupture and risk of placental abnormalities such as placenta accreta [3, 4, 5].

However, VE is also a risk factor for several maternal morbidities compared to second stage CD, such as third- or fourthdegree perineal lacerations [6], with an adjusted odds ratio of up to 13.9–14.9 [7]. Perineal lacerations can cause permanent damage to the anal sphincter and result in lifetime disability [8, 9]. At times, VE can also lead to excessive maternal blood loss during delivery, just as CD does [10].

As for neonatal complications, VE compared to intrapartum CD, has been linked to several neonatal injuries related to birth trauma, such as clavicular fracture [11], humerus fracture and Erb's palsy [12, 13]. It has also been specifically associated with neonatal head injuries, which have long-term implications such as subgaleal hematoma (SGH), intracranial hemorrhage and skull fracture [14, 15].

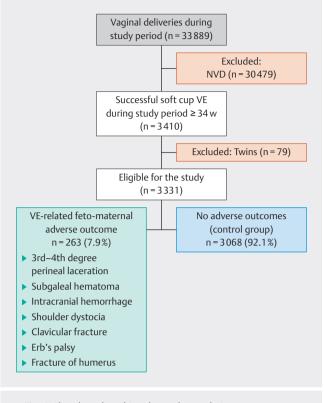
VE is also known as a risk factor for shoulder dystocia [16], a life-threatening situation in which, even if a successful extraction is achieved, some neonates will incur permanent disability due to brachial plexus nerve injury.

Many considerations affect a physician's decision to perform VE or CD during the second stage of labor. At times, looking at the severe complications sustained by the mother or the newborn due to VE, many physicians wish they would have chosen CD, even when conditions for performing VE met the American College of Obstetricians and Gynecologists (ACOG) guidelines [3] and the procedure was not contraindicated.

Previous studies have evaluated risk factors for maternal complications during VE, others have found risk factors for neonatal complications associated with VE. None of the studies to date have examined potential risk factors for the combined outcome of serious maternal and neonatal complications.

In addition, since non-metal vacuum cups are not used worldwide, maternal and fetal adverse outcomes have not been fully explored in large cohorts.

The aim of the current study, was to explore VE performed using a non-metal cup and to determine potential risk factors for maternal **or** neonatal adverse outcomes that in retrospect would have led the physician to avoid the procedure. We aimed to recognize unfavorable conditions for VE in which a thorough discussion regarding mode of delivery is needed.



**Fig. 1** Flowchart describing the study population.

## Materials and Methods

This retrospective cohort study included women delivered by means of a non-metal cup VE, January 2014 to August 2019, in a tertiary care medical center. All VE were performed at  $\geq$  34 weeks of gestation. Additional inclusion criteria were singleton pregnancies, without known genetic or structural anomalies.

We divided our cohort into two groups. The first group included deliveries with VE-related feto-maternal adverse outcomes, defined as one or more of the following: third- or fourth-degree perineal laceration, SGH, intracranial hemorrhage, shoulder dystocia, clavicular fracture, Erb's palsy, fractures of humerus (VE adverse outcomes group). The second group included deliveries without any VE-related feto-maternal adverse outcomes (control group). We compared the two groups in terms of basic maternal, labor and delivery characteristics to determine potential risk factors for VE-related adverse outcomes.

We excluded all cases of failed vacuum, since some of the outcomes included in the composite adverse outcome defined were necessarily related to the extraction of the body of the fetus through the birth canal, and also to assure that all adverse outcomes described were associated only with VE, and not with a subsequent forceps or CD.

Each VE was carried out by a senior physician who performed a full evaluation before the procedure and assured the conditions met ACOG guidelines [17]. Either a Ventouse-Mityvac (VM) or Kiwi Omnicup vacuum cup were used. The type of vacuum cup was selected by the physician. A pediatrician was present at every VE. After delivery, the performing physician completed a detailed electronic report regarding assessment of the labor pattern before and during the procedure.

