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BIRTH BY VACUUM EXTRACTION

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Birth by Vacuum Extraction

THESIS FOR DOCTORAL DEGREE (PhD)

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“Not everything that counts can be counted and not everything that can be counted counts.”

Albert Einstein

To my dad, Jan-Ove

ABSTRACT

Background: In Sweden, vacuum extraction (VE) is used in almost every tenth woman to facilitate vaginal birth. VE is an important obstetric instrument that is used when shortening of the second stage of labor is necessary. VE has been associated with increased neonatal morbidity such as extracranial and cranial injuries. The outcome of the VE depends on the right selection of patients and how the VE is performed. Despite its common use, little is known about the performance of VEs, how many extractions fail, and if failure is dangerous for the child. It is also unclear whether VE delivery has negative long-term consequences for the child.

Materials and Methods*:* In Study I, we investigated clinical performance as described in medical records in 596 VE deliveries and compared this with recommendations in local practice guidelines for VE. Detailed data on performance was collected from six different delivery units, each contributing with information about 100 VEs performed in 2013. In Study II, we investigated if women delivered by VE receive adequate pain relief and the risk factors associated with not receiving pain relief. We identified 62,568 women delivered by VE between 1999 and 2008 in the Swedish Medical Birth Register (SMBR). In Study III, the aim was to investigate the incidence of failed VEs, risk factors for failure, and neonatal morbidity in failed VEs. We collected information on singleton pregnancies delivered at term (>36+6) by either a successful VE (n=83,671) or a failed VE (n= 4747) from the SMBR. Failed VE was defined as a VE attempt with a subsequent cesarean section (CS), the use of forceps, or both. In Study IV, the aim was to investigate if birth by VE affects cognitive development as indicated by school performance at sixteen years of age. We identified 126,032 infants born as singletons without major congenital malformations, in a vertex presentation at a gestational week of 34 or more, with Swedish-born parents, and delivered between 1990 and 1993 in the SMBR. These children were followed up at sixteen years of age in the school grade registry containing all final grades in compulsory school.

Results: Clinical performances in VEs were mostly conducted according to evidence-based safe practice; however, in a few cases, inappropriate and potentially harmful performance was used. In 6% of all extractions, more than six pulls were used to deliver the infant, and in 2.3% the procedure took more than 20 minutes. Fourteen extractions (2.3%) were conducted from a high station in the maternal pelvis. The local practice guidelines on VE were incomplete and were not updated or evidence-based. Every third woman was delivered by VE without potent pain relief. VE failure occurred in 5.4% of cases. Identified risk factors for failure were for example nulliparity, fetal malposition, and mid-pelvic extractions. Failure with the extractor was associated with increased risks of subgaleal hematoma, convulsions, and low Apgar scores but not intracranial hemorrhage in the infant. Children delivered by VE had significantly lower mean mathematics test scores and mean merit grades than children born vaginally without instruments, after adjustment for major confounders. Infants delivered by emergency cesarean section had similar results as children delivered by VE.

Conclusion: Improvements in the clinical performance of VEs can be accomplished, and practice guidelines need to be improved to support safe and evidence-based practice in VE procedures. In addition, more women should receive pain relief prior to the extraction. Failed VE can be dangerous for the child, and risk factors for failure should be closely evaluated prior to the extraction to avoid this dangerous situation. In the case of failure, a subsequent CS should be performed. Birth by VE has marginal negative effects on final school grades at 16 years of age compared with children born by spontaneous vaginal delivery. Similar marginal effects were found in children delivered by emergency CS, indicating that these lower grades are rather due to difficult labor occurring prior to birth and not to the instrument itself.

LIST OF SCIENTIFIC PAPERS

I. Ahlberg M, Saltvedt S, Ekéus C. Obstetric performance in vacuum extraction deliveries in Sweden.
Submitted

II. Ahlberg M, Saltvedt S, Ekéus C. Insufficient pain relief in vacuum extraction deliveries: A population-based study. Acta Obstet Gynecol Scand. 2013;92:306-11.
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III. Ahlberg M, Norman M, Hjelmstedt A, Ekéus C. Risk factors for failed vacuum extraction and associated neonatal complications in term newborn infants.
Submitted

IV. Ahlberg M, Ekéus C, Hjern A. Birth by vacuum extraction delivery and school performance at 16 years of age. Am J Obstet Gynecol. 2014;210:361 e1-8.
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List of abbreviations

BMI	Body Mass Index
CI	Confidence Interval
CNS	Central Nervous System
CS	Cesarean Section
EA	Epidural Analgesia
HR	Hazard Ratio
ICD	International Classification of Disease
ICH	Intracranial Hemorrhage
MOD	Mode of Delivery
OASIS	Obstetric Anal Sphincter Tears
OR	Odds Ratio
PNB	Pudendal Nerve Blockade
RR	Risk Ratio
SVD	Spontaneous Vaginal Delivery
VE	Vacuum Extraction

1 INTRODUCTION

Human delivery is not always an easy process and mankind has developed different operative methods to assist women give birth. Operative delivery methods include cesarean section (CS), vacuum extraction (VE), and forceps. Instrumental vaginal delivery, being the most common method to assist women during active labor in Sweden, includes VE and forceps (Fig 1).VE accounts for more than 99.5% of all these instrumental vaginal births. As shown in Figure 1, there was an increase in VEs until 2007, when the rate decreased.

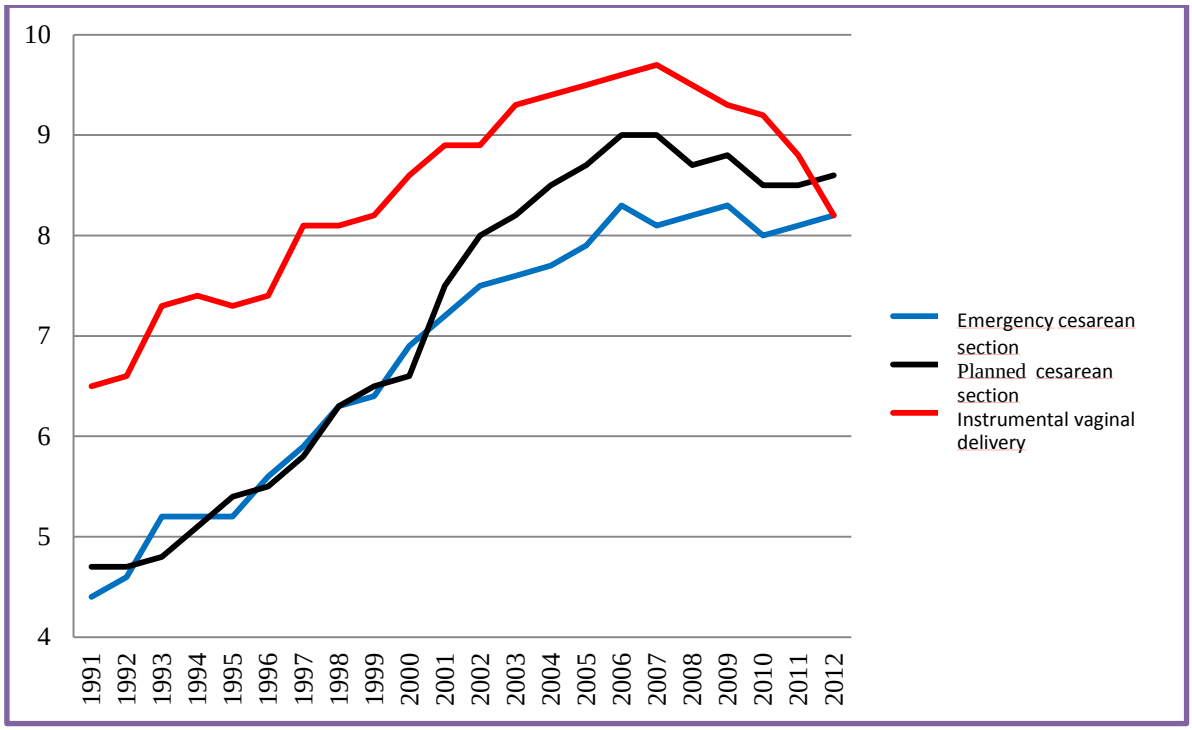


Figure 1: Proportion (%) of operative deliveries among all pregnancies from 1990 to 2012 in Sweden.

According to the Swedish Medical Birth Registry (SMBR), 15.5% of all first-time mothers and 3.2% of all multiparous women were delivered by VE in 2012 (1). In actual numbers, approximately 7,000 VEs were performed in that year. This commonly used method is considered to be a complex obstetrical intervention, and maternal and neonatal complications are being reported (2-6). To achieve a successful VE with a minimum of maternal and neonatal morbidity, the operator must select appropriate patients, carefully assess important prerequisites, and have good clinical skills and knowledge of how the tool should be used.

Despite its common use in Sweden, little attention has been paid to VE deliveries. For example, there is no information about how VEs are performed today in clinical practice and if they are performed according to evidence-based care guidelines. Further, it is not known how many extractions fail, what the risk factors for failure are, and if failed VE is dangerous for the infant. It is also not known whether this commonly used intervention has long-term consequences for the infant.

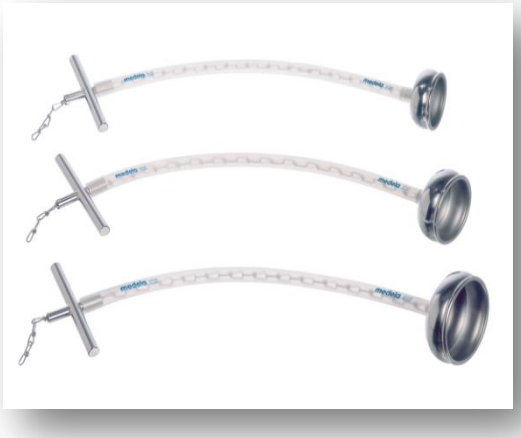
1.1 BACKGROUND

In this background chapter, VE as an intervention is described from different perspectives. First, a short historic and technical description of the instrument is presented, followed by information on when and how the tool should be used according to clinical guidelines and evidence. Last, known maternal and neonatal complications related to VE are presented.

1.2 HISTORY

The first tool invented to assist women to deliver vaginally was forceps (7). In 1849, a Scottish professor of obstetrics, Dr. James Young Simpson, invented the first VE tool called the "air tractor" as an alternative to forceps. This tool achieved limited success because of problems with vacuum force and design. In 1954, the Swedish obstetrician Tage Malmström reinvented and popularized the stainless steel cup, called the Malmström cup (Picture 1). The Malmström cup gained popularity mainly in Europe but received little attention in the United States because of concerns about reported complications in infants (8). Today, VE rates vary between countries and hospitals. In the United States, rates vary from 1% to 23%, and in the United Kingdom rates vary from 10% to 15% (5-7). Among our neighbor countries, Norway reports a use frequency of 8.3% (9), Denmark reports a use frequency of 10% (10), and Finland reports a use frequency of 10.2% (11).

Picture 1: Malmström cup



The Malmström cup was modified and improved by several inventors. Geoffrey Bird designed a new vacuum in 1969 that was intended to reduce detachments, facilitate application, and better protect the fetal scalp (8, 12) (Picture 2). Today, the Bird cup is the most commonly used model in Sweden.

Picture 2: Bird cup

Another commonly used model called the Omnicup device or the "Kiwi cup" is made of hard plastic. The advantage of this cup (and the Bird cup) is that the design enables application regardless of the fetal position. Because of the eccentrically placed suction tube, these two cups can be placed over the flexion point (please see chapter 1.6 on technique) in all fetal positions (occiput anterior, occiput posterior, and occiput transverse)(8).

A third model in use is the soft cup made out of silicone or soft plastic materials. These cups were invented in the 1980s to cause less fetal and maternal trauma compared with hard cups made out of metal. Follow-up studies show that soft cups may reduce mild transient fetal scalp injuries but do not lower the rate of more serious neonatal complications or maternal tissue trauma (13). Soft cups are also more

often associated with detachments and are less maneuverable within the birth canal because of the design; therefore, they are recommended mainly in outlet extractions (13, 14).

