Head Injuries Related to Birth Trauma in Low Birthweight Neonates During Vacuum Extraction

Kopfverletzungen durch vakuumbedingtes Geburtstrauma bei Neugeborenen mit niedrigem Geburtsgewicht

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ABSTRACT

Introduction Preterm delivery (gestational age < 34 w) is a relative contraindication to vacuum extraction. Current data do not differentiate clearly between preterm delivery and low birthweight. We aimed to evaluate the impact of non-metal vacuum cup extraction on neonatal head injuries related to birth trauma in newborns with low birthweights (< 2500 g).

Materials and Methods A retrospective cohort of 3377 singleton pregnancies delivered by vacuum extraction from 2014 to 2019. All were gestational age ≥ 34 w. We compared 206 (6.1 %) neonates with low birthweights < 2500 g to 3171 (93.9 %) neonates with higher birthweights, divided into 3 subgroups (2500–2999 g, 3000–3499 g, and ≥ 3500 g). A primary composite outcome of neonatal head injuries related to birth trauma was defined.

Results The lowest rates of subgaleal hematoma occurred in neonates < 2500 g (0.5 %); the rate increased with every additional 500 g of neonatal birthweight (3.5 %, 4.4 % and 8.0 % in the 2500–2999 g, 3000–3499 g, and ≥ 3500 g groups, respectively; p = 0.001). Fewer cephalohematomas occurred in low birthweight neonates (0.5 % in < 2500 g), although the percentage increased with every additional 500 g of birthweight (2.6 %, 3.3 % and 3.7 % in the 2500–2999 g, 3000–3499 g, and ≥ 3500 g groups, respectively, p = 0.020). Logistic regression found increasing birthweight to be a significant risk factor for head injuries during vacuum extraction, with adjusted odds ratios of 8.12, 10.88, and 13.5 for 2500–2999 g, 3000–3499 g, and ≥ 3500 g, respectively (p = 0.016). NICU hospitalization rates were highest for neonates weighing < 2500 g (10.2 %) compared to the other groups (3.1 %, 1.7 % and 3.3 % in 2500–2999 g, 3000–3499 g, ≥ 3500 respectively, p < 0.001).

Conclusions Vacuum extraction of neonates weighing < 2500 g at 34 w and beyond seems to be a safe mode of delivery when indicated, with lower rates of head injury related to birth trauma, compared to neonates with higher birthweights.

ZUSAMMENFASSUNG

Einleitung Frühgeburtlichkeit (Schwangerschaftsalter < 34 SSW) ist eine relative Kontraindikation für eine Vakuumextraktion. Die aktuellen Daten machen aber keine klare Unterscheidung zwischen Frühgeburt und niedrigem Geburtsgewicht. Ziel unserer Studie war es, die Auswirkungen einer nicht metallenen Saugglocke auf geburtsbedingte Kopfverletzungen bei Neugeborenen mit niedrigem Geburtsgewicht (< 2500 g) zu evaluieren.

Material und Methoden Es wurde eine retrospektive Untersuchung einer Geburtskohorte durchgeführt, bestehend aus 3377 Einlingsschwangerschaften, die zwischen 2014 und 2019 mit Vakuumextraktion entbunden wurden. Das Schwangerschaftsalter aller untersuchten Schwangerschaften war ≥ 34 SSW. Die Studie verglich 206 (6,1 %) Neugeborenen mit niedrigem Geburtsgewicht (< 2500 g) mit 3171 (93,9 %) Neugeborenen mit höherem Geburtsgewicht, wobei letztere in 3 Untergruppen (2500–2999 g, 3000–3499 g und ≥ 3500 g) unterteilt wurde. Der primäre kombinierte Endpunkt wurde als geburtstraumabedingte Kopfverletzungen bei Neugeborenen definiert.

Ergebnisse Die niedrigste Rate an subgalealen Hämatomen fand sich in der Gruppe von Neugeborenen mit einem Geburtsgewicht von < 2500 g (0,5 %); die Rate nahm mit jedem zusätzlichen 500 g an Geburtsgewicht zu (3,5 %, 4,4 % bzw. 8,0 % jeweils für die 2500–2999-g-, 3000–3499-g- bzw. ≥ 3500-g-Gruppe; p = 0,001). Es traten weniger Kephalhämatome in der Gruppe der Neugeborenen mit niedrigem Geburtsgewicht auf (0,5 % in der < 2500-g-Gruppe), aber der Prozentsatz nahm mit jedem zusätzlichen 500 g an Geburtsgewicht zu (2,6 %, 3,3 % bzw. 3,7 % für die 2500–2999-g-, 3000–3499-g- bzw. ≥ 3500-g-Gruppen, p = 0,020). Nach der logistischen Regressionsanalyse war zunehmendes Geburtsgewicht ein signifikanter Risikofaktor für vakuumbedingte Kopfverletzungen, mit einem angepassten Chancenverhältnis von jeweils 8,12, 10,88 bzw. 13,5 für die 2500–2999-g-, 3000–3499-g- bzw. ≥ 3500-g-Gruppe (p = 0,016). Neugeborenen mit einem Geburtsgewicht von < 2500 g (10,2 %) hatten die höchsten Einweisungsraten auf die Neugeborenenintensivstation verglichen mit den anderen Gruppen (3,1 %, 1,7 % bzw. 3,3 % für die 2500–2999-g-, 3000–3499-g- bzw. ≥ 3500-g-Gruppe, p < 0,001).

