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COMPLICATED VACUUM EXTRACTION DELIVERY: FOCUS ON TRACTION FORCE

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Complicated vacuum extraction delivery: focus on traction force

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ABSTRACT

Introduction

Vacuum extraction is a common operative vaginal delivery in the final stage of labor, and generally considered a safe alternative to emergency cesarean section. However, there is insufficient evidence regarding the causes of the rare but severe perinatal complications that may occur, such as intracranial or subgaleal hemorrhage, and possibly also asphyxia related encephalopathy. High levels of traction force and failed extraction are two suggested risk factors for adverse neonatal outcome. Therefore, the aims of this thesis were to investigate employed traction force, explore its capacity to predict a difficult extraction, and to evaluate its association to neonatal outcome. Another aim was to describe the rate of failed extraction and its associated risk factors, and to evaluate clinical team training as a tool to decrease failed extraction.

Methods and materials

The studies were mainly observational: descriptive or analytical. Although retrospective by design, the exposure data was registered prior to the outcome data, and the registrator of outcome data in study III and IV were blinded to the exposure. The population base consisted of women giving birth at Karolinska university hospital, Huddinge during the different study periods. General inclusion criteria for the majority of the studies were term, singleton pregnancy delivered by low and mid vacuum extraction. The descriptive traction force study (study II) included outlet extractions as well. For the traction force measurements in, an intelligent handle attached to a regular metal cup was used, while clinical data were acquired from electronic patient charts.

Results

In study I, we found a decreased incidence of failed extractions after implementation of a clinical team training program, RR 0,3-0,62, but no favorable effect on neonatal outcome. Study II showed higher maximum peak (momentary) force than previously reported, 452 Newton. The maximum total traction force (time force product), 1180 Newtonminutes, was confirmative of a previous metal cup study but exceeding plastic cup measurements. In study III, a diagnostic test using measured traction force for early prediction of heavy category extraction displayed a high negative predictive value (NPV 0,94), and was able to detect two thirds of heavy extractions (PPV 0,65). In study IV, we found a possible association between exposure to high level traction force and admission to the neonatal intensive care unit.

Conclusion

The traction force studies have added further details regarding the level of force employed, as well as discussions regarding possible safety limits. However, methodological limitations call for cautious interpretations. The diagnostic test of study III needs external validation, and the possible association between exposure to high level traction force and admission to the NICU may be biased by residual confounding. The evaluation of team training showed measurable effects on the rate of failed extractions, but no coincident improvement of neonatal outcome. An important strength is that we have shown that the intelligent handle is safe and well tolerated among users. Possible future areas to implement its use include pedagogical situations, feedback on high level traction force to the obstetrician, and objective documentation of the procedure.

LIST OF SCIENTIFIC PAPERS

I. MID AND LOW VACUUM ASSISTED DELIVERIES AND FAILED EXTRACTION: A HOSPITAL BASED PRE-POST INTERVENTION STUDY

Kristina Pettersson, Rebecca Götze-Eriksson, Magnus Westgren, Gunilla Ajne
In manuscript

II. TRACTION FORCE DURING VACUUM EXTRACTION: A PROSPECTIVE OBSERVATIONAL STUDY

K Pettersson, J Ajne, K Yousaf, D Sturm, M Westgren, G Ajne
BJOG 2015;122:1809–1816

III. PREDICTIVE VALUE OF TRACTION FORCE MEASUREMENT IN VACUUM EXTRACTION: DEVELOPMENT OF A MULTIVARIATE PROGNOSTIC MODEL

Kristina Pettersson, Khurram Yousaf, Jonas Ranstam, Magnus Westgren, Gunilla Ajne
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eCollection 2017.