## Data collection

Data were retrieved using the electronic maternal database of the delivery room, then crossed-tabulated with data from the Neonatal Unit and the Neonatal Intensive Care Unit (NICU). All medical records were reviewed manually to complete missing data. Data collected included:

- Maternal demographics: age, body mass index (BMI), gravidity, parity, gestational age at delivery, diabetes (pre-gestational or gestational) [18] and history of CD.
- 2. Maternal outcomes: rates of third- or fourth-degree perineal lacerations [19] and maternal blood loss during delivery.
- Labor and delivery characteristics: use of epidural anesthesia, intrapartum fever, duration of first, second and third stages of labor, indication for VE, fetal head station and position at time of VE, vacuum cup type, vacuum duration and the presence of cup detachments.
- Neonatal characteristics and outcomes: fetal weight, NICU hospitalization and VE-related neonatal adverse outcomes (SGH, intracranial hemorrhage, shoulder dystocia, Erb's palsy, fracture of humerus or clavicle).

Indications for VE were categorized as:

- 1. Non-reassuring fetal heart rate [20];
- 2. Prolonged second stage [21] and
- Maternal indications, including medical background requiring shortening second stage or maternal exhaustion.

For historical reasons, fetal head station was defined by thirds from ischial spines -3 to +3, and was divided into Mid-pelvis: S+1, Low: S+2, and Outlet: S+3 and below. VE was performed according to ACOG guidelines.

Neonatal diagnoses were determined by the senior pediatrician present at VE and during neonatal hospitalization, according to international standards and relevant imaging.

## Statistical analysis

Comparison of continuous variables between groups was performed using t-test. Categorical data were compared using Chisquare or Fisher's exact test, each when appropriate. Multivariate logistic regression and adjusted odds ratios were calculated to examine variables that had an independent effect on severe VE complications. A probability value of < 0.05 was considered significant. All analyses were performed using SPSS-25 software (IBM, Armonk, NY, USA).

## Results

During the study period, 33889 women delivered vaginally in our institution, of which 3410 had a successful VE (9.8%). A total of 3331 women met the inclusion criteria and were included in the study (**> Fig. 1**).

► Table 1 Characteristics of vacuum extraction (VE) adverse outcome group, N = 263.

Injury	Incidence among VE adverse outcome group	
Third- or fourth-degree perineal laceration, N (%)	66 (25.1%)	
Subgaleal hematoma, N (%)	154 (58.6%)	
Intracranial hemorrhage, N (%)	1 (0.4%)	
Shoulder dystocia, N (%)	22 (8.4%)	
Clavicular fracture, N (%)	23 (8.7%)	
Erb's palsy, N (%)	14 (5.3%)	
Fracture of humerus, N (%)	1 (0.4%)	
Multiple injuries (more than one), N (%)	19 (7.2%)	

Overall, 263 (7.9%) deliveries had a maternal or neonatal adverse outcome related to VE, defined as at least one of the following: third- or fourth-degree perineal laceration, SGH, intracranial hemorrhage, shoulder dystocia, clavicular fracture, Erb's palsy and fracture of humerus (VE adverse outcome group), whereas 3068 (92.1%) did not have VE-related adverse outcomes (control group). The characteristics of the VE adverse outcome group are described in ► Table 1.

We compared the two groups in terms of basic maternal, and labor and delivery characteristics to determine potential risk factors for VE-related feto-maternal adverse outcomes.

## Maternal characteristics

Women in the VE adverse outcome group were statistically younger than those without adverse outcomes (29.3 ± 4.5 vs.  $30.3 \pm 5.2$  years, respectively; p = 0.004), but this difference is not clinically significant (**> Table 2**). More were nulliparous (80.6% vs. 71.8%, p = 0.002).

Previous CD was less common in the VE adverse outcome group (3.4% vs. 8.0%, p = 0.008).

No differences were found between the groups regarding maternal BMI, gestational age at delivery, and pre-gestational or gestational diabetes mellitus rates.