Schlussfolgerungen Wenn eine Vakuumentbindung indiziert ist, scheint die Vakuumextraktion von Neugeborenen mit einem Geburtsgewicht von < 2500 g in der 34. SSW und danach ein sicherer Entbindungsmodus zu sein, der mit niedrigeren geburtsbedingten Kopfverletzungsraten assoziiert ist, verglichen mit Neugeborenen mit einem höheren Geburtsgewicht.

Abbreviations

BW	birthweight
CD	cesarean delivery
GA	gestational age
LBW	low birthweight
NICU	neonatal intensive care unit
NRFHR	non-reassuring fetal heart rate
OA	occiput anterior
SDH	subdural hematoma
SGH	subgaleal hematoma
VE	vacuum extraction

Introduction

Vacuum extractions (VE) are used in 10–13 % of deliveries in the UK [1]. In the USA, rates are decreasing [2]. Despite different attitudes, there is a worldwide consensus that early preterm delivery (gestational age [GA] < 34 w) is a relative contraindication for VE, due to an increased rate of intraventricular hemorrhage [2, 3]. However, this consensus is based mainly on empirical recommendations, while data regarding this GA and a safe lower age limit have yet to be established [4, 5]. Moreover, existing data do not differentiate clearly between preterm delivery and low birthweight (LBW). Therefore, it is uncertain whether the increased neonatal risks of VE are related to the preterm delivery or to the accompanying LBW.

VE is a risk factor for several neonatal injuries related to birth trauma [6, 7]. It has also been specifically linked to neonatal cephalohematoma, subgaleal hematoma (SGH), intracranial hemorrhage and skull fractures [4, 8, 9].

Currently, data linking a higher rate of birth trauma to decreasing GA or neonatal birthweight (BW) are controversial. Two small studies evaluated outcomes in preterms with LBW, comparing VE with unassisted vaginal delivery. Both demonstrated VE to be relatively safe for small neonates, finding no increase in neonatal morbidity or intraventricular hemorrhage [10, 11].

A larger study evaluated the risks of VE compared to other modes of delivery in preterms during labor and found higher odds ratios for intra- and extracranial hemorrhages with VE [4].

All the above studies compared VE with other modes of delivery at a certain weight threshold. This comparison is limited because VE is always associated with higher rates of neonatal complications. Therefore, to evaluate the true effect of LBW, a better comparison would be between VE performed at different neonatal weights. This comparison was conducted by Aviram et al., who compared neonatal injuries during VE using a metal vacuum cup. Birth trauma was similar between neonates with birthweights below and above 2500 grams [5].

Since metal cups are associated with more neonatal birth trauma, as compared to non-metal cups, many physicians favor the latter [12, 13, 14, 15]. Common non-metal cups include the Kiwi Omnicup (Clinical Innovations, Murray, Utah, USA) and the mushroom-shaped Ventouse-Mityvac vacuum-assisted delivery system

(CooperSurgical, Inc., Trumbull, CT, USA). Both systems consist of rigid, mushroom-shaped disposable cups. The main differences between them are the vacuum mechanism (handheld pump vs. conventional vacuum) and the traction pole (flexible in the Kiwi and rigid in the Mityvac). Previous studies comparing these two cups found no differences in adverse neonatal outcomes [16].

We aimed to evaluate the impact of VE on neonatal head injuries related to birth trauma in neonates with LBW (< 2500 g), using a non-metal vacuum cup.

Materials and Methods

This is a retrospective cohort study, including singleton pregnancies with no known genetic or structural anomalies which were delivered by VE using a non-metal cup, from January 2014 to August 2019 in a single academic institution. All VE were performed at GA ≥ 34 weeks.

To ensure that the reported birth injuries were associated with VE only, we excluded a single case of failed vacuum extraction with a subsequent forceps delivery, and included cases of either successful VE or failed VE followed by cesarean delivery.

Each VE was attended by a senior physician (a graduate of a 6-year OBGYN residency) who performed a full evaluation before the procedure and ensured that the conditions met the American College of Obstetricians and Gynecologists (ACOG) guidelines [17]. The procedure itself was performed by an OBGYN resident supervised by a senior physician, or by the senior physician himself when residents were absent or had difficulties during the procedure. This protocol was maintained irrespective of fetal estimated weight or gestational age during delivery. A pediatrician was present at every VE. All VE were performed using a non-metal cup (Ventouse-Mityvac or Kiwi Omnicup), according to physician's preference. Cup size was identical for both cups used – 50 mm. Metal cups were not used in our institution. The procedure was aborted after 3 cup detachments or when procedure duration reached more than 30 minutes, according to the guidelines of the Israel Society of Obstetrics and Gynecology [18]. After delivery, the physician completed a detailed report detailing the assessment of the labor pattern before and during the procedure.

We divided our cohort into 2 groups according to neonatal birthweights: neonates weighing < 2500 g or ≥ 2500 g. The second group was divided further into 3 subgroups: 2500–2999 g, 3000–3499 g and ≥ 3500 g. Primary and secondary outcome rates were also calculated for the proportion of newborns weighing ≥ 4000 g.

First, we compared the < 2500 g neonates with the ≥ 2500 g neonates. Subsequently, we compared the < 2500 g neonates with each of the 3 subgroups, individually. Primary and secondary outcome rates were also calculated for the proportion of newborns weighing ≥ 4000 g in group 4.

Since neonatal BW should be correlated to GA, we also performed a comparison between neonates who were small, average, and large for gestational age (SGA, AGA, LGA respectively), in order to evaluate the neonatal outcomes in each group. SGA, AGA and LGA were diagnosed according to local birthweight charts [19].