1.3 EQUIPMENT

The vacuum instrument consists of a mushroom-shaped cup of different composition, diameter (40 mm to 60 mm), and depth. Attached to this cup is a suction tube and handle placed either at the center of the cup (Malmström cup) or placed more eccentrically on the dome of the cup (Bird cup, Omnicup). The suction tube is attached either to an external vacuum source or an external handheld pump. The external electric vacuum pump and the handheld pump are both designed to create a negative pressure between 60 kPa to 80 kPa or in another unit of measurement, 0.6 kg/cm^2 to 0.8 kg/cm^2 (15). The diameter across the opening is smaller than the largest diameter of the cup. As a result, when the cup is placed on the fetal scalp and the vacuum is applied, an artificial caput succedaneum (also called a chignon) is formed and fills out the cup.

1.4 INDICATIONS FOR VE

To avoid unnecessary VEs, it is of utmost importance to have an accurate indication (14, 16-18). Standard accepted indications found in national guidelines from the American College of Obstetricians and Gynecologists and the Royal College of Obstetricians and Gynecologists (ACOG, RCOG) (19, 20) are:

- ✓ Prolonged second stage of labor
- ✓ Elective shortening of the seconded stage for maternal benfit, including maternal exhaustion
- ✓ Suspicion of immediate or potential fetal compromise

Prolonged second stage and fetal distress are by far the two most common indications for VE (21-24). In Sweden, a prolonged second stage is defined as occurring when the second stage of labor exceeds two hours without a regional or epidural block or exceeds three hours with a regional or epidural block for nulliparous women. For parous women, the limits are one and two hours, respectively. The suspicion of fetal compromise, often referred to as fetal distress, includes a non-reassuring fetal heart rate, pattern, or abruption. Elective shortening of the second stage may include situations when pushing is contraindicated because of conditions such as maternal cardiovascular or neurologic disease. Maternal exhaustion as an indication is largely subjective and not well defined (18-20).

1.5 PREREQUSITES

In order to conduct a safe extraction, certain assessments have to be made prior to the extraction, and prerequisites need to be fulfilled. Some of the prerequisites are absolute and some are recommendations. Perquisites considered absolute are:

- ✓ Fetal engagement
- ✓ Known fetal station and position
- ✓ No suspected fetal disproportion
- ✓ Empty bladder and ruptured membranes

Other prerequisites such as adequate analgesia, a fully dilated cervix, the possibility of abandoning the procedure, gestational age >33 weeks, and an experienced operator are not considered absolute but are recommendations that are relative to the clinical situation. In addition, the uterine contractions and maternal expulsion efforts should be evaluated (18, 25, 26). Some of these prerequisites are described in more detail below.

Fetal engagement, lie, and position

The first assessment is to ensure that that the fetus is in cephalic presentation and that the fetal head is engaged in the maternal pelvis. This is done by abdominal examination (Leopold's maneuvers) in combination with a trans-vaginal examination. To ensure engagement (biparietal diameter beneath pelvic inlet), only one fifth of the fetal head should be palpated abdominally and the vertex should be palpated at least at or just below the level of the ischial spines. If the fetal head is not engaged and the fetal vertex is stationed above the level of the maternal ischial spines, VE is contraindicated because it will put the infant at increased risk (16, 19, 20, 25, 27, 28).

Fetal lie refers to the relationship between the fetal (sagittal suture) and maternal midline pelvic axis, which may be longitudinal, oblique, or transverse. Fetal position refers to the position of the occiput, that is, the occiput anterior, occiput posterior, and occiput transverse position. Being certain of the fetal position and lie is essential because this information will help the operator identify the flexion point and use the right traction angle during traction (29).

Fetal station and classifications of VE

VEs are classified according to the station (level) of the presenting part, the vertex (not caput succedaneum), in relation to the maternal ischial spines (16, 17, 19, 26). In Sweden, VEs are classified into three different groups, as follows:

- ✓ Outlet — Outlet extractions include all VEs conducted when the fetal vertex has reached or almost reached the pelvic floor.
- ✓ Midpelvic — Midpelvic extractions include VEs conducted when the vertex has reached the level of the maternal ischial spines but not the pelvic floor.
- ✓ High — High level is when the vertex is stationed above the level of the maternal ischial spines (contraindicated).

Fetal disproportion

Fetal disproportion is a complex assessment, evaluated based on a summary of clinical observations, such as excessive moulding of the fetal head, slow labor, very heavy traction, and an estimated large fetus. A macrosomic fetus is not considered to be a contraindication for attempting VE, but caution is warranted because it is associated with a risk of shoulder dystocia (19).

Ruptured membranes and empty bladder

Membranes must always be ruptured in order to attach the cup to the fetal head. The urinary bladder should be emptied to avoid damage to the urethra and bladder and because a full bladder might obstruct the passage of the fetal head through the birth canal.

Analgesia in VE

Some guidelines and authors consider an epidural or spinal block to be sufficient in VEs. A pudendal nerve blockade (PNB) is recommended in cases without an epidural or spinal block (20, 25, 26). According to Vacca's handbook on VEs, infiltration of the perineum is considered to be sufficient in outlet extractions (16).

Cervix

The cervix should be completely dilated to avoid a rim of the cervix becoming caught under the vacuum cup, which will increase the risk of lacerations leading to heavy bleeding (17, 30). VE before full cervical dilatation is considered feasible by some authorities under highly select circumstances, such as delivering a second twin, in multiparous women with an almost fully dilated cervix and in circumstances where a CS is not possible and imminent delivery is necessary (8, 16).

Contractions, expulsion efforts, and maternal cooperation

To reduce the force during traction, strong contractions, effective expulsion efforts, and maternal cooperation are of utmost importance. If the contractions are insufficient, an oxytocin infusion is often used to increase the strength of the contractions. A higher traction force has been associated with maternal sphincter injury and neonatal scalp laceration (31).

Operator experience

Clinical experience with the intervention is considered to be the primary requirement for patient safety in VEs (16, 19, 20, 32, 33). In Sweden, both midwives and obstetricians should be able to perform VEs (34). There is no regulated education or any regulation to assess the necessary competencies to perform VEs. Most of the training takes place on the job under the supervision of skilled practitioners. In addition, self-acquired knowledge gained from teaching materials and courses arranged at local hospitals and information from practice guidelines is important. Recently, simulation training and training programs have been established, such as Advanced Life Support in Obstetrics (ALSO). ALSO is an evidence-based training program that has been proven effective to increase patient safety in complicated obstetrical interventions (35).To what extent ALSO is used to train VE performance in Sweden is not known by the author of this thesis.

Gestational age and weight

Most clinical guidelines do not recommend VE before 34 to 36 gestational weeks (19, 20), based on the fact that preterm infants are more likely to develop intracranial hemorrhage compared with term infants and would therefore be at higher risk if delivered by VE.

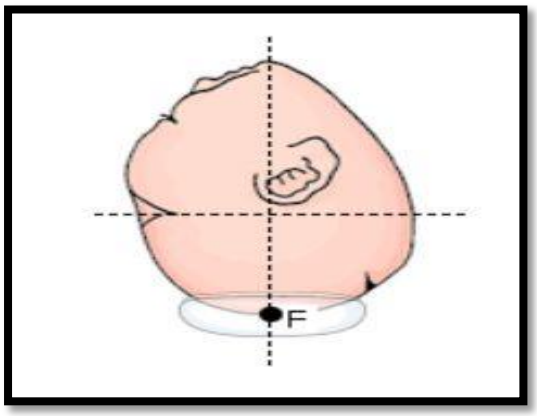
Abandoning the procedure

Not all attempted extractions are successful, and failure sometimes occurs. When the extraction fails, another mode of delivery has to be chosen; the available options are either a CS or forceps. Most guidelines recommend that the extraction should be abandoned if the fetal head does not follow with each pull or after a maximum of two detachments of the cup. Usually, no more than six pulls should be used and/or it should take no more than 15 to 20 minutes to complete the extraction (26, 27, 31, 36). There are two population-based studies indicating that the use of sequential methods constitutes an incremental risk of injury to the infant (37, 38); others claim that the sequential use of forceps is safe for infants (39-41).

1.6 TECHNIQUE

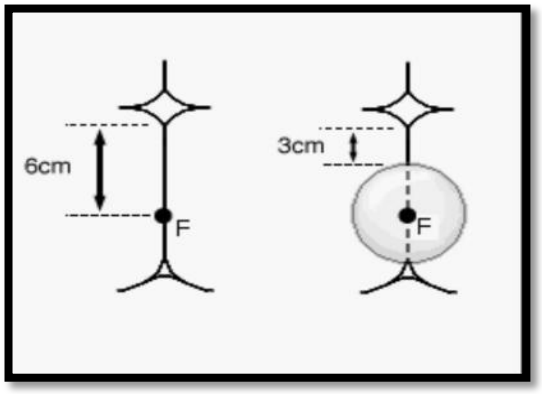
Once the prerequisites are met, the operator can continue with the intervention. First the appropriate cup should be chosen and placed over the flexion point. Anatomically, the flexion point is an imaginary spot over the sagittal sutures of the fetal skull, located approximately 6 cm posterior to the center of the anterior fontanel or 1 to 2 cm anterior to the posterior fontanel (Fig. 2). If the cup is displaced, this will result in deflexion of the fetal head and a greater diameter of the fetal skull has to pass through the birth canal, increasing the risk of failure, detachments, and force needed to deliver the infant (16, 29, 30).

Figure 2: Flexion point



The most appropriate choice of cup depends on fetal position and station. In outlet extractions, when the fetal head is in a direct occipito anterior position, any cup would be appropriate (metal, plastic, or soft rubber cups) (13). However, in VEs conducted at midpelvic stations where the fetal head will rotate, a metal cup or Omnicup should be chosen (13, 16).

Once the cup has been placed on top of the fetal skull, the operator must ensure that no maternal tissue is caught under the rim of the cup. If maternal tissue is caught under the cup, the pressure should be lowered and the tissue must be disengaged before continuing.



To attach the cup to the fetal head, a negative vacuum is applied either stepwise or rapidly using an electric vacuum pump or a handheld vacuum pump. A Cochrane review from 2012 showed that rapid versus stepwise negative pressure was associated with a shorter duration of extraction without affecting maternal or neonatal outcomes (42).

Traction should always coincide with uterine contractions, and maternal bearing down efforts are important to minimize the traction force needed. In the relaxation phase between contractions, a vacuum can be maintained or reduced; no differences have been found with regard to duration time, failure, or maternal or fetal outcomes (22). During traction, the operator should place one hand within the vagina, with the thumb on the extractor cup and one or more fingers on the fetal scalp.

The operator must follow the descent of the presenting part and pull along the axis of the pelvic curve. It is important that the operator can judge the appropriate and changing angle for traction. The angle for traction depends on the station but is usually downward in the beginning and then progressively extends upward as the head emerges. Once the head of the infant emerges, the vacuum pressure is relieved, the cup is removed, and the usual techniques to complete the delivery are employed.

Number of pulls, duration, and detachments

The maximum numbers of pulls and detachments and the maximum duration of the extraction that are safe for the infant have never been established, and evidence is sparse. The American College of Obstetricians and Gynecologists technical bulletin *Operative Vaginal Delivery* states that for VEs "there is a lack of consensus regarding the number of pulls required to effect delivery, the maximum numbers of cup detachments that can be tolerated and the total duration of the procedure" (19). Despite the lack of evidence, recommendations about these safety measures exist to protect the infant from potentially harmful extractions (17, 18, 26, 31, 43). A widely used recommendation has been the concept of the "three pull rule" to protect the infant (18). Lately, the three plus three pull rule has been considered safe for the infant, that is, three pulls for the decent phase and three pulls for the perineal phase (14, 16, 31).

The total vacuum application time should be limited to 15 to 20 minutes, according to most authorities (14, 16, 17, 19, 29, 30). Observational studies have demonstrated that with effective maternal uterine contractions and good maternal expulsive effort, almost all extractions are completed within 15 minutes (30, 36).

Cup detachments were previously thought of as a safety mechanism of the vacuum device when too much force was used but are currently considered a warning signal of incorrect placement of the cup and incorrect technique (14, 16). Most authors recommend the procedure be abandoned after a maximum of two to three cup detachments (16-20).

Episiotomy

Episiotomy can be used in VEs to prevent obstetric anal sphincter tears (OASIS) and to decrease perineal resistance (16). Usually, guidelines recommend that an episiotomy should be performed when there is a high risk of OASIS (16, 19, 20).

