**Original scientific article /** Izvirni znanstveni članek

# The impact of delivery mode on the risk of neonatal intracranial haemorrhage: a prospective population-based cohort study

# Vpliv načina poroda na tveganje za intrakranialne krvavitve pri novorojenčku: prospektivna populacijska kohortna raziskava

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**Key words**: labour; caesarean delivery; vacuum extraction; intracranial haemorrhage

**Ključne besede:** porod; carski rez; vakuumska ekstrakcija; intrakranialna krvavitev

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**ABSTRACT**

**Introduction:** The objective of the study was to examine the association between the mode of delivery and the incidence of neonatal intracranial haemorrhage.

**Methods:** Slovenian National Perinatal Information System (NPIS) data for the period 2002 through 2016 were analysed. Nulliparous women delivering singleton neonates in cephalic presentation weighting 2,500 to 4,000g were included. Incidence of neonatal intracranial haemorrhage in vacuum delivery vs. other modes of delivery was compared using the Chi-square test ($p < 0.05$ significant).

**Results:** 125,393 deliveries were included: 5,438 (4 %) planned caesarean deliveries, 9,7764 (78 %) spontaneous vaginal deliveries, 15,577 (12 %) emergency caesarean deliveries, and 6,614 (5 %) vacuum extractions. 17 (0.14/1000) neonatal intracranial haemorrhages were recorded: 12 occurred in spontaneous vaginal deliveries, two in emergency caesarean deliveries, and three in vacuum extractions. In comparison to infants born by spontaneous vaginal delivery, those delivered by vacuum extraction had higher rates of intracranial haemorrhage (odds ratio (OR) 3.70; 95% confidence interval (CI) 1.04–13.10). Risk estimates did not reach statistical significance when comparing infants born by vacuum extraction and those born by emergency caesarean delivery (OR 3.54; 95% CI 0.59–21.16).

**Discussion and conclusion:** Infants born by vacuum extraction have significantly higher rates of intracranial haemorrhage than those born by spontaneous vaginal delivery although the absolute risk is small. There are no significant differences in the rates of intracranial haemorrhage in vacuum extraction vs. emergency caesarean delivery.

**IZVLEČEK**

**Uvod:** Namen raziskave je bil preučiti povezavo med načinom poroda in tveganjem za intrakranialno krvavitev pri novorojenčku.

**Metode:** Analizirali smo podatke iz Nacionalnega perinatalnega informacijskega sistema (NPIS) za obdobje od leta 2002 do leta 2016. Vključili smo prvorodnice, ki so rodile od 2500 do 4000 g težke enojčke v glavični vstavi. Za primerjavo deležev intrakranialne krvavitve pri vakuumski ekstrakciji in drugih načinih poroda smo uporabili Hi-kvadrat test ($p < 0,05$ signifikantno).

**Rezultati:** Vključili smo 125393 porodov: 5438 (4 %) načrtovanih carskih rezov, 97764 (78 %) spontanih vaginalnih porodov, 15577 (12 %) urgentnih carskih rezov in 6614 (5 %) vakuumskih ekstrakcij. Diagnosticiranih je bilo 17 (0.14 / 1000) intrakranialnih krvavitev: 12 po spontanem vaginalnem porodu, dve po urgentnem carskem rezu in tri po vakuumski ekstrakciji. Vakuumska ekstrakcija je bila povezana s statistično pomembno povečanim tveganjem za intrakranialno krvavitev v primerjavi s spontanim vaginalnim porodom (razmerje obetov (RO) 3,70; 95% interval zaupanja (IZ) 1,04–13,10), a ne v primerjavi z urgentnim carskim rezom (RO 3,54; 95% IZ 0,59–21,16).

**Diskusija in zaključek:** Vakuumska ekstrakcija je povezana s povečanim tveganjem za intrakranialno krvavitev v primerjavi s spontanim vaginalnim porodom, vendar je absolutno tveganje majhno. Tveganje za intrakranialno krvavitev se ne razlikuje pomembno glede na operativno dokončanje poroda z vakuumsko ekstrakcijo ali urgentni carski rez.

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## Introduction

Operative vaginal delivery rate in Slovenia has remained stable over the last decades with approximately 3 % of all neonates delivered by vacuum extraction and less than 0.1 % by forceps (Lučovnik, 2016; Rossen, et al., 2017). These rates are significantly lower compared to most industrialized countries (Rossen, et al., 2017). Overall caesarean delivery rate in Slovenia rose from less than 8 % in 1987 to around 20 % in 2016 (Lučovnik, 2016). Similarly to operative vaginal delivery, however, the country's caesarean delivery rate remains lower than that reported in most European countries (Europeristat, 2010; Rossen, et al., 2017). Approximately 6 % of nulliparous women presenting with spontaneous onset of labour at term in Slovenia deliver by vacuum extraction while around 10 % undergo emergency caesarean section (Rossen, et al., 2017). Such a discrepancy in incidences of operative vaginal vs. caesarean delivery could be, at least in part, attributable to a clinician's perception of decreased risks of neonatal injury associated with caesarean delivery compared to vacuum extraction.