The primary composite neonatal outcome was defined as neonatal head injuries related to birth trauma, including one or more of the following: SGH, cephalohematomas, SDH and intracranial hemorrhages. We also calculated the rates of SGH and cephalohematomas for each group.

Secondary outcomes were neonatal intensive care unit (NICU) hospitalization rates and a secondary composite neonatal outcome including one or more of the following neonatal outcomes not related to birth trauma: Apgar scores, respiratory distress, need for mechanical ventilation, meconium aspiration, hypoxic ischemic encephalopathy, convulsions, and neonatal sepsis.

Data were retrieved using documentation in the delivery room and in the neonatal unit. All medical records were reviewed to complete missing data.

Data included maternal demographics (age, gravidity, parity, body mass index [BMI], GA at delivery, pregestational or gestational diabetes, and a history of cesarean delivery [CD]). Labor and delivery characteristics collected were use of epidural analgesia; intrapartum fever; duration of first, second and third stages of labor; indication for VE; fetal head position and station before VE; cup type; vacuum duration and cup detachments.

Data collected regarding neonatal outcomes included fetal weight, rates of SGA, AGA and LGA neonates, NICU hospitalization, and head injuries related to birth trauma (SGH, cephalohematoma, subdural hematoma (SDH) and intracranial hemorrhage). Data regarding neonatal outcomes not related to birth trauma included Apgar scores, respiratory distress and need for mechanical ventilation, meconium aspiration, hypoxic-ischemic encephalopathy, convulsions, and neonatal sepsis.

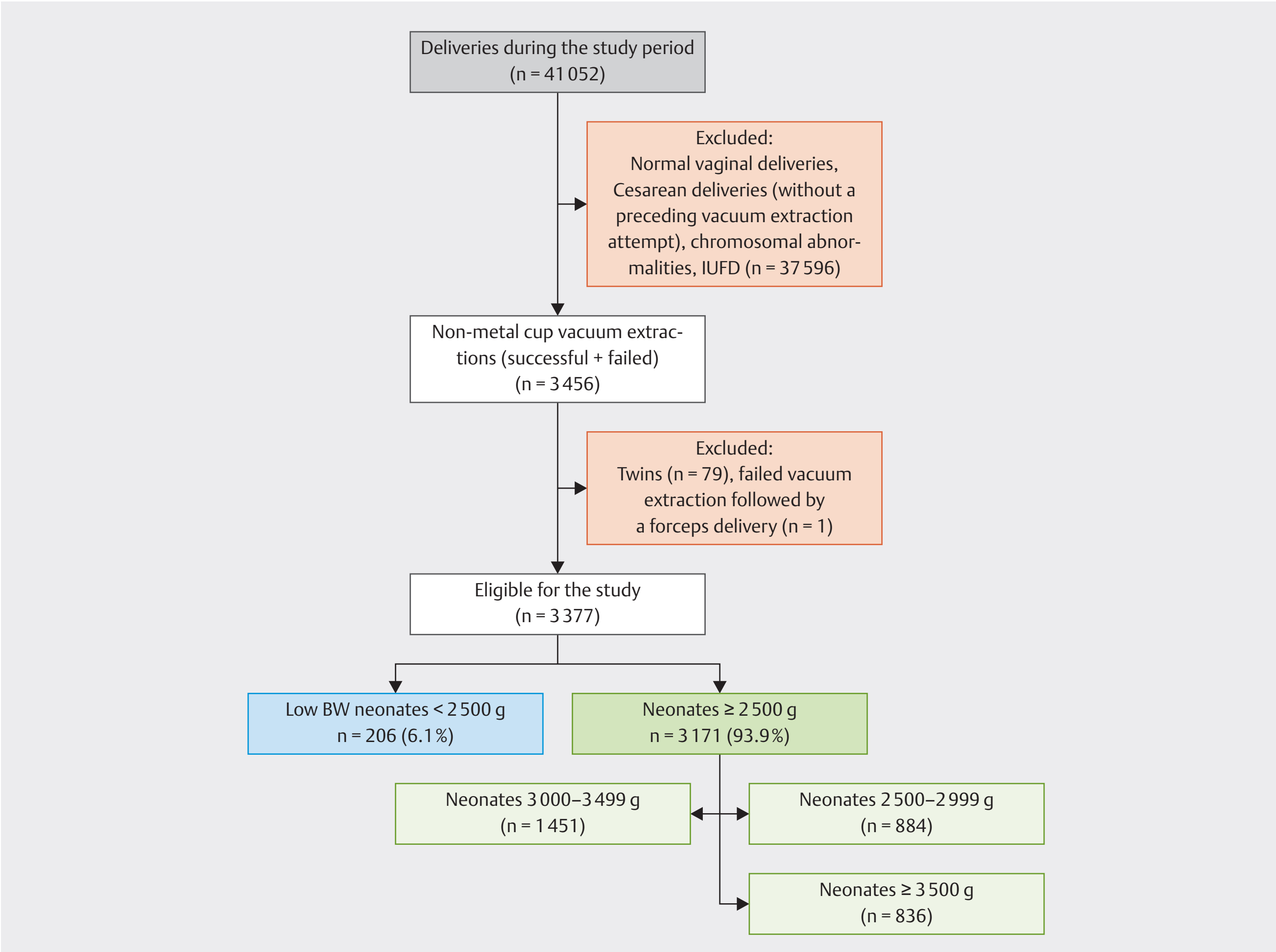
Gestational age at delivery was confirmed by first trimester crown rump length (CRL). Gestational diabetes was defined according to ACOG guidelines [20], and pregestational diabetes was defined when mentioned in the patient's medical records. Intrapartum fever was defined as two or more measurements of a temperature ≥ 38.0 degree Celsius during labor and up to 24 hours post partum. Fetal head position before VE was determined by both a vaginal examination and intrapartum sonography, and fetal head station was determined by a vaginal examination.