## Labor and delivery characteristics

The use of epidural anesthesia was more common in the VE adverse outcome group (29.3% vs. 18.1%, p < 0.001). Rates of intrapartum fever were also higher (12.9% vs. 8.3%, p = 0.011; **Table 3**).

The use of VM cup type was more common in deliveries with VE adverse outcomes (54.3% vs. 34.6%, p < 0.001). Procedure duration in these deliveries was longer (6.9 min ± 5.8 vs. 5.0 ± 3.3, p < 0.001), and vacuum cup detachment occurred more often (30.7% vs. 19.6%, p < 0.001).

Occiput anterior (OA) position was less common in the VE adverse outcome group (73.5% vs. 81.0%, p = 0.004).

Fetal head stations at VE were higher in the VE adverse outcome group. In both groups, most of the fetuses were at S+1 (midpelvis) when VE was initiated, fewer (37.5%) were at S+2 (low) and the minority (2.3%) were at S+3 and below (outlet). Yet, we found a relatively higher portion of midpelvis station in the VE adverse outcome group (63.1% vs. 56.2%, p = 0.038) and fewer at outlet station (0.4% vs. 2.6%, p = 0.031).

Non-reassuring fetal heart rate was the most common indication for VE, but its rate was relatively low in the VE adverse outcome group (61.4% vs. 76.7%, p < 0.001). Prolonged second stage was the second most common indication, and its rate was relatively high in the VE adverse outcome group (36.2% vs. 21.7%, p < 0.001).

Second stage of labor was longer in the VE adverse outcome group (173.7 min  $\pm$  79.6 vs. 135.7 min  $\pm$  81.8, p < 0.001).

Neonatal birth weight was significantly higher in the VE adverse outcome group ( $3419.1 \text{ g} \pm 460.3 \text{ vs}$ .  $3169.6 \text{ g} \pm 433.6$ , p < 0.001).

Interestingly, blood loss during delivery was lower in the VE adverse outcome group (221 ml  $\pm$  300 vs. 333.6 ml  $\pm$  200.6, p = 0.021).

Variable	VE adverse outcome group (n = 263)	Control group (n = 3068)	P value
Maternal age, years (mean ± SD; median	29.3 ± 4.5; 29	30.3 ± 5.2; 30	0.004
Maternal BMI ± SD	23.6 ± 4.6	23.3 ± 4.9	0.643
Parity ± SD	0.3 ± 0.7	$0.4 \pm 0.9$	0.023
Nulliparous (N, %)	212 (80.6%)	2202 (71.8%)	0.002
Previous cesarean delivery, N (%)	9 (3.4%)	244 (8.0%)	0.008
Gestational age [days, weeks] Mean ± SD; median	278 (39.7 w) ±8.8 (1.3 w); 279	277.3 (39.6 w) ± 9.4 (1.3 w); 279	0.193
Gestational or pregestational DM, N (%)	23 (8.7%)	216 (7.0%)	0.304

► Table 2 Baseline characteristics of women with or without feto-maternal adverse outcomes related to vacuum extraction (VE).