Multiple studies have demonstrated that vacuum extraction can result in serious neonatal injury, including intracranial haemorrhage (Plauché, 1979; Cohn, et al., 1989; Johanson, et al., 1989; Hofmeyr, et al., 1990; Williams, et al., 1991; Loghis, et al., 1992; Johanson, et al., 1993; Kuit, et al., 1993; Castillo & Fordham, 1995; Huang & Lui, 1995; Odita & Hebi, 1996; Perrin, et al., 1996; Rijhsinghani & Belsare, 1997; Towner, et al., 1999; Wen, et al., 2001; Lučovnik, 2016). Reported incidences of neonatal intracranial haemorrhage associated with vacuum extractions varied significantly ranging from 1 in 268 to 1 in 860 vacuum deliveries (Plauché, 1979; Towner, et al., 1999; Lučovnik, 2016). The extent of neonatal risks associated with vacuum delivery seem to be, therefore, very population-specific and should not be simply extrapolated from the published data but rather analysed as a part of ongoing perinatal audit in individual clinical settings.

It is not clear whether neonatal injury associated with vacuum extraction can be attributed to operative vaginal delivery procedure *per se*. Studies comparing the risks of neonatal intracranial haemorrhage associated with operative vaginal delivery and those associated with emergency caesarean section have not found a protective effect of caesarean delivery (Towner, et al., 1999). These data suggest that it is abnormal labour, rather than a specific operative obstetric procedure, that carries most risks for the neonate.

The objective of our study was to examine the association between the mode of delivery and the risks of neonatal intracranial haemorrhage using a population-based perinatal database.

## Methods

### *Description of the research procedure and data analysis*

We evaluated data from the Slovenian National Perinatal Information System (NPIS). Since 1987, NPIS registers all deliveries in Slovenia at ≥ 22 weeks of pregnancy or when the birth weight is equal to 500 g or above. Registration is mandatory by law in the country's 14 maternity units and more than 140 variables are entered into a computerized database by an attending midwife and doctor. Patient demographics, family, medical, gynaecologic and obstetric history, data on current pregnancy, labour and delivery, postpartum period, and neonatal data are collected. To assure the quality of data collected, controls are built in the computerized system, data is audited periodically, and comparisons are made with international databases, such as the Vermont Oxford network in which Slovenia participates.

For the purpose of the current study, we analysed all singleton cephalic live-born neonates born to nulliparous women between 2002 and 2016 weighing between 2,500 and 4,000g. Neonates were grouped according to mode of delivery: spontaneous vaginal delivery, vacuum extraction, caesarean delivery in labour (emergency caesarean delivery), and planned (elective) caesarean delivery before the onset of labour. The forceps is used exceedingly rarely for operative vaginal delivery in Slovenia as shown by our previous studies (Lučovnik, 2016). Therefore, we chose to exclude forceps deliveries from the current study since numbers would be too small to allow meaningful statistical analysis.

International Classification of Diseases – 10 (ICD-10) codes for "intracranial laceration and haemorrhage due to birth injury" (P10) were assessed. We also analysed specific subgroups of neonatal intracranial haemorrhage included in the ICD-10: P10.0 "Subdural haemorrhage due to birth injury", P10.1 "Cerebral haemorrhage due to birth injury", P10.2 "Intraventricular haemorrhage due to birth injury", P10.3 "Subarachnoid haemorrhage due to birth injury", P10.4 "Tentorial tear due to birth injury", P10.8 "Other intracranial lacerations and haemorrhages due to birth injury", and P10.9 "Unspecified intracranial laceration and haemorrhage due to birth injury".

The chi-square test was used to compare vacuum extraction to other modes of delivery in terms of incidences of various intracranial haemorrhages. A two-tailed $p$ value < 0.05 was considered statistically significant. The software used for statistical analysis was IBM SPSS Statistics for Windows version 21.0 (IBM Corp., Armonk, NY). This retrospective study of anonymous entries was exempt of approval by the Ethics committee.