Indications for VE were divided into:

1. Non-reassuring fetal heart rate (NRFHR) defined according to the NICHD three-tier system [21],
2. prolonged second stage, defined according to ACOG guidelines [22], and
3. maternal indications, including exhaustion or medical background requiring shortening of second stage.

For historical reasons, fetal head station was defined by thirds from ischial spines − 3 to + 3, and was divided into 3 groups – mid-pelvis: S+ 1, low: S+ 2, and outlet: S+ 3 and below. VE was only performed when the fetal head was below the ischial spines 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 (ultrasound and magnetic resonance imaging).



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

Data analysis

Distribution of continuous variables was evaluated using the Shapiro-Wilk test. Variables with a normal distribution were presented as mean + SD, and were compared using t-test. Categorical data were compared using chi-square or Fisher's exact test (as appropriate). Multivariable logistic regression was also performed using variables that were found to be significantly different between the groups in the chi-square analysis (vacuum cup type, procedure duration, intrapartum fever, head station at vacuum extraction, and duration of second stage of labor). Adjusted odds ratios and their 95 % confidence intervals were calculated. A probability value of $p < 0.05$ was considered significant. Analyses were performed using SPSS 26 software (IBM, Armonk, NY, USA).

Results

During the study period, 41 052 women were delivered in our institution, of whom 3377 (8.2 %) had a VE and met the inclusion criteria (▶ **Fig. 1**).

Overall, 206 (6.1 %) neonates were included in the LBW group (< 2500 g, group 1), 884 (26.2 %) in the 2500–2999 g group (group 2), 1451 (43.0 %) in the 3000–3499 g group (group 3) and 836 (24.8 %) in the ≥ 3500 g group (group 4). Within group 4, 108 neonates (3.2 % of the total cohort) were born with a BW ≥ 4000 g.

Birth trauma-related neonatal outcomes

The lowest rates of SGH occurred in neonates with LBW < 2500 g (0.5 %) and the rate increased with every additional 500 g of neonatal weight (3.5 %, 4.4 % and 8.0 % in the 2500–2999 g, 3000–3499 g, ≥ 3500 g groups respectively, and 16.7 % for the percentage of neonates weighing ≥ 4000 g, p = 0.001, ▶ **Table 1**).

Cephalohematomas occurred significantly less often among LBW neonates (0.5 % in < 2500 g BW) and increased with every additional 500 g of BW (2.6 %, 3.3 % and 3.7 % in the 2500–2999 g, 3000–3499 g, and ≥ 3500 g groups, respectively, p = 0.020). The proportion of neonates weighing ≥ 4000 g had relatively more cephalohematomas compared to LBW neonates, but this difference did not cross the level of significance (2.8 % vs 0.5 %, p = 0.119).

SDH and intracranial hemorrhage were rare, and occurred only in two neonates weighing 2500–3499 g.

▶Table 1 Head injuries related to birth trauma stratified by neonatal birthweight.

Variable		<2500 g (n = 206)		≥2500 g (n = 3171)		P value	2500–2999 g (n = 884)		P value	3000–3499 g (n = 1451)		P value	≥3500 g (n = 836)		P value	≥4000 g (n = 108)		P value
Head trauma (n, %)	Subgaleal hematoma	1	0.5 %	162	5.1 %	**0.001**	31	3.5 %	**0.019**	64	4.4 %	**0.003**	67	8.0 %	**0.012**	18	16.7 %	**< 0.001**
	Cephalohematoma	1	0.5 %	102	3.2 %	**0.020**	23	2.6 %	0.066	48	3.3 %	**0.025**	31	3.7 %	**0.012**	3	2.8 %	0.119
	Subdural hematoma	0	0.0 %	2	0.1 %	1.000	1	0.1 %	1.000	1	0.1 %	1.000	0	0.0 %	-	0	0.0 %	-
	Intracranial hemorrhage	0	0.0 %	2	0.1 %	1.000	1	0.1 %	1.000	1	0.1 %	1.000	0	0.0 %	-	0	0.0 %	-
	Total head trauma	2	1.0 %	266	8.4 %	**<0.001**	55	6.2 %	**0.001**	113	7.8 %	**<0.001**	98	11.7 %	**<0.001**	21	19.4 %	**< 0.001**

▶Table 2 Multivariable logistic regression analysis of factors associated with neonatal head injuries.

Variable	P value	Odds ratio	95 % Confidence interval
Neonatal weight (< 2500 g vs. ≥ 2500 g)	0.016	11.30	1.57, 81.50
Vacuum cup type (VM)	< 0.001	1.79	1.33, 2.41
Procedure duration (every added minute)	< 0.001	1.11	1.07, 1.15
Head station at vacuum extraction	0.343	2.00	0.48, 8.36
Duration of second stage	0.862	1.00	0.99, 1.01
Intrapartum fever	0.930	1.02	0.63, 1.67

Variables that differed significantly between BW groups in univariate analysis were included in the multivariable logistic regression analysis. These included: neonatal weight, vacuum cup type, procedure duration, head station at VE, duration of second stage, intrapartum fever.

▶Table 3 Adjusted odds ratio for neonatal head injuries by increasing BW.