1.7 FACTORS ASSOCIATED WITH VE

The risk factors associated with VE are induction of labor, nulliparity, the use of epidural analgesia, short maternal stature, increasing maternal age, increasing fetal weight, increasing fetal head circumference, and the use of continuous cardiotocography (24, 44-46). Many of these risk factors are also related to prolonged labor, for example, maternal age (47) and height (48), nulliparity (49-53) , gestational age, and birth weight (54).

1.8 MATERNAL COMPLICATIONS

The most frequently reported maternal complication in VE deliveries is OASIS. Compared with spontaneous vaginal delivery, some studies report an increased odds ratio (OR) of 2 (55, 56) and 3 (57, 58) for OASIS, while other studies do not report any increased risk (59-61). Compared with forceps, VE is related to a decreased risk of an OASIS (62, 63). Rates of OASIS in VEs vary between studies from 3.1% to 14.8%, the highest rate found in Sweden (4, 56, 64, 65). Other acute maternal complications in VEs are postpartum hemorrhage and cervical tears (3, 62, 66). Hemorrhage can either be a cause of lacerations and/or atony (52) due to prolonged labor that occurs prior to the extraction. VE is also related to a negative birth experience for both the mother and father (67-74).

1.9 NEONATAL COMPLICATIONS

Neonatal injuries related to VE vary from mild lacerations of the fetal scalp to intracranial hemorrhage. Mild scalp effects such as chignon, red marks, and bruising are very common side effects of the vacuum and are of no clinical significance to the infant but may of course

cause the parents anxiety. Scalp abrasions and lacerations occur in approximately 10% of all extractions, with reassuring long-term follow-up data (75, 76). Retinal hemorrhage has been shown to be related to VE, with an incidence of 49% (62) but with no long-term effects on the child (77, 78). Infants delivered by VE are also at a higher risk of neonatal jaundice, (79) skull fractures (80-83), and shoulder dystocia (84-87).

Emil was born in 2012 using VE. Today, he is a healthy child. This picture is published with permission from his mother.

Extracranial bleeding, such as cephalohematomas and subgaleal hematomas, are related to VE, and factors that will increase the risk include cup detachments and prolonged and heavy traction (29, 75, 88-90). Cephalohematoma is an accumulation of blood between the periosteum and the fetal bone plate (i.e., os parietale). The amount of blood that can be lost in this space is limited since the bleeding occurs underneath the periosteum, which is attached at the periphery of each bone plate (5). The incidence of cephalohematomas in VEs ranges from 5% to 10%, depending on the type of cup used (13, 62). The reported incidence of subgaleal hematoma in VEs varies between 0% and 21% (83, 91, 92). A subgaleal hematoma is not limited by space, and the infant may bleed excessively; the bleeding occurs underneath the galea aponeurotica (5).

Intracranial hemorrhage is a rare but severe complication reported in all modes of delivery. Intracranial hemorrhage includes subarachnoid, intraventricular, subdural, and intraparenchymal hemorrhage. Subdural hemorrhage is almost always considered a result of birth trauma, while the other types of hemorrhage have a more complex etiology resulting from hypoxia and ischemia (82). Studies report an increased risk in VEs compared to spontaneous vaginal delivery (6, 37), while other do not (38).

VEs have been shown to be related to minor asymptomatic brain lesions without clinical symptoms in the neonatal period (83, 93). The question of whether or not these minor lesions might have a negative long-term effect on a child's cognitive development has been raised. There are a few rather old studies on long-term effects that all report reassuring results, but they struggle with power problems and often lack the possibility of controlling for important confounders (94-97).

1.10 GUIDELINES ON VE

Clinical practice guidelines are developed to support clinicians in decision making and to support evidence-based care. Sweden does not have a tradition of national practice guidelines; instead, each clinic is responsible for the creation of practice guidelines. This means that every birth clinic writes their own practice guidelines on how VEs should be performed. In 2010, the Swedish Society for Obstetricians and Gynecologists (SFOG) wrote a practice guideline on VE ; this can be found on their homepage (98). Whether this guideline is used in practice at the different obstetrical units in Sweden is not known. This guideline includes information about the following:

- Accepted indications, prolonged labor, fetal distress, maternal exhaustion, and maternal indications such as cardiac disease or hypertensive disorders. Correction of fetal lie is also considered an acceptable indication.

- Contraindications for VE: fetal vertex above the level of the maternal ischial spines (high extraction), breech presentation, transverse lie, brow or face presentation, gestational age < 34 weeks, incomplete dilatation of the cervix, intact fetal membranes, unengaged fetal head, or suspected cephalopelvic disproportion.
- The extraction is recommended to be abandoned if more than two cup detachments occur, if the fetal vertex is not at the pelvic floor after three contractions/pulls or after three pulls without progress, or if the woman is not expected to deliver within 15 minutes or at the most 20 minutes after the attachment of the cup.
- Obstericians with experience should primarily perform VEs, especially in the case of a nullipara with a midpelvic extraction with an indication of either fetal distress or prolonged labor. In the case of an emergency, a midwife with the necessary competence can perform outlet extractions.

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In summary,

delivery by VE is a common intervention used in everyday practice in Sweden. Although life-saving and important the intervention is associated with serious complications in the mother and infant. The outcomes of extractions depend on the appropriate selection of patients, correct clinical performance, and the skill of the operator. From a public health point of view, it is important to investigate how VEs are being performed and to investigate outcomes related to the use of VEs.

2 AIMS

The specific aims of this thesis are:

- To investigate how VEs are perfomed in Sweden today (Study I).
- To investigate if women receive adequate pain relief during delivery by VE and risk factors for not receiving pain relief (Study II).
- To investigate the incidence of failed VEs, risk factors for failure, and neonatal complications related to failed VEs (Study III).
- To investigate if birth by VE affects a child's cognitive development (Study IV).

3 MATERIALS AND METHODS

3.1 SETTINGS

All studies in this thesis are based on statistics collected from health data registers. Sweden is a country with good opportunities for research on register data because of the existence of these nationwide registers. The registers are often based on the unique and systematic personal identification numbers that Swedish citizens have been assigned since 1947 (99). These personal identification numbers are the very foundation of all large-scale medical register linkages (99).The structure of the four different studies in this thesis is presented in Table 1.

Table 1: Overview of the four studies in the thesis

Study	**Research question**	**Study design**	**Data source**	**Exposure**	**Outcome**	**Statistics**
I	To investigate how VEs are performed in Sweden today	Descriptive study	Obstetrix database and medical records	Variables described: indication for VE, type of cup, number of pulls, gestational age, fundal pressure, traction time, number of detachments, fetal station, fetal position, episiotomy, operator		Descriptive statistics: proportions, median, min-max
II	To investigate if women receive adequate pain relief during delivery by VE and the risk factors for not receiving pain relief	Descriptive and analytic study	Swedish Medical Birth Register	Parity, fetal station, fetal position, maternal BMI, indication for VE, maternal smoking, single parenthood	Pain relief/no pain relief	Descriptive statistics and logistic regression
III	To investigate the incidence of failed VEs, risk factors for failure, and neonatal complications related to failed VEs	Cohort study	Swedish Medical Birth Register	Successful VE/Failed VE	Low Apgar score, intracranial hemorrhage, subgaleal hematoma, convulsions	Logistic regression
IV	Does birth by VE affect a child's cognitive development?	Cohort study	Swedish Medical Birth Register and various Swedish health data registers (please see below for a more detailed description)	Mode of delivery	Mean merit grades and mean mathematics grades	Linear regression

3.1.1 Data sources

Swedish Medical Birth Register

In Sweden, almost all pregnant women regularly visit midwives for antenatal care and give birth at a hospital. All costs are paid by tax revenues, meaning that care is free of charge. Midwives and physicians caring for women throughout antenatal care, delivery, and postnatal care are obligated to register data on each individual, which is forwarded every year to the SMBR. Data is recorded in a standardized way from a woman's first antenatal visit (occurring before gestational week 15 in 95% of all pregnancies) to postnatal care (100). It is mandatory for all delivery clinics in Sweden to submit information on all live born and stillborn infants after 22 completed gestational weeks to the register; approximately 99% of all births in Sweden are included (101). The SMBR was evaluated by Cnattingius et al. in 1990 and by the National Board of Health and Welfare in 2003. The results of these evaluations showed that it contains high quality "hard data", such as birth weight and mode of delivery, and that only a small percentage of births are missing (1% to 2%). The most serious loss of data is related to infant diagnoses (101, 102).

The Swedish Educational Register was implemented in 1985 and contains information on each person's highest achieved educational level. It is held by Statistics Sweden. The register contains educational information for people registered as living in Sweden and being 16 to 74 years of age by January 1 every year. It has high coverage as about 98% of all residents are registered (103).

The School Grade Registry kept by Statistics Sweden contains information on all school grades at the final examinations and graduation for each pupil leaving compulsory school (usually at the age of 16). Data is collected each year in June. The quality of the register is regarded as high, with few missing reports (104).

The Total Enumeration Income Survey is held by Statistics Sweden and contains information on incomes, taxes, and social economic assistance. The database is updated annually and contains data from 1990 onwards (105).

The Register of the Total Population was established in 1968 and is held by Statistics Sweden. It contains information on deaths, births, marital status, migration, and country of birth for residents born outside Sweden (106).

The Swedish Hospital Discharge Register was established in 1964 and since 1987 includes information on all hospital discharges, diagnoses, surgery codes, and hospital stay duration. The diagnoses are based on the World Health Organization's international classification of disease (ICD)(107). The register was evaluated in 2009 by the National Board of Health and Welfare, which concluded the quality is generally good (106).

The Obstetrix Database is held by Stockholm County Council and is a relatively new register. Data is collected directly from medical charts and until now was only available from hospitals situated in Stockholm and Gotland. This register has not been validated.

3.2 METHOD STUDY I

The study population consisted of 600 consecutively collected VEs from six different hospitals over a 10-month period in 2013 (6 March to 15 December). All units contributed data on 100 VEs. Five units were located in Stockholm and one was located in Västmanland County. The number of annual births at the participating units was approximately 1,700, 3,000, 3,700, 4,800, 6,700, and 7,400. All these delivery units use the computerized VE template to document clinical performance during VEs. Data on 500

deliveries was collected from the Obstetrix database, held by Stockholm County Council. This database was used because it includes detailed data from the VE template. Data that was collected on 100 VEs from the hospital located in Västmanland County was retrieved directly from the VE template in the medical charts from two assigned midwives. Variables that were collected were indication for VE, fetal station, fetal presentation, gestational age, type of cup, number of pulls, extraction time, number of detachments, episiotomy occurrence, fundal pressure, and operator.

We also asked each participating delivery unit to send the local practice guideline for VEs. Variables that were reviewed in the practice guidelines were the same as those collected from the medical charts.

3.2.1 Statistical calculations

Data were presented as mean, min and max, numbers and proportions (%). Statistical calculations were conducted using SPSS for Windows (SPSS Inc., Chicago, IL, USA).

3.3 METHOD STUDY II

We identified 62,568 women with singleton pregnancies who were delivered by VE in gestational weeks 37+0 to 41+0 between 1999 and 2008 in the SMBR. We collected information about epidural analgesia, spinal block, PNB, infiltration of the perineum, parity, maternal age, body mass index, fetal station, fetal position, indication for VE, smoking, and single parenthood. Epidural block, spinal block, and PNB were considered potent pain relief in all extractions. In outlet extractions, infiltration of the perineum was considered adequate.

3.3.1 Statistical analysis

Pain relief used in VE deliveries was presented as proportions. Nulliparous and multiparous women were analyzed in separate categories. We also described the use of pain relief in separate VE categories; outlet extractions and midpelvic extractions (including high extractions). Maternal and labor risk factors for being delivered without pain relief were first analyzed using univariate logistic regression. Logistic regression was used because the dependent outcome variable (pain relief/no pain relief) was dichotomous. The association between the dependent outcome and each independent variable was analyzed separately and was presented as ORs with 95% confidence intervals (CIs). We also conducted multivariable logistic regression to estimate adjusted OR with a 95% CI for each independent significant risk factor for not receiving pain relief. Each independent variable was analyzed separately, with adjustments for all other significantly related factors in the univariate model. Statistical analyses were conducted using SPSS for Windows (SPSS Inc., Chicago, IL, USA).