IV. TRACTION FORCE AS A RISK FACTOR FOR ADVERSE NEONATAL OUTCOME IN VACUUM EXTRACTION: A HOSPITAL BASED COHORT STUDY OF MEASURED TRACTION FORCE IN MID AND LOW EXTRACTIONS

Kristina Pettersson, Magnus Westgren, Mats Blennow, Gunilla Ajne
In manuscript

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LIST OF ABBREVIATIONS

VE	Vacuum extraction
ECS	Emergency cesarean section
CS	Cesarean section
OVD	Operative vaginal delivery
ICH	Intracranial hemorrhage
HIE	Hypoxic ischemic encephalopathy
OR	Odds ratio
CI	Confidence interval
MRI	Magnetic resonance imaging
CTG	Cardiotachogram
NICU	Neonatal intensive care unit
N	Newton
Nmin	Newtonminutes
PAR	Population attributable risk
LR	Likelihood ratio
PPV/NPV	Positive/negative predictive value
LASSO	Least absolute shrinkage and selection operators
OASIS	Obstetric anal sphincter injuries

1 INTRODUCTION

1.1 HISTORICAL CONTEXT

Vacuum extraction (VE) is second to emergency cesarean section (ECS) the most commonly employed mode of operative delivery in the final stage of labor. In the early days of operative delivery, all interventions were performed exclusively on maternal indication. During the late 19th century, cesarean section (CS) was still rarely performed on fetal indication because of the high risk of lethal maternal complications such as hemorrhage, infection or uterine rupture in future pregnancies (1). A vaginal forceps extraction with craniotomy of the fetal head or vacuum extraction on a dead fetus was more forbearing on the woman compared to an intraabdominal operation. (2) (3).

In the mid 20th century, the Swedish obstetrician Tage Malmström developed a precursor to the modern vacuum device (4) that eventually led to a broad clinical acceptance of the vacuum extraction method (5). Further technical modifications of the cup, as well as publishing of clinical guidelines ensued during the following decades (6).

Although some argue that in low resource settings, CS on fetal indication should still be avoided due to the risk of maternal complications, the world health organization recommends CS, forceps and VE to be performed on fetal or maternal indication (7); in modern obstetrics the goal of healthy infants is virtually at par with the goal of healthy mothers. During the late 20st century, VE outnumbered obstetric forceps, since the procedure is relatively easily mastered and allegedly less harmful to the woman, although the latter notion has been questioned repeatedly (8).

1.2 VACUUM EXTRACTION IN MODERN OBSTETRICS

European data from 2010 show that operative vaginal delivery (OVD) is performed in 0.5 to 16.4 percent of all deliveries, and in most of western and northern Europe, where forceps is a rarity and OVD nearly exclusively means VE, rates varied around ten percent (9). In Sweden, VE rates have decreased from around nine percent in 2010 to less than seven percent in 2016 (10).

As the predominant mode of OVD, VE plays an important role in avoiding emergency cesarean section (ECS) and its complications, and a contemporary increase in cesarean sections has intensified the debate of the role of operative vaginal delivery (11). However, rare cases of neonatal mortality (12) or severe morbidity (13-15) after vacuum extraction raise questions about how and during what circumstances extraction can *cause* perinatal trauma. Any situation where instrumental delivery intervention is called for implies a risk increase per se, and one central question in the debate is therefore whether an increased risk of adverse neonatal outcome following vacuum extraction is due mainly to bias by indication, or should be substantially attributed to some aspect of the actual vacuum extraction procedure. In a qualitative review of OVD and the pathology of its possible complications, Towner argues that although perinatal morbidity in cases of dystocia occurs as an effect of head molding due to cephalopelvic disproportion, an improper application and use of excessive traction force can increase the impact on the fetal head. (16). In the same review, the authors address the insufficient evidence of the field, and call for further population based studies to assess the relative outcome of rare events. Similarly, the American College of Obstetrics and gynecology ACOG comment on the present lack of specific knowledge regarding OVD: "Few specific aspects of (...) technique have been studied" (17).

There are certain circumstances of VE that frequently occur in discussions of how the procedure may be harmful, including prolongation of the operation, cup detachments, failure to deliver by vacuum, and excessive traction force. Although all of the topics above have been studied to various extents, the understanding of if and how they are etiologically linked to adverse perinatal outcome is insufficient. During a VE with poor progress, the obstetrician is left with naught but his or her subjective judgement, and traction force measurement may add more objectivity to the decision making. Therefore, the main aim of this thesis was to investigate employed traction force, explore its capacity to predict a difficult extraction, and to evaluate its association to neonatal outcome. The clinical dilemma that permeates these studies concerns patient safety: when does the risk of continued traction exceed that of an ECS with a descended fetal head?