Variable	P value	Odds ratio	95 % Confidence interval
< 2500 g	–	1	–
2500–2999 g	0.040	8.12	1.10, 59.78
3000–3499 g	0.018	10.88	1.49, 79.28
≥ 3500 g	0.011	13.52	1.84, 99.38
≥ 4000 g	0.008	17.44	2.10, 144.49

The primary outcome of head injuries related to birth trauma, including one or more of the injuries mentioned above, increased significantly with increasing neonatal BW, from 1 % in neonates weighing < 2500 g, vs. 6.2 %, 7.8 % and 11.7 % in the 2500–2999 g, 3000–3499 g, ≥ 3500 g groups, respectively, and 19.4 % in the group of neonates weighing ≥ 4000 g, p < 0.001 (▶ **Table 1**).

Logistic regression found three independent, significant risk factors for neonatal head injuries: higher neonatal weight (≥ 2500 g compared to < 2500 g) – with an adjusted odds ratio (OR) of 11.30 (95 % confidence interval = 1.57, 81.50, p = 0.016), longer procedure duration (OR 1.11 for every added minute, CI = 1.07, 1.15, p < 0.001) and use of the Ventouse-Mityvac cup (OR 1.79, CI = 1.33, 2.41, p < 0.001). Duration of second stage labor, head station at the time of VE, and intrapartum fever were not significant in terms of neonatal head injuries (▶ **Table 2**). The ORs for neonatal head injuries with increasing neonatal BW were 8.12, 10.88, and 13.52 for the 2500–2999 g, 3000–3499 g, and ≥ 3500 g groups, respectively, and 17.44 for BW ≥ 4000 g, (p = 0.008), (▶ **Table 3**).

▶ **Table 4** General neonatal outcomes stratified by neonatal birthweight.

Variable (n, %)	< 2500 g (n = 206)		≥ 2500 g (n = 3171)		P value	2500–2999 g (n = 884)		P value	3000–3499 g (n = 1451)		P value	≥ 3500 g (n = 836)		P value	≥ 4000 g (n = 108)		P value
Apgar 5 min ≤ 7	3	1.5 %	25	0.8 %	0.242	4	0.5 %	0.104	11	0.8 %	0.403	10	1.2 %	0.729	1	0.9 %	1.000
Convulsions	0	0.0 %	2	0.1 %	1.000	0	0.0 %	–	1	0.1 %	1.000	1	0.1 %	1.000	0	0.0 %	–
Respiratory distress	2	1.0 %	20	0.6 %	0.392	4	0.5 %	0.318	7	0.5 %	0.310	9	1.1 %	1.000	4	3.7 %	0.187
Need for mechanical ventilation	2	1.0 %	14	0.4 %	0.255	3	0.3 %	0.240	6	0.4 %	0.261	5	0.6 %	0.630	0	0.0 %	–
Meconium aspiration	0	0.0 %	5	0.2 %	1.000	2	0.2 %	1.000	2	0.1 %	1.000	1	0.1 %	1.000	0	0.0 %	–
Hypoxic ischemic encephalopathy	0	0.0 %	3	0.1 %	1.000	0	0.0 %	–	2	0.1 %	1.000	1	0.1 %	1.000	1	0.9 %	0.344
Neonatal sepsis	0	0.0 %	5	0.2 %	1.000	1	0.1 %	1.000	2	0.1 %	1.000	2	0.2 %	1.000	0	0.0 %	–
Secondary composite outcome	7	3.4 %	81	2.6 %	0.461	17	1.9 %	0.194	35	2.4 %	0.400	29	3.5 %	0.960	5	4.6 %	0.555
NICU admission	21	10.2 %	79	2.5 %	< 0.001	27	3.1 %	< 0.001	24	1.7 %	< 0.001	28	3.3 %	< 0.001	5	4.6 %	0.130

General neonatal outcomes

NICU hospitalization rates were highest among neonates weighing < 2500 g (10.2 %) compared to the other groups (3.1 %, 1.7 % and 3.3 % in the 2500–2999 g, 3000–3499 g, and ≥ 3500 g group, respectively, $p < 0.001$) and were comparable between neonates weighing < 2500 g and neonates weighing ≥ 4000 g (10.1 % vs. 4.6 % $p = 0.130$; ▶ **Table 4**).

No differences were noted between the groups regarding the Apgar scores ≤ 7 at 5 minutes, respiratory distress, need for mechanical ventilation, meconium aspiration, hypoxic-ischemic encephalopathy and neonatal sepsis, or the total secondary composite neonatal outcome.

Demographic characteristics

No differences were found between the groups regarding the demographic characteristics, except for GA at delivery, which, as was to be expected based on the study design, increased with increasing birthweight for each weight group. (▶ **Table 5**).

Maternal BMI were generally similar between groups, except it was lower among mothers who delivered infants in the 2500–2999 g group (21.8 ± 4.7 vs. 25.1 ± 5.2, $p = 0.005$). Maternal obesity rates (BMI > 30 kg/m^2) were also lower in that group (0.5 % vs. 1.9 %, $p = 0.046$).

Nulliparity rates were similar between all groups, excluding women who delivered neonates ≥ 3500 g in whom nulliparity percentage was lower (70.5 % vs. 80.6 %, $p = 0.004$).

Labor and delivery characteristics

The rates of intrapartum fever were significantly lower in women delivering LBW neonates and increased with increasing neonatal BW (4.9 % in < 2500 g group vs. 5.7 %, 8.9 % and 13.0 % in the 2500–2999 g, 3000–3499 g and ≥ 3500 g groups respectively, $p = 0.038$; ▶ **Table 6**).