3.4 METHOD STUDY III

The study population was identified in the SMBR between 1990 and 2010 and included all women (and their newborn infants) with singleton pregnancies who gave birth at term (gestational age >36 completed weeks) to a live infant in cephalic presentation by either successful VE (n=83,671) or by failed VE (n=4,747). Failed VE was defined as a VE attempt followed by either the use of forceps, CS, or both forceps and CS. Further, we collected information on maternal age, parity, maternal height, body mass index, gestational age, epidural analgesia, indications for VE, infant birth weight, and position and station of fetal head.

3.4.1 Statistical analyses

We used logistic regression presented as crude and adjusted OR and a 95% CI to estimate the association between maternal, pregnancy, labor, and neonatal characteristics and risk of failure with the VE. We further conducted logistic regression analyses to estimate crude and adjusted OR with a 95% CI for the association between the predictor variables of successful and failed VE and dichotomous dependent outcome variables such as intracranial hemorrhage, neonatal convulsions, Apgar scores < 7 at five minutes of age, and subgaleal hematoma. In the analyses, infants delivered with successful VEs served as the reference group. We used two models to adjust for potential confounders. In Model 1, we adjusted for year of birth, parity, maternal height, gestational week, sex, and infant birth weight. In Model 2, we added adjustments for induction of labor, episiotomy position of fetal head, station of fetal head, epidural analgesia, and indication for the operative delivery. Year of birth was entered as a continuous variable in accordance with a linear secular trend, and all other variables were entered as categories. Missing data were entered as a separate category in the analyses. Statistical analyses were conducted using SPSS for Windows (SPSS Inc., Chicago, IL, USA).

3.5 METHOD STUDY IV

We identified 126,032 firstborn singletons born to native Swedish parents delivered between 1990 and 1993. Only infants born after gestational week 34, with an alive and resident mother at the child's age of 15, without serious malformations, not born in breech presentation, and not delivered with the use of forceps were included. The children were followed up at 16 years of age between 2003 and 2006 in the School Grade Registry. From this register information on each individual, final mean merit grades and mean mathematics grades were collected. To be able to control for social and medical confounders, such as parental educational level, income, psychiatric diagnoses, drug abuse, socioeconomic status, and residency, the personal identification number of the mother was used to collect information on these variables in the different registers described in the Methods section 3.1.1. Pregnancy and labor confounders, such as information about the mother's age at birth, mode of delivery, smoking habits in early pregnancy, maternal diseases, and complications during pregnancy and labor, were collected from the SMBR. Data on perinatal confounders, such as sex, gestational age, birth weight, head circumference, and whether the child was small for the gestational age or large for the gestational age, were also collected. Potential mediators, such as cephalohematoma, intracranial bleeding, central nervous system (CNS) complications, convulsions after birth, and Apgar scores at five minutes, were also collected from the SMBR.

3.5.1 Statistical analyses

We conducted linear regression analyses to estimate crude and adjusted mean differences (β-coefficient) in final mean mathematics and mean merit grades and their 95% CI in relation to mode of delivery. Linear regression describes the association between two variables, assuming a linear relationship between the variables. The regression coefficient gives the change in value of the dependent outcome per unit change in the predictor exposure variable. In the analyses, spontaneous vaginal delivery served as reference group. Each predictor variable was entered separately to evaluate the effect on the dependent outcome variable. Finally, three models were used to present the results. Model 1 was adjusted for year of graduation and sex only. In Model 2, we added the following socioeconomic, demographic, and maternal morbidity variables to the confounders in Model 1: maternal age, highest educational level in the household one year before graduation, urban/rural residency one year before graduation, single-parent household, maternal smoking, maternal drug abuse, maternal

alcohol abuse, and maternal psychiatric diagnosis. In Model 3, we added the following potential medical confounders to the variables in Model 2: small for gestational age, large for gestational age, oligohydramnios, polyhydramnios, maternal diabetes, preeclampsia, head circumference, and gestational age. Further, we adjusted for potential mediators in terms of diagnosed neonatal trauma in the last model, which was not presented in the article. Statistical analyses were conducted using SPSS for Windows (SPSS Inc., Chicago, IL).

4 ETHICS

One of the main aspects in medical research ethics is that each study participant is informed about the purpose of the study, what will be done, and the possible effects of the intervention. Participation should be voluntary and participants should be able to withdraw from the study at any time. All this constitutes informed consent. However, large population-based studies seldom require informed consent because of the inconvenience of obtaining consent from a large number of people and because retrospective studies in no way affect treatment. Further, in order to protect study participants from any discomfort, anonymous data should be used. The benefits and importance of the knowledge gained from the research must also always be weighed against the possible discomfort participating individuals might experience.

All four studies were approved by the Regional Research and Ethics Committee in Stockholm, Sweden. Study IV was also approved by the department heads at each participating delivery clinic.

Study I: Approval numbers 2008/1322-31 and 2010/593-32. Study II: Approval numbers 2008/1322-3, 2010/593-32, and 2012/1945-32. Study III: Approval numbers 2008/1322-31 and 2010/593-32. Study IV: Approval number 2013/653-31/1.

5 RESULTS

This section is a summary of the results in the four studies in this thesis. For a complete presentation, all four studies are found at the end of the thesis.

5.1 STUDY I

The final study population consisted of 596 women delivered using VE. Of these births, 595 were singletons and one was a twin delivery. Of the 596 extractions, 42 failed (7%).

All but one VE had an accepted indication for the intervention noted in the medical journal. Fetal distress was the most frequent indication among both multiparous (40%) and nulliparous (33%) women, followed by prolonged labor. Every fourth extraction had a double indication of some kind. The majority of all VEs (>70 %) were conducted from the midpelvic level, and 2.3% were conducted from a high level. In almost 10% of the cases, the fetal position was assessed as an occipito posterior position. Only 4% were preterm infants, and all but one had reached gestational age >33. One infant was delivered by a soft rubber cup at the gestational age of 32 weeks. Only five extractions were conducted using a soft rubber cup, and in most cases a metal cup was used (74%). Of all the extractions, 60% were completed with less than four pulls. The maximum numbers of pulls necessary to deliver the infant was 14 in a nulliparous woman and 12 in a multiparous woman. More than six pulls were necessary in 31 (8%) nulliparous women and in five (2%) multiparous women. Half of the women were successfully delivered within five minutes of application of the cup; this was more common among multiparous women (53%) compared to nulliparous women (45%). In 14 women (10 nulliparous and four multiparous), it took more than 20 minutes to deliver the infant. In one nulliparous woman, it took 41 minutes to complete the extraction, and in one

multiparous woman it took 28 minutes. Most of the extractions did not have any cup detachment (84%). In 30 (5%) extractions, more than one cup detachment occurred. Only 2.7% of the VEs were performed by a midwife.

Difficult extractions; defined as an extraction with either more than six pulls and/or a duration of more than 20 minutes and/or more than two cup detachments were more common in midpelvic extractions and in extractions conducted because of prolonged labor. Difficult extractions also increased with increasing birth weight.

All hospitals had local practice guidelines governing VE delivery. Of the 11 variables studied, three were present in all guidelines: indication for VE, maximum duration time, and maximum number of detachments. The three main indications for VE mentioned in all guidelines were fetal distress, prolonged labor, and maternal exhaustion. Recommended maximum duration time varied from 15 to 20 minutes, and acceptable number of detachments varied from one to three. Regarding VE classification (outlet, midpelvic, and high), information was missing completely in two guidelines, poorly described in one, and inconsistent in the remaining three. Only one guideline recommended a maximum of six to eight pulls before abandoning the procedure. Instead of defining a maximum number of pulls, varying recommendations on when to abandon the procedure in relation to number of pulls was described in four guidelines. For example, one guideline recommended the procedure be abandoned if the fetal head was not at the pelvic floor after three pulls, and another recommended the procedure be abandoned if the fetal head was not at the pelvic floor after five pulls. Three guidelines considered three pulls without progress to be an indication for abandoning the procedure.

Only one guideline stated necessary experience for the obstetrician to conduct outlet and midpelvic extractions. In the remaining five, necessary experience in the obstetrician to conduct different VEs was not mentioned. Conditions for when a midwife can perform a VE were either in the case of an emergency, in outlet extractions, or if an obstetrician is informed prior to the extraction.

5.2 STUDY II

A total of 62,568 women delivered by VE were identified in the SMBR. The majority of women (78%) were nulliparous, and 65% of the extractions were registered as being outlet extractions. Of all VEs, about half of the multiparous women and every third nulliparous woman were delivered without potent pain relief. Potent pain relief refers to the use of epidural analgesia, a spinal block, or a PNB. Of the midpelvic extractions, 27% of all nulliparous women and 50% of all multiparous women did not receive potent pain relief prior to extraction. Of the outlet extractions, when infiltration of the perineum was added as a potent method to use, 15% of all nulliparous women and 29% of all multiparous women were delivered without potent pain relief.

In the univariate regression model on risk factors for not receiving potent pain relief during VE, statistically significant related factors were multiparity, indication of fetal distress, outlet extractions, fetal malposition, maternal age >35 years, and overweight or obese women. Smoking and single parenthood were not statistically significant.

In the adjusted model, risk factors for being delivered without potent pain relief were multiparity with a two-fold risk compared with nulliparity. Indication of fetal distress increased the risk by 70% compared with indication of prolonged labor. Extraction conducted from the outlet had a 30% increased risk compared with extraction conducted from the midpelvic level, and extractions where the fetus was in a malposition had a slightly increased risk (11%) compared with extractions where the fetus was in an occipito anterior position.

Table 1: Logistic regression for not receiving pain relief in relation to pregnancy and labor characteristics.

	Adjusted OR (95% CI)
Parity[1]	
Nulliparous	1 (ref)
Multiparous	2.29 (2.20-2.38)
Indication[2]	
Dystocia	1 (ref)
Fetal distress	1.74(1.68-1.81)
Missing	1.20 (1.15-1.26)
Type of extraction[3]	
Mid/High	1 (ref)
Outlet	1.34 (1.29-1.39)
Fetal position [4]	
Occipito anterior	1 (ref)
Other	1.11 (1.05-1.17)
Missing	1.25 (1.15-1.26)

[1] Adjusted for indication, fetal station, fetal position, maternal age, maternal BMI
[2] Adjusted for parity, fetal station, fetal position, maternal age, maternal BMI
[3] Adjusted for parity, indication, fetal position, maternal age, maternal BMI
[4] Adjusted for parity, indication, fetal station, maternal age, maternal BMI

5.3 STUDY III

The final study population included 88,418 women delivered by VE between 1999 and 2010. Of these extractions, 94.6 % were successful and 5.4 % failed. The rate of failed VEs increased over the 12-year study period, increasing 0.5% from 4.9% to 5.4%. The most preferred subsequent method was CS (74%). In 26% (n=1236) of the failed VEs, a subsequent use of forceps was chosen, out of which 16% (n=194) failed again, and a final CS had to be used to deliver the infant. The incidence of a subsequent use of forceps decreased from 1.2 to 0.7% over the 12-year period.

Crude and adjusted maternal pregnancy, labor, and neonatal risk factors for failed VEs were identified. After adjusting for independent risk factors, we found that nulliparity, short maternal stature (< 160 cm), and the use of epidural analgesia was significantly associated with failed VE. Epidural analgesia increased the risk of failure by 70%, and nulliparity increased the risk of failure by 87%. Increasing birth weight was positively correlated with the risk of failure, that is, infants weighing more than 4500 grams had a three-fold risk of failure compared to infants weighing 3001 to 3500 grams.

The most pronounced risk factor for failure was fetal malposition. Extractions of fetuses in occipito posterior positions and other malpositions had a six- and seven-fold risk, respectively, of failure compared to extractions of fetuses in occipito anterior positions.

The multivariate regression model on the risk of neonatal complications in association with failed VEs showed that infants born after a failed VE had a statistically significant OR of 1.9 for convulsions, 2.6 for low Apgar scores, and 7.3 for subgaleal hematomas compared to infants born by successful VE, after adjustment for confounders. Intracranial hemorrhage was not statistically significantly associated with failed VEs in the crude or the adjusted model.

Figures 4 and 5 show crude rates of neonatal complications in relation to failed and successful VEs.