		VE adverse outcor	ne group (N=263)	Control group (N	l = 3068)	P value
Epidural (N %)		77 (29.3%)		555 (18.1%)		< 0.001
Intrapartum fever (N, %)		34 (12.9%)		255 (8.3%)		0.011
Vacuum type	Kiwi	116 (45.7%)		1907 (65.4%)		< 0.001
	VM	138 (54.3%)		1007 (34.6%)		
Procedure duration (min)	Mean ± SD; median	6.9 ± 5.8; 5		5.0 ± 3.3; 5		< 0.001
Vacuum detachment (N, %)		78 (30.7%)		571 (19.6%)		< 0.001
Fetal position OA (N, %)		180 (73.5%)		2307 (81.0%)		0.004
Head station at VE (N, %)	Mid-pelvis	154 (63.1%)		1585 (56.2%)		0.038
	Low	89 (36.5%)		1159 (41.1%)		0.160
	Outlet	1 (0.4%)		74 (2.6%)		0.031
Vacuum indication (N, %)	NRFHR	151 (61.4%)		2194 (76.7%)		< 0.001
	Prolonged second stage	89 (36.2%)		622 (21.7%)		
	Maternal indication	6 (2.4%)		46 (1.6%)		
Labor duration, minutes,	First stage	600.6 ± 249.5		645.1 ± 429.5		0.631
mean, SD	Second stage	173.7 ± 79.6		135.7 ± 81.8		< 0.001
	Third stage	9.2 ± 6.9		9.5 ± 6.9		0.451
Neonatal birth weight, g	Mean ± SD	3419.1 ± 460.3		3169.6 ± 433.6		< 0.001
Delivery blood loss, ml	Mean ± SD	221 ± 300		333.6 ± 200.6		0.021
NICU admission (N, %)		11	4.2%	85	2.8%	0.189

>Table 3 Labor and delivery characteristics of women with or without feto-maternal adverse outcomes related to vacuum extraction (VE).

SD = standard deviation; VM = Ventouse-Mityvac; NRFHR = Non-reassuring fetal heart rate

No differences were noted between the groups regarding the duration of first and third stages of labor and the rates of NICU admission.

## Logistic regression

Logistic regression indicated seven independent risk factors for VE-related feto-maternal adverse outcomes (**► Table 4**). These included nulliparity (adjusted odds ratio [OR] 1.82 (95% CI 1.11–2.98, p = 0.018), use of epidural anesthesia (OR 1.99, 95% CI 1.42–2.80, p < 0.001), use of VM cup (OR 1.86, 95% CI 1.35–2.54, p < 0.001), prolonged second stage as indication for VE (OR 1.54, 95% CI 1.11–2.15, p = 0.010), vacuum cup detachment (OR 1.66, 95% CI 1.18–2.34, p = 0.004), increasing procedure duration (OR 1.07 for every additional minute 95% CI 1.03–1.11, p < 0.001) and increasing neonatal birthweight (OR 3.42 for every additional kg, 95% CI 2.33–5.02, p < 0.001). OA position was found to be a protective factor against severe VE complications (OR 0.62, 95% CI 0.43–0.89, p = 0.010).

Maternal age, history of CD, intrapartum fever and fetal head station at VE were not significant in terms of VE adverse outcomes (► Table 4, ► Table 5).

## Failed VE

A total of 47 women had a failed VE and were excluded from the study. Their basic maternal characteristics of age, parity, nulliparity, previous CD, gestational age at delivery, gestational diabetes mellitus and maternal BMI were similar to those included in the study, but their labor and delivery characteristics differed significantly. Women who experienced failed VE had a lower percentage of OA position (47.6% vs. 74.7%, p<0.001), higher head station at the beginning of VE (82.6% vs. 56.7% at midpelvis, p = 0.004) and a higher rate of prolonged second stage as the indication for VE (58.7% vs. 22.9%, p<0.001). Mean neonatal BW in the failed VE group was higher than in the successful VE group (3429 ± 422 g vs. 3189 ± 441 g, respectively; p<0.001). Rates of use of each vacuum cup type were similar in both groups.

## Discussion

The purpose of this study was to determine potential risk factors for adverse maternal or neonatal outcomes related to VE, including third- or fourth-degree perineal laceration, SGH, intracranial hemorrhage, shoulder dystocia, clavicular fracture, Erb's palsy and fracture of humerus. ► Table 4 Multivariable logistic regression analysis of factors associated with VE-related feto-maternal adverse outcomes.