2 BACKGROUND

2.1 VACUUM EXTRACTION GOOD PRACTICE

Evidence based guidelines aimed at OVD are published by several professional societies, and Swedish guidelines are mainly in accordance with international organizations (17, 18). The project Safe delivery care (19) has enunciated a program and advocated its national implementation. An item list of the Swedish guidelines' indications and cautions is presented below.

- **Indications**
- Prolonged labor, maternal fatigue
- Fetal distress
- **Contraindications**
- Incomplete dilation of the cervix
- Presenting part is above the level of the ischial spines
- Pathological lie – face, breach, brow
- Cephalopelvic disproportion
- Preterm <34v or estimated fetalweight <2kg
- Caution 34 – 36 v
- Suspected fetal coagulopathy
- **Abandon procedure and consider converting to cesarean section if:**
- Two cup detachments occur
- The fetal head does not advance during traction
- The fetal head has not reached the pelvic floor after three tractions/contractions
- More than six tractions are required
- The woman is not estimated to deliver within 15-20 minutes from cup application

An important safety task for the obstetrician is a risk assessment prior to operative vaginal delivery, and one important part is an estimation of the position and descent of the fetal head. Traditionally, a clinical evaluation based on abdominal and digital exam constitute the golden standard, but it has been suggested that ultrasonography might add objectivity and precision to the assessment: a mere clinical diagnosis of occiput posterior position, when the fetus is “looking up” towards the mothers abdominal side instead of the anatomically more adapted face down, may be incorrect in about 20 percent (20, 21). In the Swedish classification of fetal head station, only one mid high (“medelhög”) station between high and outlet is defined. Internationally, this older classification has been replaced by an additive distinction between *mid* and *low* (figure 2.1).

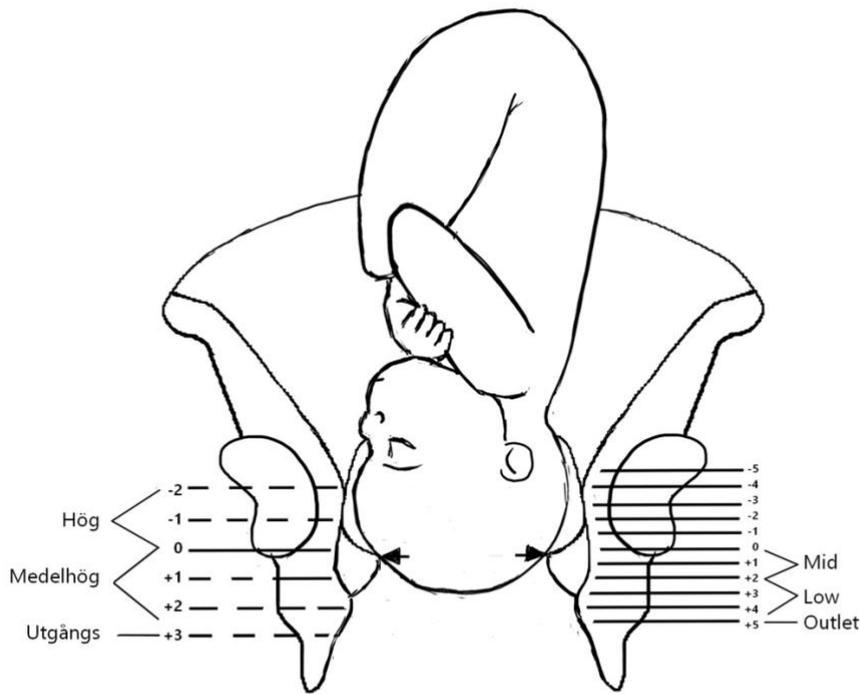


Figure 2.1
Fetal head station. Swedish (internationally obsolete) and international classification.

Another divergence is seen in the recommended maximum number of pulls before considering abandoning the procedure: most international guidelines state three pulls to reach the outlet station (pelvic floor) (17, 18), whereas the Swedish instructions include the whole extraction and recommend a maximum of six pulls to achieve delivery.

A correct placement of the vacuum cup anterior to the posterior fontanelle allows an optimal matching of the pelvic and head diameters, granted that the obstetrician directs the pull along the pelvic axis (22). If the cup is suboptimally placed, for example due to an undiagnosed occiput posterior position, or if the obstetrician fails to pull along the pelvic axis, there is reasonably an increased risk of cup detachment, and failed extraction or need of excessive traction force.