Figure 5: Rates of neonatal complications in successful and failed VEs (1/1000)

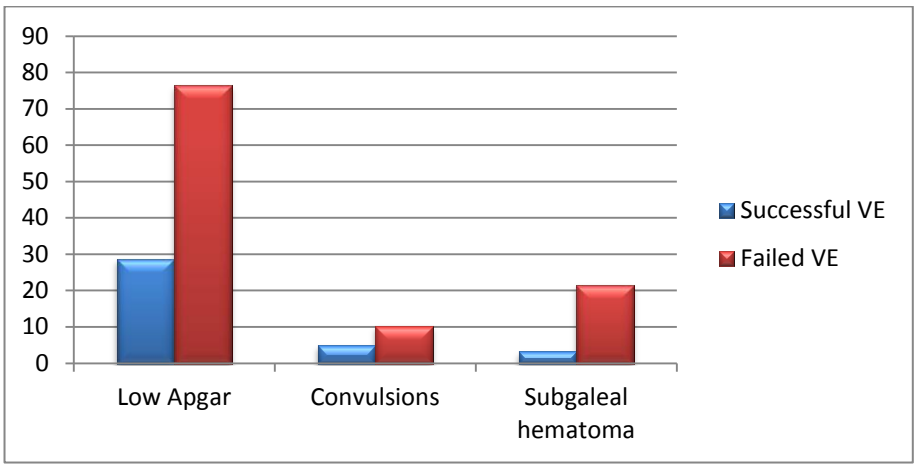
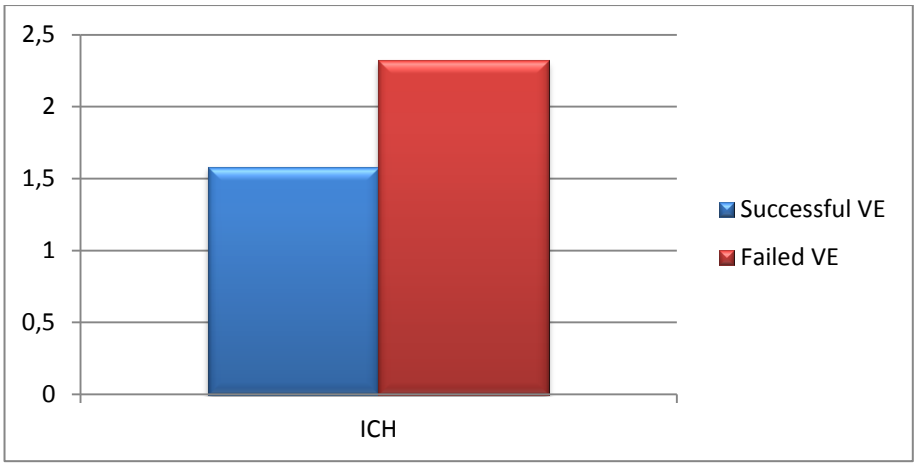


Figure 5: Rates of intracranial hemorrhage (ICH) in successful and failed VEs (1/1000)



The rate of intracranial hemorrhage among all extractions (failed and successful) was 1.62/1000 births. Rates of intracranial hemorrhage in separate failed VE groups showed that 1.87/1000 infants delivered by the subsequent use of forceps were diagnosed with ICH, 2.01/1000 infants delivered by subsequent CS were diagnosed with ICH, and 10.3/1000 infants were delivered using all three methods (VE+forceps+CS) were diagnosed with ICH.

5.4 STUDY IV

The final study population included 126,032 children, where 14,494 (11.5%) were delivered by VE, 8,753 (7. 0%) were delivered by non-planned CS, 2,386 (1.9%) were delivered by elective CS, 361 (0.3%) were delivered by VE and subsequent CS, and 100,038 (79.4%) were delivered by spontaneous vaginal delivery.

Neonatal factors that were more common in VEs compared with spontaneous vaginal delivery were male sex, increasing head circumference, and gestational age >42 weeks. Further, maternal diabetes, preeclampsia, oligohydramnios or polyhydramnios, and being small or large for gestational age were more common in VE deliveries compared with spontaneous vaginal deliveries. Increasing maternal age increased the risk of VE.

Mean mathematics test scores remained relatively stable over the years 2006 to 2009, ranging from 40.0 to 40.4. The mean grade point average increased from 218.8 in 2006 to 226.0 in 2009. Girls had better mean merit grades than boys 235 compared to 212, respectively—whilst mean mathematics grades did not particularly differ between girls and boys—40.5 compared to 40.0, respectively. Mean merit and mathematics grades increased gradually with increasing gestational age and increasing head circumference. There was a linear correlation between maternal age and grades; the older the mother, the better the grades. Children born to mothers with a psychiatric diagnosis, smoking mothers, and single mothers had lower mean merit grades and mean mathematics grades compared with the overall mean merit grades and mean mathematics grades in the study cohort. Grades also increased gradually with increasing household income and increasing educational level.

Mean mathematics grades

In the first analysis on the association between mode of delivery and mean mathematics grades, we could show that crude mean mathematics grades were slightly higher in children delivered by VE compared with those born by spontaneous vaginal delivery. After adjustment for year of birth and infant sex, mean mathematics grades remained significantly higher in children born by VE compared with children born by spontaneous vaginal delivery. In the second linear regression model with the addition of several maternal confounding factors, children born by VE had statistically significant lower grades compared with children born by spontaneous vaginal delivery. When each confounder was entered in the model separately, maternal age was the one that affected the beta coefficient the most. In the last and final linear regression model with the addition of all perinatal and pregnancy confounders, we were able to show that children born by VE had significantly lower mean mathematics test scores compared with children born by spontaneous vaginal delivery. Similar results were found for children delivered by emergency CS, as shown in Table 2.

Table 2: Linear regression for mathematics test scores in relation to mode of delivery (MOD)

MOD	MEAN	Model 1		Model 2		Model 3	
		B	(95% CI)	β	(95% CI)	B	(95% CI)
SVD	40.2	Ref		ref		Ref	
VE	40.5	0.34	(0.08 to 0.60)	-0.35	(-0.60 to -0.11)	-0.51	(-0.76 to -0.26)
VE+CS	40.3	0.26	(-1.28 to 1.80)	-0.83	(-2.27 to 0.61)	-1.08	(-2.52 to 0.36)
Emergency CS	40.2	0.02	(-0.30 to 0.35)	-0.50	(-0.81 to -0.19)	-0.51	(-0.82 to -0.20)
Planned CS	40.4	0.27	(-0.33 to 0.87)	-0.54	(-1.11 to -0.03)	-0. 51	(-1.10 to 0.08)

Model 1: Year of graduation and sex. Model 2: Same as above, adding maternal age, educational level and residency, single-parent household, maternal smoking, maternal drug abuse, maternal alcohol abuse, and maternal psychiatric diagnosis. Model 3: Same as above, adding small for gestational age, large for gestational age, oligohydramnios, polyhydramnios, maternal diabetes, preeclampsia, head circumference, and gestational age.

We also adjusted for mediators in the last model (not shown in table), such as a diagnosis of intracranial hemorrhage, neonatal seizures, and other neonatal CNS complications. These mediating factors only had a marginal effect on the regression coefficient. Children delivered by VE had -0.49 CI (-0.74 to -0.23) points less in mean mathematics grades compared to children delivered by spontaneous vaginal delivery. Children delivered by an emergency CS had a -0.50 CI (-0.82 to - 0.18).

Mean merit grades

Crude mean merit grades were slightly higher in children delivered by VE compared to children born by spontaneous vaginal delivery (224 /223). After adjustment for year of birth and infant sex, mean merit grades remained significantly higher (+ 2, 12 points) for children born by VE compared to children born by spontaneous vaginal delivery. In the second linear regression model adding maternal confounding factors, no statistically significant differences in mean merit grades were found between children born by VE and children born by spontaneous vaginal delivery. However, in the last model adding all pregnancy, maternal, perinatal, and socioeconomic factors, children born by VE had lower mean merit grades (-1,05 CI; - 1.87 to -0.23) compared to children born by spontaneous vaginal delivery. The only other exposure group with a statistically significant difference in mean merit grades was that composed of children delivered by emergency CS, who also showed lower grades (-1.20 CI; -2.24 to -0.16) compared with children born by spontaneous vaginal delivery

Table 3: Linear regression for mean merit grades in relation to mode of delivery

MOD	MEAN	Model 1		Model 2		Model 3	
		β	(95% CI)	β	(95% CI)	β	(95% CI)
SVD	223.8	ref		ref		ref	
VE	224.3	2.12	(1.23 to 3.01)	-0.77	(-1.59 to 0.04)	-1.05	(-1.87 to -0.23)
VE+CS	222.9	1.03	(-4.24 to 6.29)	-3.96	(-8.75 to 0.83)	-4.30	(-9.10 to 0.49)
Emergency CS	223.1	0.73	(-0.39 to 1.84)	-1.47	(-2.50 to -0.45)	-1.20	(-2.24 to -0.16)
Planned CS	225.4	2.08	(0.01 to 4.15)	-1.43	(-3.33 to 0.47)	-0,90	(-2.85 to 1.05)

Model 1: Year of graduation and sex. Model 2: Same as above, adding maternal age, educational level and residency, single-parent household, maternal smoking, maternal drug abuse, maternal alcohol abuse, and maternal psychiatric diagnosis. Model 3: Same as above, adding small for gestational age, large for gestational age, oligohydramnios, polyhydramnios, maternal diabetes, preeclampsia, head circumference, and gestational age.

We also adjusted for mediators in the last model (not shown in table), such as diagnosis of intracranial hemorrhage, neonatal seizures, and other neonatal CNS complications. These mediating factors only had a marginal effect or no effect on the regression coefficient. Children delivered by VE had -1.01 CI (-1.88 to -0.16) points less in mean merit grades compared to children born by spontaneous vaginal delivery. Children delivered by emergency CS had a -1.20 CI (-2.28 to -0.13).

Subgroup analysis

Two subgroup analyses were conducted in order to try to control for confounding by indication and selection bias in the study cohort.

To try to control for confounding by indication, we used the same regression models but restricted the study population to term infants with Apgar scores ≥7 at five minutes and without a diagnosis of fetal distress. The results in these analyses showed the same pattern with higher crude mathematics and merit grades in children born by VE compared to children born by spontaneous vaginal delivery. In the last model adding all potential confounders, children delivered by VE had -0.47 CI (-0.78 to -0.15) mean mathematics test scores and -0.74 CI (-1.77 to -0.30) mean grade point average compared to children born by spontaneous vaginal delivery.

We excluded 12,523 children from the study cohort because they did not have registered grades at 16 years of age. To assess the risk of possible selection bias in the study cohort, logistic regression was used to assess if children delivered by VE had a higher risk of no registered grades compared to children not delivered by VE. The odds of having no registered mathematics test scores or no registered merit grades were 0.99 CI (0.91 to 1.08) and 0.70 CI (0.58 to 0.86) for children delivered by VE compared to those delivered without VE, respectively. Based on these results, we assume that the exclusion of children without grades did not bias our results.

To test for the strength of the association expressed as standard mean differences, the effect sizes of VE compared with spontaneous vaginal delivery were calculated using Cohen's D. The results of this analysis showed that the effect size for mathematics tests scores was 0.08 and the effect size for mean grade average was 0.09, which are marginal effects according to the criteria suggested by Cohen, in which effects between 0.20 and 0.40 are considered small (108).

Cohens's *d*

$$M_1 - M_2 / SD_{pooled}$$

$$SD_{pooled} = \sqrt{\frac{(SD_1^2 + SD_2^2)}{2}}$$

6 DISCUSSION

In this section, methodological issues, research findings, and possible clinical implications will be discussed.

6.1 METHODOLOGICAL CONSIDERATIONS

6.1.1 Study design

All studies in this thesis are observational, based on register data. Study I and Study II are mainly descriptive. Study III and Study IV are cohort studies. Using prospectively collected information from registers to achieve the aims of this thesis has strengths and limitations. One important limitation is that there is no possibility to affect the design of the background, exposure, and outcome variables. One always has to rely on the quality of the registers. Further, there might be several important variables not available in the registers. For example, there is no information in the SMBR on how VEs are performed or indicators for true fetal asphyxia, factors that probably affect the outcomes in Study III and Study IV. The major strengths when using registers is that information is prospectively collected, thus minimizing recall bias and information bias. It is also possible to collect information on a large study population, which enabled us to study small differences and rare outcomes. It is important to

bear in mind that results from observational studies must be interpreted with caution because of the inherited risk of bias, confounding, misclassification, and effect modification (discussed later in this section). As with all observational studies, no conclusion on causation can be drawn from the results and instead associations are studied.