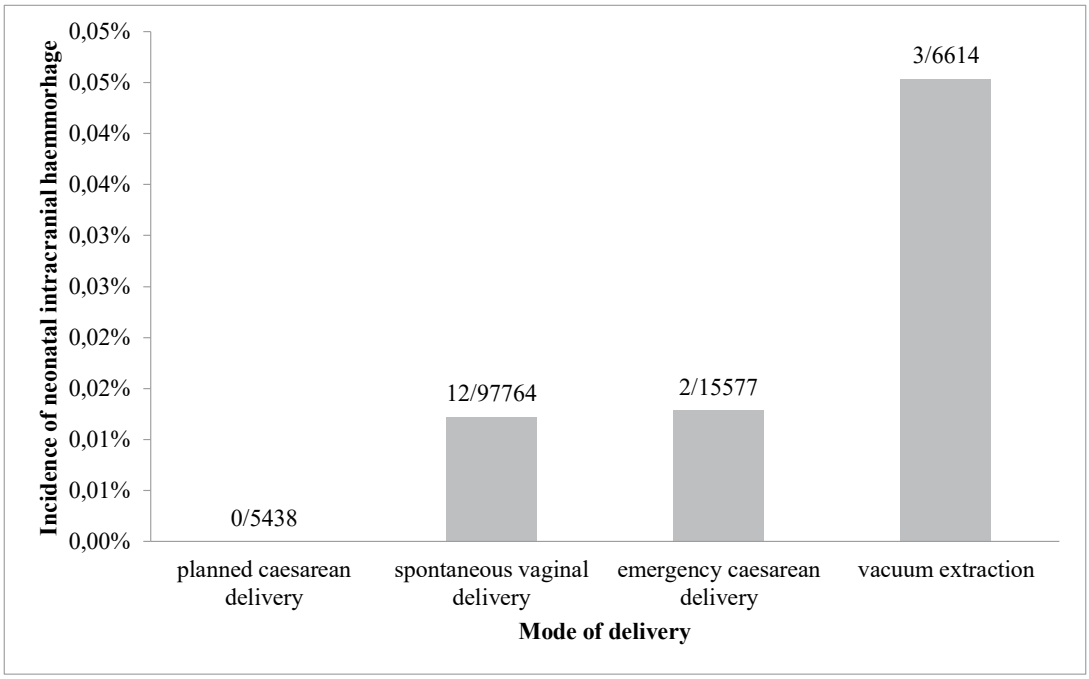


**Figure 1:** *Incidence of neonatal intracranial haemorrhage according to mode of delivery*
**Slika 1:** *Pojavnost intrakranialne krvavitve pri novorojenčkih glede na način poroda*

## Results

We included 125,393 deliveries in the analysis. 97,764 (78 %) were spontaneous vaginal deliveries, 6,614 (5 %) vacuum extractions, 15,577 (12 %) caesarean deliveries in labour (emergency caesarean deliveries), and 5,438 (4 %) planned (elective) caesarean deliveries before the onset of labour. Overall, 17 neonatal intracranial haemorrhages were recorded among nulliparous women with singleton pregnancies and cephalic foetal presentation during the study period (incidence 0.14/1000 all included deliveries). Of these, 12 occurred in spontaneous vaginal deliveries, two in emergency caesarean deliveries, three in vacuum extractions and none in planned caesarean deliveries (Figure 1).

Of 17 neonatal intracranial haemorrhages, five were subdural haemorrhages, all occurring in spontaneous vaginal delivery. Five were cerebral haemorrhages: three in spontaneous vaginal delivery, one in emergency caesarean delivery, and one in vacuum extraction. Three were intraventricular haemorrhages: one in spontaneous vaginal delivery, one in emergency caesarean delivery, and one in vacuum extraction. There was also one subarachnoid haemorrhage in spontaneous vaginal delivery and three not specified intracranial haemorrhages (two in spontaneous vaginal deliveries and one in vacuum extraction).

As compared with infants born by spontaneous vaginal delivery, those delivered by vacuum extraction had significantly higher rates of intracranial haemorrhage (odds ratio (OR) 3.70; 95% confidence interval (CI) 1.04–13.10). Risk estimates for neonatal intracranial haemorrhage did not reach statistical significance when comparing spontaneous vaginal delivery to planned caesarean delivery and to emergency caesarean delivery (OR 1.39; 95% CI 0.08–23.50 and OR 1.05; 95% CI 0.23–4.67, respectively). Similarly, the odds of intracranial haemorrhage did not differ significantly when comparing infants born by vacuum extraction and by planned caesarean delivery (OR 5.76; 95% CI 0.30–111.56) and those born by vacuum extraction and emergency caesarean delivery (OR 3.54; 95% CI 0.59–21.16).