2.2 MODE OF DELIVERY AND NEONATAL OUTCOME

The absolute frequency of severe neonatal morbidity is low, but the diversity in different reports is large, partly due to variations in methodology and definitions that yield diverging results. For instance, population based studies often lack data on indication of the operation, stage of labor at ECS, and fetal head station at OVD. Furthermore, some authors analyze outcome as composite variables, whereas others meticulously define subgroups of different types of ICH. Therefore, quantitative comparison of different studies is difficult, maybe not even advisable.

In the only systematic review comparing different modes of OVD, the strongest finding regarding neonatal outcome was a *trend* towards more cephalohematoma with metal cup vacuum extraction (23). In the Practice bulletin (2015) review published by the American college of obstetrics and gynecology, the authors favor the continued use of any OVD, arguing that the differences in ICH and mortality between different modes of operative delivery are consistently small. They further claim that this conformity supports the view that poor outcome in OVD compared to spontaneous delivery is explained largely by indication bias; In this view, difficult labor rather than vacuum extraction would cause most of the adverse outcome.

2.2.1 Patophysiology of central nervous system lesions

Even before the clinical role of vacuum extraction was fully established, ideas of how traction force could affect the fetal head were presented, with emphasis on the possible tearing of the falx cerebri and rupture of sagittal sinus at forces exceeding 200 N (24) (25). Early reports on perinatal trauma following vacuum extraction include a review from 1979, describing an incidence of intracranial hemorrhage (ICH) of 3,5/1000, and 3,3/100 incidence of encephalopathy (13). In 1996 a case report issued an alert on undiscovered skull fractures (26), and in the 1980s it was established that the majority of subgaleal (subaponeurotic) hematomas occurred after OVD, a finding consistently replicated in later studies (27) with a frequency of 3-7.6/1000 after VE as compared to 0.1-0.6/1000 in spontaneous vaginal deliveries (15).

Population based studies of ICH and hypoxic ischemic encephalopathy (HIE) at term, irrespective of mode of delivery, show ICH 3.8-4.9/10.000 and HIE 2.5/1000 in Sweden, and in England ICH 1.7/10.000 and HIE 2.5-3/1000 (all gestational ages) (28, 29). These national cohorts support the notion that ICH is relatively rare at term and predominantly a complication of prematurity, whereas encephalopathy and seizures occur mainly among term infants (30).

ICH in term infants seems to be over-represented after difficult labor, possibly operative delivery, and fetal predisposition such as low platelet count (31). The lesions predominantly consist of subdural hematomas (32, 33), whereas the typical ICH of prematurity is intraventricular (34). In a retrospective case-control study (n=53) of symptomatic and radiologically confirmed intraparenchymal ICH, intratentorial hemorrhage was not only over-represented after vacuum extraction, but also showed a trend to a higher mortality rate compared to isolated supratentorial hemorrhage (35). The understanding that various types of head lesions have different risk factors or causal paths can be related to the discussion of possible force induced head injury in section 2.3 below.

Apart from ICH and subgaleal hematomas, encephalopathy and seizures constitute a group of possible traumatically induced central nervous system impact. The pathophysiology as to how these asphyxia related conditions would be caused by traumatic pressure and traction is not readily evident, and the issue of indication bias is central here: one of two major indications for instrumental delivery is fetal distress. This group of disorders poses large diagnostic difficulties regarding etiology, since encephalopathy, besides trauma can be caused by sepsis, meningitis or metabolic disorders (36). Despite their well established relation to vacuum extraction, cephalohematomas are not considered further, due to their benign and spontaneously resolving nature. The most clinically important aspect of cephalohematomas is arguably the increased risk of neonatal jaundice (37).