Variable**	Adjusted Odds Ratio (OR)	95% CI	P value
Nulliparity	1.82	1.11-2.98	0.018
Epidural anesthesia	1.99	1.42-2.80	< 0.001
Vacuum cup type – Ventouse-Mityvac	1.86	1.35–2.54	< 0.001
Prolonged 2 nd stage as VE indication	1.54	1.11–2.15	0.010
OA position	0.62	0.43-0.89	0.010
Vacuum cup detachment*	1.66	1.18-2.34	0.004
Procedure duration (each additional minute)*	1.07	1.03-1.11	< 0.001
Increasing neonatal BW (each additional kg)	3.42	2.33-5.02	< 0.001

\* R square for procedure characteristics (duration and cup detachment): 0.041

\*\* R square for all variables: 0.152

► Table 5 Multivariable logistic regression analysis of factors unassociated with VE-related feto-maternal adverse outcomes.

Variable	Adjusted Odds Ratio (OR)	95% CI	P value
Maternal age	0.99	0.96–1.02	0.422
History of cesarean delivery	1.23	0.51–2.99	0.643
Intrapartum fever	1.14	0.71-1.82	0.586
Fetal head station before VE	0.91	0.71-1.82	0.583

While previous studies explored neonatal complications and maternal complications separately, we chose to combine these complications under the same composite outcome, as they all have long-term implications and should be considered when choosing to perform VE. By doing so, we aimed to help physicians avoid performing VE under unfavorable conditions that could result in permanent injury to the mother or the newborn, and consider CD instead. This study is also the first large cohort focusing on adverse outcomes related to non-metal vacuum cups.

We found seven independent risk factors for VE-related fetomaternal adverse outcomes: nulliparity, epidural anesthesia, use of VM cup, prolonged second stage as indication for VE, vacuum cup detachment, increasing procedure duration and greater neonatal weight. OA position was a protective factor against VE adverse outcomes.

Our findings agree with those of previous studies regarding risk factors for SGH and intracranial hemorrhage [22, 23, 24], and risk factors for shoulder dystocia or neonatal birth trauma [16, 25, 26]. Third- or fourth-degree perineal lacerations during VE were reported to be associated with nulliparity and increasing neonatal weight [24, 27]. Our study results agree with those of previous reports.

Our findings may be explained by the logic assumption that more difficult VEs increase the amount of force exerted on the mother's pelvis and on the fetus, and thus, cause greater trauma to both. The use of the VM mushroom-shaped cup was a risk factor for severe VE complications in our cohort, compared to the Kiwi-OmniCup. These findings were not reported in a previous study conducted on a smaller cohort [28], but it might have been underpowered for these rare outcomes.

Of note, the overall rate of SGH in our cohort was 4.6% (154/ 3331). This prevalence is similar to previously published studies [29, 30].

The worldwide consensus is that VE is the preferred modality of delivery for the mother compared to CD during the second stage of labor, as it is associated with lower rates of maternal morbidity and mortality [7, 31]. CD is also associated with increased risks for fertility and future pregnancy [32]. In 2014, the ACOG recommended encouraging operative vaginal delivery as a strategy to reduce the rates of CD [21]. However, a recent study raised the concern that encouraging higher rates of VE could result in increases in severe perinatal and maternal morbidity [32].

When exploring the published data, we found that severe maternal complications during CD are relatively rare, with an incidence of about 0.6–2.7% [33, 34]. As for long-term outcomes of CD, morbidity is also rare, and there are even some beneficial maternal effects to CD compared to vaginal deliveries, such as reduced rates of pelvic organ prolapse [32]. On the other hand, the risk for third- or fourth-degree perineal lacerations during VE is about 4.5–6.5% [35]. Of these, 61% of women will remain with symptoms that impair their quality of life [9]. Thus, in the presence of unfavorable conditions, we believe that one should not try to perform a VE at any cost.

VE is considered beneficial to the newborn compared to second stage CD because it is quicker in terms of fetal extraction; thus lowering the risk for hypoxic damage when fetal distress is suspected during delivery [36]. Yet, data comparing these two modalities are conflicting, with one study reporting higher rates of neonatal adverse outcomes with CD [37], and another showing higher rates with VE [38].