## Discussion

Vacuum extraction was associated with neonatal intracranial haemorrhage although absolute risk was small (incidence of approximately 0.5/1000 vacuum deliveries). The association between intracranial haemorrhage and vacuum delivery has already been described in previous publications (Plauché, 1979; Cohn, et al., 1989; Johanson, et al., 1989; Hofmeyr, et al., 1990; Loghis, et al., 1992; Williams, et al., 1991; Johanson, et al., 1993; Kuit, et al., 1993; Towner, et al., 1999 ). The reported incidences, however, varied significantly between studies. In 1979, Plauché found one intracranial haemorrhage in every 286 infants delivered by Malmström metal vacuum extractor (Plauché, 1979). Since then, plastic cups were introduced and more recent studies described

significantly lower rates (less than 1 % ) of intracranial haemorrhage associated with vacuum deliveries (Cohn, et al., 1989; Johanson, et al., 1989; Hofmeyr, et al., 1990; Williams, et al., 1991; Loghis, et al., 1992; Johanson, et al., 1993; Kuit, et al., 1993; Towner, et al., 1999). Nevertheless, all studies reported higher incidences of neonatal intracranial haemorrhage than the 1 in 2,205 vacuum deliveries found in our analysis. This relatively low incidence is not necessarily the result of plastic vacuum cups or some other technique or training improvements, but may also be due to other factors, such as increasing rates of caesarean deliveries or a shorter period of neonatal observation (since maternal hospitalizations times decreased in the last decades).

We found no significant difference in the rates of intracranial haemorrhage in infants born by vacuum extraction compared to those born by emergency caesarean delivery. A large cohort study published by Towner and colleagues (1999) using the same inclusion criteria as the present study also found no differences in rates of intracranial haemorrhage in vacuum extraction as compared to caesarean delivery in labour, i.e. emergency caesarean delivery. These data, together with our results, suggest that it is not the operative intervention *per se*, but an abnormality in the progress of labour to increase the risks of neonatal intracranial injury. Given the potentially catastrophic consequences of neonatal intracranial haemorrhage and the current inability to predict dystocia it is perhaps tempting to speculate that planned caesarean delivery before the onset of labour could be the safest delivery option for nulliparous women. There are, however, several well-known short- and long-term maternal as well as neonatal risks associated with planned caesarean delivery that need to be taken into account before reaching such conclusions. Short-term maternal complications are postpartum cardiac arrest, wound hematoma, hysterectomy, major puerperal infection, anaesthetic complications, venous thromboembolism, and haemorrhage that requires hysterectomy (Liu, et al., 2007). Potential long-term maternal risks include adverse consequences in future pregnancies, such as higher incidence of placenta praevia and accreta, uterine rupture, bladder and bowel injuries, and postpartum hysterectomy along with major blood loss and other surgical complications (NIH, 2006; Ecker, 2013). The main short-term neonatal adverse effect of a planned caesarean delivery is respiratory morbidity, which includes transient tachypnea of the neonate, neonatal respiratory distress syndrome, and persistent pulmonary hypertension (NIH, 2006; ACOG, 2013; Ecker, 2013). These complications are even more common when caesarean deliveries are performed before completed 39 weeks of gestation, as demonstrated also by Vidic and colleagues (2016) in a recent analysis of NPIS data. Neonatal long-term risks associated with planned caesarean delivery are increased incidence of asthma, diabetes type 1, and other autoimmune as well as endocrine diseases (Cardwell, et al., 2008; Thavagnanam, et al, 2008).

Our study has strengths and limitations. The strength of the study is that we analysed a population-based perinatal dataset that includes data from all the country's 14 maternity units and many practitioners with diverse experiences and skills. We were able to include a 15-year period, which is long enough to provide a meaningful analysis of rarer outcomes due to Slovenia's small number of deliveries. The main weakness is that NPIS does not document neonatal readmissions and some neonatal intracranial haemorrhages may have been misses leading to an underestimation of true incidence of these injuries. Another important limitation of the study is its retrospective observational nature, which does not allow accounting for all potential confounders. It has to be noted, however, that conclusions on the risks of operative vaginal delivery vs. caesarean delivery will always be based on observational data since randomized studies in this field cannot be expected due to logistic and ethical issues. It is, therefore, important to collect and audit data on the mode of delivery and neonatal morbidity in such local cohort studies in order to further improve perinatal care.

## Conclusion

Infants born by vacuum extraction have significantly higher rates of intracranial haemorrhage than those born by spontaneous vaginal delivery although the absolute risk is low. There are no significant differences in rates of intracranial haemorrhage in infants born by vacuum extraction and those born by emergency caesarean delivery. Our results suggest that it is dystocia, and not vacuum extraction per se, to be the main risk factor for neonatal intracranial haemorrhage.

## **Conflict of interest** / Nasprotje interesov

The authors declare that no conflicts of interest exist. / Avtorja izjavljata, da ni nasprotja interesov./

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## **Ethical approval** / Etika raziskovanja

This retrospective study of anonymous entries was exempt of approval by the ethical committee. / Raziskava predstavlja retrospektivno analizo anonimiziranih podatkov in zato ni potrebovala posebnega dovoljenja komisije za etiko.

## **Author contributions** / Prispevek avtorjev

Both authors contributed equally to study design, literature search and writing the manuscript. / Oba avtorja sta enako prispevala k zasnovi raziskave, pregledu literature in pisanju besedila.

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