To establish a likely association between exposure and outcome, five main criteria (Hill's criteria of causation) should be present (109):

- ✓ *Strength of the association* (the relationship must be clear)
- ✓ *Consistency* (should be able to be repeated in other populations)
- ✓ *Temporality* (exposure must come before outcome)
- ✓ *Plausibility* (the association must make sense biologically)
- ✓ *Biological gradient* (dose–response relationship)

6.1.2 Validity

The internal validity of a study is dependent on the absence of systematic or random errors in the data. It simply means that the study measured what it set out to measure. The external validity refers to the possibility to generalize the results of the study to other populations not being studied. The external validity of a study naturally depends on the quality of the internal validity. If there are measurement errors in the data, for example, the external validity will count for nothing. The external validity is also something that needs to be discussed and judged. Whether the results found in one study population can be extrapolated to another non-studied population depends on the similarity between the studied and non-studied populations.

6.1.3 Systematic errors/bias

Systematic errors include *selection bias, information bias (misclassification), lack of possibility to control for possible confounders, and effect modification.* Systematic errors can occur in any study, regardless of study size. These problems can only be avoided and planned for in the beginning of the research process.

Selection bias is one of the main systematic errors aside from information bias and confounding. When selection bias is present in the studied cohort, the studied subjects are either disproportional in relation to the probability to be exposed and/or there is a loss to follow- up and/or when certain exclusions from the study population are made.

Information bias is present when there is inaccurate recording, coding, or classifications of exposure and outcome. Misclassification of these variables can be either non-differential or differential. Non-differential means when misclassification is equal in all study groups, and non-differential means when misclassification is unevenly distributed between study groups.

Confounding bias is a major concern in epidemiological research. It refers to when the estimated association between exposure and outcome relates to a third factor. A confounder is always related to both exposure and the outcome and accounts for some, or in a few rare cases, all the observed relationships. The researcher must also be aware that the assumed confounder might be an intermediating factor in the causal pathway between exposure and outcome. In well-designed randomized controlled trials, confounding is not an issue because all known and unknown factors are equally distributed between study groups. This is not the case in cohort studies, for example, and cofounding has to be dealt with by the selection of study subjects (restriction) , stratification for various levels of potential confounders, or by the use of multivariable regression models in which confounding factors are taken into account in the analysis.

Effect modification or interaction refers to when then observed strength of the association between exposure and outcome is affected by a third factor. Effect modification is sometimes hard to identify and should have a plausible biological explanation. In contrast to a confounder that is an unwanted effect, effect modification is something that should be identified and presented. To identify important effect modifications, stratified analyses should be conducted to be able to present stratum-specific risk estimates.

Finally, the results of a study can be affected by *random errors*. Random errors are present when the estimated association occurs by chance and not because of a true difference. In epidemiological research, chance is controlled by calculating the CIs of the risk estimate. The confidence level is often set to 95%, meaning that there is only a 5% chance that the true estimate is due to chance, provided that the CI does not contain either 1 (RR, OR, HR) or 0 (mean difference). The risk of random errors is related to the study size and is seldom a problem in large population-based studies.

Study I is based on detailed data from 596 VE deliveries collected from relatively large units. According to the SMBR in Sweden, there are 46 different delivery units with annual birth rates ranging from approximately 300 to 7,200 per year. Among these units, the proportion of VEs varies from 5.5 % to 14% (1). Annual birth rates might affect how VEs are performed and who is performing them. For example, annual birth rates will affect numbers of obstetricians in training and the level of competence on the labor ward during day and night. This means that it is uncertain whether the results in this study can be extrapolated to all other clinics in Sweden. The strength in this study was that data on clinical performance was collected from the same VE template used at the six participating delivery units, thus minimizing the risk of missing data and misclassification. Further, VEs were included consecutively at each clinic, minimizing the risk of selection bias.

In Study II, no selection was made and all women delivered by VE over a 10-year period were included; therefore, selection bias should not be an issue. Instead, this study might suffer from information bias, more precisely, misclassification bias. We studied which kind of anesthetic method was used in women delivered by VE. Two methods that were described were PNB and infiltration of the perineum. These methods are used by midwives both shortly before birth to decrease perineal pain and after birth to anesthetize before suturing lacerations of the vagina. The register does not contain information on when the pain relief was given. Therefore, there is a risk that the number of women without pain relief during the extraction might be higher. Naturally, the quality of these data also depends on the correct documentation by midwives in clinical practice. Also, there is a high risk of misclassification in the variable fetal station. In this study, 66% of the VEs were documented as being outlet extractions. This figure seems high both from our clinical experience and when comparing with the results in Study I, where 21% of extractions were documented as outlet extractions. We believe that some of the outlet extractions in this study more likely were midpelvic extractions.

In Study III, preterm infants were excluded from the study cohort. This selection was made because prematurity itself is a risk factor for intracranial hemorrhage. Our findings can therefore only be extrapolated to term-born infants. It might be that the results in this study suffer from loss to follow-up and that the true rates of intracranial hemorrhage, convulsions, and subgaleal hematoma are in fact higher. That infant diagnoses are of lesser quality, with missing cases in the SMBR, was shown in a validity study from 1990 by Cnattingius et al (103). However, there is no reason to believe that infant diagnoses are less frequently reported in one exposure group, and we believe that it occurs completely at random in the study cohort. If loss to follow-up bias occurs completely at random, it will not affect the risk estimate but naturally will affect the proportions. There were a lot of missing cases, especially

regarding fetal station and position and especially in the failed VE group, which might affect the results.

In Study IV, several selections of the studied cohort were made. For example, children without registered school grades were excluded from the study. To control for the risk that child without school grades were to a higher extent delivered by VE, we used logistic regression to investigate possible selection bias in the study cohort. No indication of any selection bias because of this restriction was found. Further, we excluded children with non-native Swedish parents. Parental educational level was considered to be an important confounder in the casual pathway between mode of delivery and the child's scholastic performance at 16 years of age. Among immigrants, data on educational level is of lesser quality, and missing data would be a problem. However, there is no reason to believe that our results should not be able to be extrapolated to children delivered by VE born to non-native Swedish mothers. There is also a risk of random misclassification in the exposure variable; mode of delivery, that is, VE could be documented by mistake as a spontaneous vaginal delivery and vice versa. This random risk would presumably be equal in all different exposure groups. Since spontaneous vaginal delivery is the largest group, rates of misclassification would be highest in this group. If this bias is present in the results, it would mean that the true observed mean difference in school grades could be greater than estimated. Confounding by indication is also an issue in this study because VE is often used in complicated labors. To try to control for confounding by indication, stratified analyses excluding infants delivered because of fetal distress and or with Apgar scores < 7 at five minutes of age were performed. These results indicated that confounding by indication was present because the β-coefficient (mean difference) was smaller in these results. Indication for operative delivery and Apgar scores must be considered imprecise proxies for true fetal asphyxia, and there is a risk of residual confounding in the final results.

6.2 FINDINGS AND IMPLICATIONS

In this chapter, the findings in the four studies are discussed and an attempt will be made to discuss the findings from a practical and clinical point of view.

Clinical performance in vacuum extractions (Study I and Study II)

In Study I investigating how VEs are performed, we found that most extractions are conducted according to evidence-based safe practice. For example, all but one extraction had an accepted indication. Most extractions were successfully completed with less than four pulls, without any detachment, and within 15 minutes. Absolute prerequisites such as known fetal station and position were assessed and documented in almost all extractions. However, there were several potentially harmful extractions conducted where inappropriate techniques were used. Fetal engagement was not ensured in 14 cases (2.3%), in 36 extractions (6%) more than six pulls were used, and in 14 extractions (2.3%) the time limit of 20 minutes was surpassed. There is little doubt that inappropriate use can be dangerous for the infant and the mother and should be avoided (110-112). Prolonged duration of the extraction has been related to fetal scalp injuries and subgaleal hematomas (27, 89, 91, 113). High extractions will increase the risk of complications during the extraction, such as detachments, heavy traction, long duration, and many pulls, all risk factors for adverse neonatal outcomes (29, 31, 32, 75, 88-90, 110, 111).

Further, we also found that fundal pressure was used in 11% of all extractions. This method was not described in any practice guideline and has not been found by the author of this thesis as a recommended intervention in VEs in any review, international guideline, or educational textbook. The reason for fundal pressure should be to enable vaginal delivery and to compensate for poor contractions or maternal expulsion technique. Fundal pressure has been

related to increased risk of maternal OASIS, neonatal brachial plexus injury, and transfer to neonatal intensive care units; the positive effect of the intervention has not been established (114). Fundal pressure should be used with caution, and further research on possible positive and negative effects in VEs should be evaluated.

Episiotomy was used in 16% of all VE deliveries. In Sweden, mediolateral episiotomies are performed because midline episiotomies are clearly related to increased risk of OASIS, particularly in instrumental deliveries (115, 116). Lately, large retrospective studies indicate that episiotomies are protective against OASIS in VEs (4, 117). As Sweden has relatively high rates of OASIS (14%) (58) in VEs compared to, for example, Finland (3.4%) (4), where episiotomies are more frequently used, it would be beneficial to evaluate the effect of episiotomies on the risk of OASIS in randomized trials.

More than every third woman was delivered by VE without potent pain relief. Of midpelvic extractions, 27% of all nulliparas and every second multipara were delivered without potent pain relief. To give a woman potent pain relief prior to a VE can be considered important for several reasons. First, VE is related to major vaginal lacerations (2, 58) and consequently maternal discomfort. Second, inadequate pain relief in VEs has been shown to affect birth experiences negatively (72). As VE has been associated with a negative birth experience in a number of studies (68, 70, 71, 118), improvements in the use of pain relief can be considered important.

Of those women who did not have an epidural or a spinal block when delivered by VE (which accounted for about half of all women), only 4.5 % received a PNB. These results are somewhat surprising because, according to our clinical experience, a PNB is considered the best method to use prior to a VE. An explanation for the low usage might be that the overall usage of PNBs has decreased over the last decades, as shown in Figure 6. A PNB can be technically difficult to apply, and the midwife has to be experienced in the technique. The overall decreased use of PNBs has most likely led to the reduced ability of midwives to apply these injections.

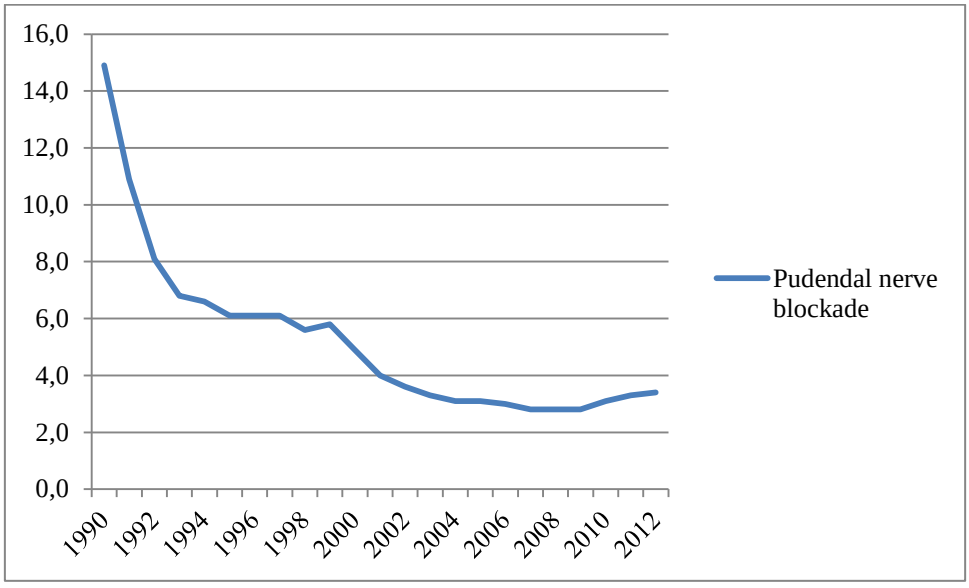


Figure 6: Proportions (%) of PNB among all deliveries in Sweden between 1990 and 2012(1).

A further explanation for the low use of PNBs might be that they can decrease the maternal urge to bear down effectively, which is an unwanted effect in VEs (119). It might also be

that the actual effect of a PNB is questioned among the clinical staff, which has been confirmed in a Cochrane review stating that a PNB has unclear effects on pain (120).