Although an attempt for guick extraction to avoid hypoxic ischemic damage is understood, fetal distress is not the only indication for VE. Many VEs are performed for other indications, such as prolonged second stage or maternal conditions requiring shortening the second stage [39]. In these situations, time from decision to extraction has minimal importance; thus, VE loses its potential beneficial effect for the fetus compared to CD. Moreover, it seems that VEs performed specifically for prolonged second stage are associated with higher rates of severe maternal and perinatal morbidity/mortality compared to CD [7, 38]. This makes sense because the indication itself implies feto-pelvic dystocia. Our study also found prolonged second stage as indication for VE to be a risk factor for severe complications. Thus, when considering VE due to prolonged second stage or due to maternal indications, an informed decision should be made based on the risks versus benefits. Intrapartum trans-perineal ultrasound or digital feedback might also help predict an upcoming complicated VE and assist in the decision-making process [40, 41].

Interestingly, although previous reports have suggested that midpelvic VE places the neonate at risk for adverse outcomes compared to CD [31, 42], our study found that head station was not a significant risk factor for VE-related adverse outcomes.

Another aspect to consider are the similarities found between the characteristics of deliveries that resulted in VE-related adverse outcomes and the failed VE population. Both had relatively higher neonatal birthweights, lower rates of OA position, higher fetal head stations and higher rates of prolonged second stage as the indication for VE. Previous studies also found these characteristics as risk factors for failed VE [43, 44]. As is known, failed VE can result in high morbidity for the mother and the newborn [44, 45], which should be considered when deciding whether to perform VE under unfavorable conditions or CD.

#### Strengths and limitations

The strengths of our study are that it included a large, homogenous cohort. Data were retrieved from a single institution with a strict protocol for VE. Only successful procedures using a nonmetal cup were included.

The main limitation of our study is its methodological design as a retrospective cohort study. Relevant information, such as the severity of maternal and neonatal injuries, and their long-term outcomes, such as fecal incontinence and neurological deficits are lacking. However, we assume that the rates of permanent damage due to VE-related adverse outcomes are similar to those reported in the literature; thus, enabling an informed decision based on our study findings. Data regarding whether the onset of labor was induced or spontaneous are also missing, but we believe this information is relatively unimportant. Diagnosis of fetal head station by vaginal examination alone might have been subjective. Factors such as operator technique and experience could have affected the outcomes, and data regarding location of the cup in relation to the neonatal head sutures were also missing and might have influenced neonatal head injuries.

## Conclusions

VE is an important modality in modern obstetrics; yet, occasionally it results in maternal and neonatal adverse outcomes, which can cause lifetime disability. Our study found seven independent risk factors for VE-related feto-maternal adverse outcomes: increasing neonatal weight, epidural anesthesia, use of VM cup, vacuum cup detachment, prolonged second stage as indication for VE and increasing procedure duration. OA position was a significant protective factor against VE adverse outcomes. This information may help medical staff performing VEs make an informed decision regarding VE or CD during the second stage of labor. Additional large-scale, prospective studies are needed to establish the risk factors for VE-related adverse outcomes.

## Declarations

Funding: This study was not funded.

**Availability of data and material:** Data can be made available upon reasonable request from the corresponding author.

Author contributions: Gal Cohen: Project development, Data Collection, Manuscript writing and editing. Hanoch Schreiber, Michal Ovadia: Data collection. Gil Shechter-Maor, T Biron-Shental: Revised manuscript critically.

**Ethics approval:** The study was approved by the Meir Medical Center Ethics Committee in August 2019, approval number 0246–19-MMC. Since the study was based on patient records, informed consent was not required.

## Acknowledgement

The authors thank Navah Jelin, MS for data analysis and Faye Schreiber, MS for editing the manuscript. They are employees of Meir Medical Center.

#### Conflict of Interest

The authors declare that they have no conflict of interest.

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