The duration of VE was significantly shorter in women delivering LBW neonates, and increased with increasing neonatal BW (4.5 minutes in < 2500 g group vs. 4.8, 5.3 and 5.5 minutes in the 2500–2999 g, 3000–3499 g and ≥ 3500 g groups respectively, $p = 0.012$).

Fetal head stations at the beginning of extraction were also similar. In all BW groups, most of the fetuses were at S+ 1 (midpelvis) when VE started. Lower percentages were at S+ 2 (low) and a minority were at S+ 3 and below (outlet). However, we found a relatively higher proportion at the outlet station in the LBW group (5 % vs. 1.4–3.2 %, $p = 0.019$).

NRFHR was the most common indication for VE, and its rate decreased significantly with every additional 500 g of neonatal BW (85.2 % in the LBW group and 80.2 %, 74.4 % and 68.2 % in the 2500–2999 g, 3000–3499 g, ≥ 3500 g groups, respectively, $p < 0.001$). Prolonged second stage was the second most common indication, and its rate increased significantly with every additional 500 g of neonatal BW (10.9 %, 18.7 %, 23.9 % and 30.3 %, respectively; $p < 0.001$).

Duration of first and second stages of labor were the shortest for LBW neonates and increased significantly with increasing BW, as presented in ▶ **Table 6**.

▶Table 5 Baseline characteristics in relation to neonatal birthweight.

Variable	<2500 g (n = 206)		≥2500 g (n = 3171)		P value	2500–2999 g (n = 884)		P value	3000–3499 g (n = 1451)		P value	≥3500 g (n = 836)		P value
Maternal age (years), mean ± SD	30.2 ± 5.2		30.2 ± 5.4		0.937	30.4 ± 5.2		0.654	29.9 ± 5.1		0.491	30.6 ± 5.3		0.363
Parity, mean ± SD	0.4 ± 0.9		0.4 ± 0.8		0.584	0.3 ± 0.7		0.293	0.41 ± 0.8		0.899	0.6 ± 1.0		0.008
Nulliparity (n, %)	166	80.6 %	2478	78.8 %	0.411	736	83.3 %	0.360	1153	79.5 %	0.709	589	70.5 %	0.004
Previous cesarean delivery (n, %)	14	6.8 %	248	7.8 %	0.593	64	7.2 %	0.824	119	8.2 %	0.487	65	7.8 %	0.631
Gestational age [days, (weeks)], mean ± SD	262.1 (37.4) ± 11.1 d		277.3 (39.6) ± 9.3 d		< 0.001	274.2 (39.2) ± 9.4 d		< 0.001	278.7 (39.9) ± 7.4 d		< 0.001	282.0 (40.4) ± 6.5 d		< 0.001
GDM (n, %)	17	8.3 %	228	7.2 %	0.569	60	6.8 %	0.460	109	7.5 %	0.708	59	7.1 %	0.555
Maternal BMI, mean ± SD	25.1 ± 5.2		23.2 ± 4.9		0.077	21.8 ± 4.7		0.005	23.4 ± 5.2		0.145	23.9 ± 4.6		0.259
Maternal obesity (BMI > 30) (n, %)	4	1.9 %	37	1.2 %	0.313	4	0.5 %	0.046	22	1.5 %	0.555	11	1.3 %	0.513

GDM = gestational diabetes mellitus

The most common cup type used in all weight groups was the Kiwi OmniCup. It was used most often in the LBW group and decreased with increasing neonatal BW. The Ventouse-Mityvac was used least for LBW neonates, and its use increased with increasing neonatal birthweight (22.1 % among neonates weighing < 2500 g, vs. 33.5 %, 37.1 % and 41.6 % in the 2500–2999 g, 3000–3499 g, ≥ 3500 g groups respectively, p < 0.001).

No differences were noted between groups regarding rates of epidural anesthesia, occiput-anterior (OA) position rates and vacuum cup detachment rates.

Neonatal outcomes of SGA and LGA neonates

Since neonatal BW should be correlated to GA, we also evaluated neonatal outcomes stratified by GA-related BW, comparing SGA, AGA and LGA neonates. Our cohort included 374 (11.1 %) SGA neonates, 2810 (83.2 %) AGA neonates and 193 (5.7 %) LGA neonates.

Compared to the AGA group, the SGA group had lower rates of SGH (0.5 % vs. 4.8 %, p < 0.001), lower rates of cephalohematomas (1.1 % vs. 3.3 %, p = 0.015), and lower rates of total head injuries related to birth trauma (1.6 % vs. 8.3 %, p < 0.001). No cases of SDH or intracranial hemorrhage occurred in SGA neonates. When assessing for general neonatal outcomes, no differences were noted between the groups including NICU hospitalization rates (4.3 % vs. 2.8 %, p = 0.107). Basic maternal characteristics were similar between groups except for higher rates of nulliparity (87.2 % vs. 77.7 %, p < 0.001) and lower rates of gestational diabetes (4.3 % vs. 7.7 %, p = 0.018) in the SGA group compared to the AGA group. Comparing delivery characteristics revealed lower rates of epidural anesthesia in the SGA group (15.8 % vs. 20.3 %, p = 0.038), as well as lower rates of prolonged second stage as the indication for VE (12.0 % vs. 23.8 %, p < 0.001).