2.2.2 Clinical studies on mode of delivery and neonatal outcome

Studies on relative risks of adverse neonatal outcome by mode of delivery display divergent results. In two population based cohorts, the incidence of ICH was approximately increased by a factor 2-10 in OVD compared to spontaneous vaginal delivery (28, 38), and the risk of HIE twofold, while Walsh et al found a four-fold increased incidence of neonatal encephalopathy in *any* operative delivery (3.2- 4.7/1000) compared to spontaneous delivery

(39). A US population cohort found a decreased risk of neonatal seizures and assisted ventilation after VE compared to forceps delivery. A Swedish population based register study on delivery mode and newborn complications among *obese* women, concluded that morbid obesity in itself is a risk factor for neonatal morbidity, but there was no correlation to mode of delivery (40). There is a limited number of studies investigating specific characteristics of VE (such as prolonged duration, excessive number of pulls or cup detachments) and their relation to adverse perinatal outcome, and the results are discrepant (41) (42) (43).

2.2.3 Image screening for head trauma

Most studies on outcome related to the central nervous system observe only symptomatic neonates, identified by clinical signs of compromise. However, image based screening investigations have shown a large number of insults in asymptomatic infants: In a prospective study of 111 asymptomatic term neonates, MRI screening found subdural hematomas in six percent (3/49) after spontaneous vaginal delivery, eight percent (1/13) after vacuum extraction, and 28 percent (5/18) after failed vacuum. Only the latter represented a significant difference compared to spontaneous delivery (32). The authors argue that the quick resolution of the findings (4 weeks) and normal neurological status suggest little clinical significance of these silent insults. Similarly, another prospective imaging screening study of 913 infants undergoing vacuum extraction and screening with transfontanelar ultrasound found ICH and skull fractures in asymptomatic infants with benign prognosis. The incidence was lower compared to the MRI study: 0.77 percent (7/913) ICH (exclusively intraventricular hemorrhage) (42), perhaps reflecting the inferior accuracy of ultrasound in detecting extra-axial hemorrhage such as subdural hematomas (44). The authors of these two screening studies agree that routinely investigating clinically healthy newborns should be avoided.

2.2.4 Vacuum extraction vs emergency cesarean section

A large population-based Swedish cohort study comparing ECS (n=75,216) and vacuum extraction (n= 87,150) observed an increased risk of ICH after vacuum delivery (19/10 000) vs ECS (7/10 000) but no significant difference regarding convulsions or encephalopathy (28). A likewise large New York city register study (n = 122,507)

compared incidence of severe central nervous system-related outcome (ICH and convulsions) by operative mode of delivery, and found no significant difference regarding seizures in ECS vs VE. However, a decreased risk of seizures in forceps deliveries was identified, while subdural hematomas were more frequent in all OVD compared to ECS. The authors argue that the risk of seizures may be more clinically relevant because of their long term prognostic value (45).

Generally, the epidemiological studies described above do not include the scope of investigating what particular details of the extraction procedure may be harmful. More often than not, all operations are included and analyzed collectively, independent of cervical dilatation at ECS and fetal head station at VE. A US multicenter cohort (n=2531) attempted to minimize bias by indication by adding such details: they compared VE or ECS delivery at low (+2) fetal head station or below (that is, cases where VE might have been a plausible alternative), and found no difference in composite neonatal outcome (46). Because of the favorable maternal outcome, the authors concluded that attempted VE at low cavity fetal head station can be recommended as the first line option.

Another cohort of fully dilated low deliveries (n=2518) found no difference in composite neonatal outcome following attempted VE vs ECS. However, there was a significant decrease in composite adverse neonatal outcome after attempted forceps delivery (OR 0.44, 95% CI 0.27-0.72) (47). The authors of these studies made explicit claims to avoid confounding by indication by their choice of comparison groups, but there is an unfortunate limitation to low fetal head station; one could argue that a higher degree of cephalic disproportion is present at labor arrest at a higher station, and thus more likely a need for excessive traction force.

A recent Canadian population based study compared maternal and perinatal morbidity after *mid* cavity OVD or ECS, stratified by indication, and found an increased risk of perinatal morbidity following VE that was even more pronounced when the indication was dystocia (48). The authors argue that this reflects the lower baseline morbidity among dystocia cases, but an alternative interpretation is that the excess morbidity may be due to the high traction force required in dystocia cases. Another large cohort study observed no significant difference in mortality or encephalopathy between VE and CS, including a sub-analysis of ECS at fully dilated cervix (39).