We found that adjusted risk factors for not receiving pain relief were multiparity, indication of fetal distress, and outlet extraction. Common to these three factors is an expected or wanted short duration of the extraction, and therefore pain relief might be considered unnecessary. Further, in a situation of suspected fetal distress, pain relief might be considered of low priority and time consuming. However, these reasons are not acceptable reasons for not administering pain relief. Even in the case of an outlet extraction or if a woman is giving birth to her second child, the extraction can cause intense pain and be a frightening experience; thus, every effort should be made to give good care.

As we found that potentially harmful extractions are being performed in Sweden today and that many women are delivered without potent pain relief, improvements in clinical performance must be made. We also found that practice guidelines on VE are incomplete and not evidence-based. Effective strategies to overcome knowledge translation and improve care on an individual level in obstetrics have been shown to be audit, feedback, and clinical training (121). To improve clinical practice in VEs, these multifaceted strategies, along with the creation and implementation of evidence-based clinical guidelines could be important tools to decrease maternal and fetal complications. A well-written guideline on VE may also constitute a good basis for conducting audits, personal feedback, and clinical training.

Vacuum extraction and infant outcomes (Study III and Study IV)

The vast majority of all VEs are successful with few serious adverse neonatal outcomes, which is in line with previous research (37, 38). However, sometimes the extraction fails and when a sequential method has to be used, the infant seems at incremental risk of adverse cranial outcomes. Our results that a failed VE increases the risk of convulsions, depressed Apgar scores, and subgaleal hematomas are in line with those of two other large population-based studies (37, 38). We were not able to detect any significantly increased risk of intracranial hemorrhage, as was found in both Gardella's and Towner's studies. Our different results might be due to a lack of power or it might also be that failed VEs were performed differently in the studied cohorts. Important risk factors for failed VEs were mostly in line with previous findings, such as fetal malpositions, nulliparity, large infants, fetal station above the outlet, and induced labor (122-124). We did not find any elevated risk for high maternal BMI, or indication of prolonged labor among older women, which have been found to be risk factors for failure in another study (124). The finding that BMI does not increase the risk of failure is interesting and has possible explanations. For example, BMI has been shown to be related to a prolonged first stage of labor but a shorter second stage compared with women with normal BMIs (125). It has also been shown that once the obese woman reaches the second stage, obesity will not affect her ability to push (126). Further, obese women have been found to have increased intra-abdominal pressure (127), which also might affect their ability to push effectively.

We also found that short maternal stature (< 160 cm) and the use of epidural analgesia were risk factors for failure. Short maternal stature can increase the risk of pelvic-fetal disproportion, which might explain our results. That epidural analgesia increases the risk of failure is in contrast to the findings of Ben-Haroush, where regional analgesia decreased the risk of failure (122). These different results are hard to explain, but the use of oxytocin might be important. Neither the study by Ben-Haroush nor our study had access to information on the use of oxytocin. The use of epidural analgesia has also been related to increased infant birth weight (128), which means that women who receive an epidural might have two risk factors present for a failed extraction epidural analgesia and a large infant.

The best method to use after a failed VE has not been established. Smaller studies indicate that a subsequent use of forceps is safe for the infant (39, 41, 88, 129), while the study by Towner indicates that a subsequent CS is safer for the infant (37). In our study, few failed VEs were performed with a sequential use of forceps which probably reflects the overall low use of forceps in Sweden. The low usage also makes is difficult to compare our results to countries where forceps is more common. Our results however indicate that forceps should be avoided in the case of a failed VE. This conclusion is made because when forceps is chosen, there is always a risk of another failure, which seems to put the infant at incremental risk. Further as forceps are seldom used today and their use involves a technically complicated procedure, one can question if today's obstetricians are adequately trained in this technically difficult instrument. Last, it is easy to imagine the effect of being exposed to this dramatic abdominal birth on the birth experience when two instruments are used before a final CS has to be done.

The finding that infants delivered by a sequential method after a failed VE had almost a seven-fold increased risk of subgaleal hematoma needs to be highlighted. This extracranial bleeding with a diffuse swelling can be difficult to diagnose initially, and some of these infants will be cared for in the normal postpartum unit. It is therefore of utmost importance that all midwives know that a failed VE increases the risk of subgaleal hematoma because they are the primary caregivers during this period of a newborn's life.

In this study, we cannot tell *why* infants delivered by sequential methods have increased risks of morbidity, but it might be related to how the first VE attempt was performed. Whether inappropriate use (i.e., excessive number of pulls, long extraction, pulls without progress, etc.) is more common in failed VEs needs to be investigated in future studies.

In Study II, we wanted to study if the "average" VE without clinically apparent acute neonatal complications had an effect on the child's cognitive development. To study the effect of an exposure on an outcome that occurs several years later, in our case 16 years later, is of course vitiated by several problems. To address these problems, we used a large sample size to be able to detect small differences and had access to good quality data on both the exposure and outcome, with few missing cases and with the possibility to collect information on several important confounders from different registers.

The results showed that children delivered by VE had statistically significantly *slightly* lower mean mathematic grades and mean merit grades compared with children born by spontaneous vaginal delivery. These results are in contrast with previous research on the long-term effects in children delivered by VE, which all show reassuring results with no differences in intelligence tests, vision tests, child development tests, etc. (94-97). Even though we found significant differences, we think that our results should be interpreted in a similar way, that delivery by VE seems safe for the infant in the long-term. This conclusion is reached for two reasons. First, the differences found in school grades were small, so small that it is not likely that they will affect the child's future education. Second, we could show that children delivered by an emergency CS had similar results as children delivered by VE, indicating that it is not the mode of delivery that affects the results but rather difficult labor occurring prior to the birth of the infant.

One concern about our results is that children delivered by a failed VE had the lowest mean mathematics and mean merit grades of all children in the studied cohort. These results were not statistically significant, probably due to power problems because there were only 361 children delivered by sequential methods. As the use of sequential methods was related to convulsions and low Apgar scores in Study III, these results raise concerns, and larger studies on the long-term effects on these children might be important. Low Apgar scores have been shown to have a negative impact on school grades at 16 years of age (130).

7 CONCLUSIONS AND CLINICAL IMPLICATIONS

- ✓ Most of the VEs perfomed were done according to safe practice; however, a few potentially harmful extractions were performed. Practice guidelines on VE were incomplete and not evidence-based.To improve patient safety in VEs, clinicians need to be well aware of contraindications and safety measures for VE. Further, practice guidelines need to be complete and evidence-based to support clinicans in performing safe extractions.

- ✓ Every third woman was delivered by VE without potent pain relif. To ensure good care during VEs, improvments in pain relief are necessary.

- ✓ Failed VE is a risk factor for adverse neonatal outcomes, such as convulsions, depressed Apgar scores, and subgaleal hematomas. Prior to an extraction, a detailed risk assessment should be made to identify patients with a high risk of failure in order to choose the most appropriate technique during VE and the most appropriate mode of delivery. A subsequent use of forceps should not be employed to deliver the infant; instead, a CS should be performed. If the infant is not transferred to the neonatal intensive care unit because of complications, midwives caring for the infant on the postpartum ward need to be informed of mode of delivery and the subsequent risks. Close evaluation of the infant after a failed VE is of utmost importance because the risk of subgaleal hematoma is increased.

- ✓ Birth by successful vaginal VE had marginal negative effects on the childs cognitive development in terms of school performance at 16 years of age. These marginal effects are probaly due to difficult labor occuring prior the birth of the infant and not to the instrument. However, this assumption can only be made under the circumstance that the extractions are performed according to safe practice. This knowledge can be used by midwives and obstetricians during postpartum care when counseling parents after the delivery if they are worried about the child’s future health.

8 FUTURE RESEARCH

- ✓ The effect of pain relief in VE deliveries should be evaluated in future studies.

- ✓ We found that most, but not all VEs were perfomed according to safe practice. Whether or not adverse maternal and neonatal outcomes are related to the performance of VEs (i.e., number of pulls, duration of the extraction, dislocation of the cup) is not known and needs to be investigated in future research.

- ✓ Failed VE is an unwanted situation with inherent risk for infants and mothers. Future research on preventive actions, such as ultrasound assessment of fetal lie prior the extraction, the effect of oxytocin, and operator experience, needs further inverstigation. In addition, long-term outcomes in infants exposed to failed VEs need to be investigated.

- ✓ Last, VE might be a lifesaving intervention and definitely has a place in obstetrics. However, reducing the need for VE and increasing the number of spontaneus vaginal deliveries is beneficial for both mothers and infants. Therefore, it is important to investigate if improvements in obstetric care can prevent unnessesary and potentially dangerous VEs.

9 POPULÄRVETENSKAPLIG SAMMANFATTNING

Bakgrund:

Varje år föds 100 000 - 110 000 barn i Sverige. Utav dessa barn så föds ca 8 % (7000 barn/år) med hjälp utav en så kallad vakumextraktion, i dagligt tal även kallad för sugklocka. Förstföderskor föder oftare med hjälp utav en sugklocka (14 %) jämfört med omföderskor (3 %). Sugklockan är ett instrument som används i slutet av förlossningen för att snabba på förlossningen antingen på grund av att barnet visar tecken på syrebrist eller att kvinnan medicinska skäl inte bör krysta ut barnet på egen hand eller om förlossningsvärkarna är för svaga och förlossningen går för långsamt(värksvaghet). Alternativ till att använda en sugklocka är antingen att förlösa med en tång eller att utföra ett akut kejsarsnitt. De två absolut vanligaste orsakerna till förlossning med sugklocka är hotande eller misstänkt syrebrist hos barnet eller värksvaghet.

Den moderna sugklockan som används idag uppfanns på femtiotalet av den svenska obstetrikern Tage Malmström som ett alternativ till förlossningstången, eftersom tångförlossning var förenat med stora vaginal bristningar. Sugklockan blev snabbt populär i Sverige och används idag över stora delar av världen. Sugklockan består av en rund kopp av metall, hård plast eller silikon och på denna kopp finns det en kedja med handtag samt en slang (v.g. se bild på sidan 8) som är kopplad till en elektrisk maskin eller till en hand driven pump. Tekniken innebär att operatören lägger på klockan på barnets huvud på en speciell punkt som heter flexion point (v.g. se bild på sid 11) och skapar sedan ett undertryck (vakuum) i klockan med hjälp utav pumpen. I och med detta undertryck så kommer barnets hud och skalp att sugas fast i klockan. När klockan sitter fast så kan obstetrikern eller barnmorskan dra i handtaget samtidigt som kvinnan får en värk och krystar. På så sätt kommer barnet att födas fortare än om kvinnan krystar själv.

Att föda eller födas med hjälp utav en sugklocka är inte riskfritt för kvinnan eller barnet. Komplikationer hos kvinnan är främst bristningar i vulva och vagina. 14 % av alla kvinnor som föder med hjälp av en sugklocka i Sverige får en så kallad sfinkter skada vilket kan jämföras med ca 5-6 % bland kvinnor som föder spontant vaginalt. Även stora blödningar och en negativ förlossningsupplevelse är vanligare hos kvinnor förlösta med sugklocka jämfört med de kvinnor som föder spontant vaginalt. För barnet finns en ökad risk för blåmärken och svullnad på skalpen, blödningar under skalpen så kallade kefal hematom och subgalealhematom, intrakraniella blödningar, plexus skador, retinala blödningar och låg Apgar. Om förlossning med sugklocka är farligt för barnet på längre sikt är ännu inte klarlagt.

Orsaker till komplikationer i samband med sugklocka är relaterat till kvinnans, förlossningens och barnets status före extraktionen men även till hur klockan används. Kända riskfaktorer för negativt utfall hos både mor och barn är t.ex. förstföderska, förlossningsinduktion, stora barn, långsam förlossningsprogress, om barnet bjuder sig onormalt i bäckenet, om barnets huvud inte har trängt ner tillräckligt långt i bäckenet. Utförandet under själva extraktionen som påverkar utfallet är t.ex. operatörens erfarenhet, antal drag, antal minuter som används

för att dra ut barnet, vilken typ av klocka som används, hur många gånger klockan släpper från barnets huvud osv. Eftersom en förlossning med sugklocka innebär en risk för stora bristningar och även en negativ förlossningsupplevelse så rekommenderas ofta att kvinnan ska få adekvat smärtlindring inför förlossningen. Adekvat smärtlindring anses vara epidural eller spinal bedövning, pudendusblockad eller om en utgångsklocka anläggs infiltration av perineum.