Compared to the AGA group, the LGA group had higher rates of SGH (13.0 % vs. 4.8 %, p < 0.001) and higher rates of total head injuries related to birth trauma (15.5 % vs. 8.3 %, p = 0.001), although rates of cephalohematoma were similar between groups (2.6 % vs. 3.3 %, p = 0.570). No cases of SDH or intracranial hemorrhage occurred in LGA neonates. When assessing for general neonatal outcomes, no differences were noted between the groups except for respiratory distress which was more common for LGA neonates (2.1 % vs. 0.6 %, p = 0.036). NICU hospitalization rates were similar between groups (3.1 % vs. 2.8 %, p = 0.786). Basic maternal characteristics were also similar between groups, except for lower rates of nulliparity in the LGA group compared to the AGA group (69.4 % vs. 77.7 %, p = 0.008). Comparing delivery characteristics revealed higher rates of prolonged second stage as the indication for VE in the LGA group (39.1 % vs. 23.8 %, p < 0.001). Use of the Ventouse-Mityvac cup was more common in the LGA group (43.6 % vs. 36.3 %, p = 0.044).

▶Table 6 Labor and delivery characteristics in relation to neonatal birthweight.

Variable		< 2500 g (n = 206)		≥ 2500 g (n = 3171)		P value	2500–2999 g (n = 884)		P value	3000–3499 g (n = 1451)		P value	≥ 3500 g (n = 836)		P value
Epidural (n, %)		33	16.0 %	639	20.2 %	0.150	166	18.8 %	0.356	301	20.7 %	0.114	172	20.6 %	0.141
Intrapartum fever (n, %)		10	4.9 %	288	9.1 %	**0.038**	50	5.7 %	0.647	129	8.9 %	**0.051**	109	13.0 %	**0.001**
Vacuum cup type	Silastic	42	22.1 %	1120	37.3 %	**< 0.001**	279	33.5 %	**0.002**	513	37.1 %	< 0.001	328	41.6 %	**< 0.001**
	Kiwi	148	77.9 %	1883	62.7 %		553	66.5 %		869	62.9 %		461	58.4 %	
Procedure duration (min) mean ± SD		4.5 ± 3.2		5.2 ± 3.7		**0.012**	4.8 ± 4.3		0.359	5.3 ± 3.4		**0.003**	5.5 ± 3.3		**0.001**
Vacuum detachment (n, %)		41	21.4 %	610	20.4 %	0.763	155	18.7 %	0.395	282	20.5 %	0.794	173	22.2 %	0.805
Position occiput-anterior (n, %)		145	70.4 %	2353	74.5 %	0.190	643	72.8 %	0.482	1073	74.2 %	0.244	637	76.8 %	0.054
Head station at time of VE (n, %)	Mid-pelvis	103	57.5 %	1670	57.1 %	0.914	452	56.0 %	0.709	766	57.2 %	0.932	452	58.2 %	0.877
	Low	67	37.4 %	1187	40.6 %	0.400	329	40.8 %	0.410	544	40.6 %	0.413	314	40.4 %	0.463
	Outlet	9	5.0 %	66	2.3 %	**0.019**	26	3.2 %	0.237	29	2.2 %	**0.021**	11	1.4 %	**0.002**
Vacuum indication (n, %)	NRFHR	156	85.2 %	2208	74.3 %	**0.001**	656	80.2 %	0.115	1012	74.4 %	**0.001**	540	68.2 %	**< 0.001**
	Prolonged second stage	20	10.9 %	718	24.2 %	**< 0.001**	153	18.7 %	**0.019**	325	23.9 %	**< 0.001**	240	30.3 %	**< 0.001**
	Maternal indication	7	3.8 %	45	1.5 %	**0.017**	9	1.1 %	**0.018**	24	1.8 %	0.062	12	1.5 %	**0.042**
Labor duration, minutes, mean ± SD	First stage	432.5 ± 266.0		655.0 ± 425.6		**0.009**	637.8 ± 376.4		**0.009**	685.2 ± 460.1		**0.007**	624.1 ± 417.1		**0.027**
	Second stage	103.9 ± 79.0		140.9 ± 82.0		**< 0.001**	131.3 ± 81.9		**< 0.001**	141.3 ± 82.4		**< 0.001**	150.3 ± 80.2		**< 0.001**
	Third stage	10.0 ± 8.0		9.5 ± 6.9		0.295	9.8 ± 7.8		0.776	9.4 ± 6.6		0.270	9.1 ± 6.1		0.102

NRFHR = non-reassuring fetal heart rate; VE = vacuum extraction

Discussion

Principal findings

We aimed to evaluate the impact of VE on neonatal head injuries related to birth trauma in newborns with a GA ≥ 34 w with LBW (< 2500 g) compared to higher birthweights, using a non-metal vacuum cup. This comparison allowed the evaluation of VE safety in LBW neonates.

We found that the lowest rates of SGH and cephalohematomas occurred in neonates with BW < 2500 g and increased with every additional 500 g of neonatal weight. Logistic regression found increasing neonatal weight to be a significant risk factor for neonatal head injuries. When evaluating neonatal outcomes unrelated to birth trauma, no differences were noted between the groups, except for NICU hospitalization rates, which were the highest among neonates weighing < 2500 g, mainly for observation.

According to our data, the overall rate of SGH in VE was 4.8 %. This prevalence is similar to that in previously published studies [23, 24]. We found lower rates of SGH in neonates with LBW (0.5% vs. 3.5–8.0%, p = 0.001). These findings were found in some previous studies but not in all. Plauché [25] identified both preterm delivery and fetal macrosomia as risk factors for SGH, while Aviram et al. [5] found no differences in SGH rates for different BW. Our study was the first large cohort study to look at a specific population of newborns using non-metal cup VE.

The overall rate of cephalohematomas in VE in our study was 3.1 %, one third of the rate reported in the literature [2]. Rates of cephalohematomas were also lowest among neonates with LBW (0.5% vs. 2.6–3.7%, p = 0.020). These findings are probably related to underdiagnosis but may also be related to the specific cup we used. These findings have yet to be demonstrated in further studies, as previous studies showed no difference in cephalohematoma rates between different BW groups [5, 26].

VE is associated with specific risks due to the indications for the procedure and due to the procedure, itself. Nevertheless, we found that neonates in the < 2500 g group had a lower total rate of head injuries related to VE compared to neonates with higher weights. This result agrees with other studies [5, 10, 11] and further expands their findings, since our study is the first to demonstrate a lower risk of injury due to VE among LBW neonates compared to those with higher birthweights, and not just no difference between groups.

Our findings may be explained by the assumption that lower fetal weight, accompanied by a smaller head diameter, eases the passage of the fetal head through the pelvic canal, thereby making the VE shorter and less traumatic for the fetus. This explanation agrees with our findings of a higher percentage of outlet stations among the LBW neonates compared to those with higher BW.

We found NICU hospitalization rates to be highest among LBW neonates. These findings agree with earlier observations in late preterm infants [5, 27, 28]. With that said, NICU hospitalization for LBW neonates is part of our institutional medical protocol and was mainly for observation. This could also explain why NICU hospitalization rates were similar among SGA, AGA and LGA neonates: the selection of neonates for NICU hospitalization in our institution is based on absolute neonatal birthweight rather than the GA-related BW percentiles.

Prolonged second stage as an indication for VE increased significantly with every additional 500 g of neonatal BW, as did the durations of the first and second stages of labor. This is a reasonable difference because high fetal weight is a known risk factor for prolonged first and second stages of labor [29, 30]. Prolonged labor may explain why we found higher rates of intrapartum fever in women delivering higher BW neonates.

VE duration was shorter in women delivering LBW neonates and increased with increasing BW. Logistic regression found increasing procedure duration to be a significant risk factor for neonatal head injuries. These findings agree with studies showing higher rates of neonatal skull injuries with increasing procedure duration [26, 31]. After adjusting for confounding variables, increasing BW remained a significant risk factor for neonatal head injuries. Thus, differences in procedure duration cannot fully explain the lower rates of head injuries we found in the LBW neonates.

The use of the Ventouse-Mityvac cup type was the lowest among the LBW neonates and increased with increasing birthweight. This could be explained by the tendency of the Kiwi-Omni cup to detach and thus, operators prefer to avoid using it when estimated fetal weight is high. Interestingly, when performing a logistic regression analysis, the Ventouse-Mityvac cup was found to be an independent risk factor for neonatal head injuries, in addition to increasing neonatal BW and procedure duration. These results might be explained by the tendency of the Kiwi to detach, making this cup protective, as it prevents the operator from applying too much force to the newborn's skull compared to the Ventouse-Mityvac. However, as mentioned earlier, detachment rates were similar between the BW groups. Another explanation could be the lack of flexibility of the Ventouse-Mityvac traction pole, making it more traumatic for the newborn's skull. Previous studies evaluating the Ventouse-Mityvac compared to the Kiwi Omnicup only found the metal cup to be associated with neonatal adverse outcomes [16, 32].

Strengths and limitations

The strengths of our study include the large homogeneous cohort, as data were collected from a single institution with the same protocol for VE, and included only VEs using a non-metal cup.

This study is not free of limitations. Due to its retrospective design, it lacks important data, such as neonatal head circumference. However, we believe that circumferences matched neonatal BW and increased proportionally with increasing BW. Factors such as technique and operator experience, as well as the location of the cup in relation to the fetal head sutures were missing and might have influenced the development of head injuries. Our cohort may have a selection bias, because birthweight was not known at the time of delivery, and most of the small neonates were probably considered by the senior physician large enough to undergo VE. We chose to include the cases of failed vacuum extraction with a subsequent CD in our cohort in order not to eliminate neonates with birth trauma caused by an attempt at vacuum extraction from the analysis. We cannot fully exclude the possibility of additional trauma caused by the manipulation of the fetal head during CD, yet given the low rates of failed VE in our cohort (0.01 %) and given the fact that previous reports associate second-stage CD mainly with fractures and not hematomas [33], we believe the total effect of these cases on our results is negligible.

As far as we know, this is the first cohort comparing VE head injuries related to birth trauma in different neonatal weights and demonstrating a lower risk of head injuries in LBW neonates. This is also the largest study performed regarding VE and LBW neonates using non-metal vacuum cups. Since prospective randomized studies are unlikely to be performed, we believe our data are valuable and may useful when consulting with patients.

Conclusion

VE delivery of neonates weighing < 2500 g at 34+ weeks of gestation seems to be a safe mode of delivery when indicated. It resulted in lower rates of head injuries related to birth trauma, compared to neonates with higher birthweights. This information may be useful in the delivery room, for counseling and reassuring patients, as well as for the medical staff performing VE. Additional larger-scale studies are needed to establish the outcomes of VE in lower birthweights or for younger GA.

Declarations

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

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.

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Contributors' Statement

Gal Cohen: project development, data collection, manuscript writing and editing. Hanoch Schreiber, Nir Mevorach: data collection. T Biron-Shental, Gil Shechter-Maor, Ofer Markovitch: revised manuscript critically.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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