Innan en sugklocka används så måste ett flertal bedömningar göras för att avgöra om sugklocka är den mest lämpliga metoden att förlösa kvinnan och barnet. Krav som ska uppfyllas enligt riktlinjen från Svensk Förening för Obstetrik och Gynekologi är:

- ✓ Indikation: hotande foster asfyxi, värksvaghet, kontraindikation för krystning, uttröttad moder.
- ✓ Förutsättning: cervix fullvidgad, brustna hinnor, inga yttre palpabla segment, vid fosterhuvud vid eller nedom spinae (ej mot bäckenbotten) krävs erfaren operatör, speciellt hos förstföderskor med värksvaghet, känd position.
- ✓ Kontraindikation: säte, ansiktsbjudning, fosterhuvud ovan spinae, misstänkt koagulopati, misstänkt disproportion.

Ibland så misslyckas sugklockan och barnet måste förlösas med hjälp av en annan metod, antigen ett akut kejsarsnitt eller med hjälp utav en tång. Två stora studier från USA har visat att en misslyckad sugklocka är en risk för allvarliga skador hos barnet som t.ex. intrakraniella blödningar, kramper, subgaleala hematom och låg apgar. Hur vanligt det är med misslyckad sugklocka i Sverige och om en misslyckad sugklocka innebär en ökad risk för barnet är inte känt.

Syfte:

Trots att förlossning med sugklocka är en vanlig metod i Sverige så finns det relativt sett lite forskning gjord inom detta område. Denna avhandling är en del utav ett större forskningsprojekt som syftar till att kartlägga denna förlossning med sugklocka ur ett flertal aspekter. De specifika syftena med denna avhandling var att kartlägga;

- Att kartlägga hur sugklockan används i Sverige med fokus på teknik samt att jämföra handläggandet med rekommendationer i lokala riktlinjer på förlossning med sugklocka (Studie I).
- Hur kvinnor är smärtlindrade inför en förlossning med sugklocka och riskfaktorer för att förlösas utan smärtlindring (Studie II)
- Att karlägga incidensen av misslyckade sugklockor, orsaker till misslyckad sugklocka och barnutfall efter en misslyckad sugklocka (Studie III)
- Om förlossning med sugklocka påverkar barnets kognitiva utveckling i ett längre perspektiv (Studie IV)

Metod och resultat:

För att kunna besvara dessa fyra frågor så använde vi oss utav registerdata från ett flertal olika register. Främst hämtades information från Svenska Medicinska Födelseregistret (Studie II-IV) men även data från ett flertal andra svenska register användes (Studie I och IV). För en närmare beskrivning av alla register v.g. se sid 18.

I den första delstudien granskades 596 journaler på kvinnor som hade fött med hjälp utav en sugklocka under 2013. Vi samlade in data från 6 olika sjukhus och varje sjukhus bidrog med data på 100 förlossningar. Vi samlade in data från den dokumentationsmall som används i Obstetrix för att dokumentera förlossning med sugklocka. Vi samlade in data på: indikation, gestationsålder, antal dragningar, val av klocka, extraktionstid, antal klocksläpp, episiotomi, station i bäckenet, bjudning och yttre press. Vi samlade även in aktuella riktlinjer på förlossning med sugklocka från varje deltagande klinik.

All förlossningar förutom en hade en accepterad indikation dokumenterad. Indikation värksvaghet var den vanligaste bland förstföderskor och hotande fosterasfyxi bland omföderskor. De flesta av förlossningarna med sugklocka lyckades (93 %). De flesta barn förlöstes med mindre än 4 dragningar (60 %), utan något klocksläpp (84 %) och inom 15 minuter (91 %). I de allra flesta fall valdes en metallklocka. Majoriteten av alla klockor anlades från en medelhög station (75 %) och 14 stycken anlades från en hög station (2,3 %). Ca 10 % av alla barn låg i en avvikande bjudning när klockan anlades. Operatören gjorde en episiotomi på 16 % av alla kvinnor och yttre press användes i 11 %. Nästa alla klockor utfördes av en läkare och endast 2,7 % utfördes av en barnmorska. I ett fåtal fall fann vi att utförandet avvek från gängse rekommendationer. I 6 % (36 st.) av alla förlossningar med sugklocka användes fler än 6 dragningar och i 2,3 % (14 st.) varade extraktioner mer än 20 min. I 2.3 % (14 st.) bedömdes fosterhuvudet står ovan spinae när klockan anlades.

Innehållet i de sex riktlinjerna som granskades var delvis bristfälligt och varierade gällande innehåll, definitioner och omfattning. T.ex. så varierade accepterade antal klocksläpp från 1-3, max extraktionstid varierade mellan 15-20 minuter och alla utom en riktlinje saknade information om vilken kompetens hos obstetrikern som är viktigt när en sugklocka ska anläggas. Det var bara en riktlinje som definierade max antal dragningar (6-8 dragningar). Station i bäckenet beskrevs i tre utav sex riktlinjer och i dessa tre så definierades en hög klocka olika. I två riktlinjer ansågs en hög klocka föreligga när barnets huvud stod vid spinae och i en när barnets huvud stod ovan spinae.

I studie II användes Medicinska Födelseregistret för att inhämta data om hur kvinnor smärtlindras inför en förlossning med sugklocka. Totalt inkluderades 62 568 kvinnor förlösta med sugklocka i fullgången tid mellan åren 1998-2008. Vi samlade in data på olika metoder att smärtlindra under en förlossning med sugklocka (epidural blockad, spinal blockad, pudendusblockad och infiltration av perineum) samt andra variabler som kunde utgöra en riskfaktor för att få eller inte få smärtlindring t.ex., paritet, indikation för sugklocka, typ av sugklocka osv. Våra resultat i studie I visade att var tredje kvinna blir förlöst med en

sugklocka utan adekvat smärtlindring. Utan adekvat smärtlindring menas i detta fall att kvinnan förlöstes med sugklocka utan en epidural, spinal eller pudendusblockad. Det var vanligare att omföderskor inte fick bedövning (ca 50 %) än förstföderskor (ca 30 %). När enbart utgångsklockor granskades och infiltration av perineum inkluderades som adekvat smärtlindring var det fortfarande var tredje omföderska som förlöstes utan smärtlindring och 15 % av alla förstföderskor. Riskfaktorer för att förlösas utan smärtlindring var framförallt om kvinnan var omföderska, om det var en utgångsklocka eller om indikationen var hotande fosterasfyxi.

I studie III användes Medicinska födelseregistret för att samla in data på alla kvinnor och deras barn som förlöstes med sugklocka (lyckad och misslyckad) i fullgången tid mellan 1990-2010. Vi samlade in data på olika graviditetsvariabler och förlossningsvariabler samt fyra olika neonatala diagnoser; låg Apgar < 7 vid fem minuters ålder, kramper, subgaleala hematom och intrakraniell blödning. Totalt var det 88 418 förlossningar med sugklocka som identifierades och utav dessa misslyckades 4747 st. (5.4%) och 83 671 st. (94,6 %) lyckades. Från 1990 till 2010 ökade andelen misslyckade sugklockor med 0,5 % från 4,9 % till 5,4 %. De flesta, 74 %, utav dessa misslyckade sugklockor avslutades med ett akut kejsarsnitt. Av alla misslyckade klockor (4747) så användes en efterföljande tång i 26 %. Utav dessa 26 % misslyckades tången i 16 % (198 st) och ett slutgiltigt kejsarsnitt fick användas. Riskfaktorer för att misslyckas med sugklockan var främst om barnets huvud låg i vidöppen bjudning eller någon annan avvikande bjudning. Om barnets huvud stod ovan bäckenbotten så utgjorde det en risk för misslyckad klocka jämfört med om huvudet hade trängt ner mot bäckenbotten. Förstföderskor hade högre risk för misslyckad klocka jämfört med omföderskor och korta kvinnor hade högre risk än långa kvinnor. Om kvinnan hade en EDA ökade risken med 40 % jämfört med om hon inte hade EDA.

Barn som förlöstes med antingen en tång eller ett kejsarsnitt efter en misslyckad sugklocka hade en sjufaldigt ökad risk för att drabbas av ett subgalealt hematom, nästan dubbelt ökad risk för kramper och mer än dubbelt så hög risk för låg Apgar vid fem minuters ålder. Det fanns ingen ökad risk för intrakraniella blödningar bland barn där sugklockan misslyckade jämfört med barn som förlöstes med en lyckad sugklocka.

I studie IV ville vi studera om förlossning med sugklocka påverkar barnets kognitiva utveckling på längre sikt. Kognition mättes i termer av resultatet på det nationella provet i matematik och det sammanvägda slutbetyget i nionde klass. Alla barn som föddes mellan 1990-1993 i huvudbjudning av en svenskfödd mor utan någon allvarlig missbildning och som föddes i graviditetsvecka > 33 identifierades i Medicinska födelseregistret. Vi exkluderade alla barn som förlöstes med hjälp utav en tång. Den slutgiltiga studiepopulationen bestod av 126,032 barn som grupperades utifrån förlossningsätt; spontan vaginal(referens), sugklocka, akut kejsarsnitt, planerat kejsarsnitt och dubbla förlossningsätt (sugklocka + kejsarsnitt). Alla dessa barn följdes sedan upp i ett register som har information om grundskolebetyg. Information om barnets slutbetyg i matematik baserat på nationella prov samt slutgiltigt meritvärde samlades in. Barn som förlöstes med sugklocka hade statistiskt

signifikant lägre medel betyg i matematik och meritvärde i nionde klass jämfört med barn som föddes helt normalt. Skillnaderna var små: 0.51 poäng mindre i matematikbetyg (medel 40,2) och 1.05 poäng mindre i meritvärde (medel 223,8). Barn förlösta med ett akut kejsarsnitt hade också något lägre betyg jämfört med barn som föddes spontant vaginalt (matematik - 0,51 och meritvärde - 1,20).

Sammanfattning:

De allra flesta förlossningar med sugklockor utförs i enlighet med säkert handläggande. I ett fåtal fall användes dock ett potentiellt riskfyllt handläggande såsom, många dragningar och lång extraktionstid samt att sugklockan anlades när fostrets huvud stod ovan spinae (hög station). Att anlägga en klocka på en hög station anses vara en kontraindikation för sugklocka. Våra resultat pekar åt att det finns förbättringar som kan göras i klinik för att öka patientsäkerheten i samband med förlossning med sugklocka. Lokala skriftliga riktlinjer på förlossning med sugklocka bör också revideras och uppdateras i samband med detta förbättringsarbete. Förutom uppdaterade riktlinjer bör förlossningskliniker granska hur förlossningar med sugklocka genomförs på lokal nivå och återkoppa detta till berörd personal för att undvika potentiellt farliga extraktioner.

Kvinnor får i hög utsträckning inte den smärtlindringen som rekommenderas inför en förlossning med sugklocka och förbättringar kan göras. Användning av pudendusblockad och infiltration av perineum bör förbättras och även utvärderas i framtida studier.

Misslyckad sugklocka innebär en ökad risk för kramper subgaleala hematom och låg Apgar hos barnet,. Riskfaktorer för en misslyckad sugklocka som tex avvikande bjudning, fosterhuvud ovan bäckenbotten och kvinnans längd går att bedöma innan klockan anläggs. Denna riskbedömning bör vägleda vem som är bäst lämpad att genomföra sugklockan eller om ett annat förlossningssätt ska användas. Det verkar som om ett akut kejsarsnitt är den säkraste metoden för barnet efter en misslyckad sugklocka. Det är viktigt att barnmorskor och undersköterskor som vårdar barnet på BB för tydlig information om att sugklockan misslyckades, så att noggrann övervakning av barnet på BB sker på grund av den ökande risken för subgaleala blödningar. Vad det är som utgör den ökade risken för barnet i samband med en misslyckad sugklocka (t.ex. antal dragningar och tid) bör granskas i framtida forskning.

Förlossning med sugklocka påverkar barnets kognitiva utveckling mätt i termer av skolbetyg marginellt. Eftersom både barn förlösta med sugklocka och ett akut kejsarsnitt hade lägre betyg än barn födda med en spontan vaginal födsel så talar detta för att det snarare är orsaken till val av förlossningsmetod som orsakar denna sänkning i betyg än själva metoden i sig. Dessutom kan denna marginella sänkning av betyg anses vara så liten att det inte är troligt att det kommer att påverka barnets framtida kognitiva förmågor.

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