2.2.5 Long term cognitive impairment

Hypoxic ischemic encephalopathy (HIE) is graded as mild, moderate or severe according to the Sarnat score. Moderate and severe HIE have a substantial risk of short and long term developmental impairment or neonatal death (49). Mild HIE is traditionally considered associated with normal development, and therefore not warranting hypothermia treatment in the newborn (36). However, Odd et al observed impaired functioning at eight years of age in children who experienced perinatal asphyxia without moderate or severe HIE (50). In accordance with these findings, Dupont et al suggest that there may be significant misclassification of academic infants, leading to an undertreatment. (51). In a review of predictors and long term outcome in asphyctic children, Ahearne et al conclude that the functional impairment of HIE survivors becomes more apparent with increasing age. These studies and their line of reasoning taken together might be interpreted as an underestimation of the range of HIE cases that would benefit from hypothermia treatment, and possibly also of the long term developmental impairment due to birth asphyxia.

A number of large Swedish retrospective sibling controlled cohort studies have searched for correlations of mode of delivery and long term morbidity; No association was found between OVD and asthma or allergy (52), attention deficit disorder or autism spectrum disorder (53, 54) or diabetes (55). One large Swedish register-based study showed a statistically significant decrease in school performance in adolescents born by VE or ECS compared to spontaneous vaginal delivery. The difference was very small in absolute numbers (grade point average approximately 222 compared to 223) and similar in both operative modes of delivery, suggesting a minimal clinical significance, and no specific effect of vacuum extraction (56). However, a recent unpublished study of cognitive function in seven-to-ten-year olds delivered by mid or low vacuum extraction showed a significantly larger proportion of abnormal function compared to expected outcome in a normal population (*Romero S et al. Behaviour and development screening in children at 7 to 10 years of age born after low or mid pelvic vacuum-assisted delivery. 2018. Poster nr 15, Nordic federation of obstetrics and gynecology*).

2.2.6 Failed vacuum extraction

Failed VE refers to an attempted vacuum delivery where one or more (forceps and/or ECS) additional operational procedures are needed to achieve delivery. The frequency of failure

ranges from 4.5 – 10 percent. A higher frequency of cup detachment (57) and failure is commonly reported with plastic cup extractions compared to metal (58, 59). The employment of sequential methods seems to entail an increased risk for adverse perinatal outcome.

Several studies have set out to identify which clinical characteristics precede failed extraction, and the common factors include fetal weight, short maternal stature or high maternal weight, no prior vaginal delivery, mid cavity fetal head station or occiput posterior position (60-63). Results from a large case-cohort study of increased risk with maternal age and BMI have not been replicated (64), and the predictive capacity of induction or augmentation of labor and epidural analgesia is inconsistent between studies. In a Cochrane review comparing different instruments in OVD, VE was more likely to fail compared to forceps: RR 0.65 (CI 0.45-0.94) (23).

Most studies are too small to report on severe complications like ICH, and although some have shown an increased risk of asphyxia (a more common outcome), results are inconsistent between studies (38, 58, 60, 65, 66). Subgaleal hematoma has been reported as over-represented in failed attempts at vacuum extraction (27). In a 2005 British National review of neonatal deaths with confirmed central nervous system injury, 24 out of 37 had undergone failed attempts at OVD (12). One large register based cohort (60) found an increased rate of neonatal convulsions, but not ICH, while Towner et al (38) found ICH as well as convulsions to be increased. In absolute numbers, Towner observed 1/265 (35.7/10 000) ICH in failed vacuum extractions, compared to 11.7/10 000 in successful vacuum (RR 3.2 (CI 1.4-7.5)), and convulsions displayed an even higher relative risk: RR 5.9 (CI 3.4-10.1). In a screening study of asymptomatic infants, MRI detected signs of ICH in 28 percent of infants after failed attempts at vacuum extraction. (32). In a Malaysian study reporting an unusually high incidence of subgaleal hematomas, failed extraction was a risk factor (67).

2.3 TRACTION FORCE AND FORCES ACTING ON THE FETAL HEAD DURING VACUUM EXTRACTION

The forces acting on the fetal head during vacuum extraction can be sorted into three categories: the negative pressure induced when applying the cup to the scalp, the friction and compression caused by pressure from the restricted birth canal including forces from active bearing down efforts, and the additional force exerted by pulling on the traction handle. A schematic illustration of these forces is shown in figure 2.3. The possible extra- and intracranial effects of these forces are discussed in the following sections.

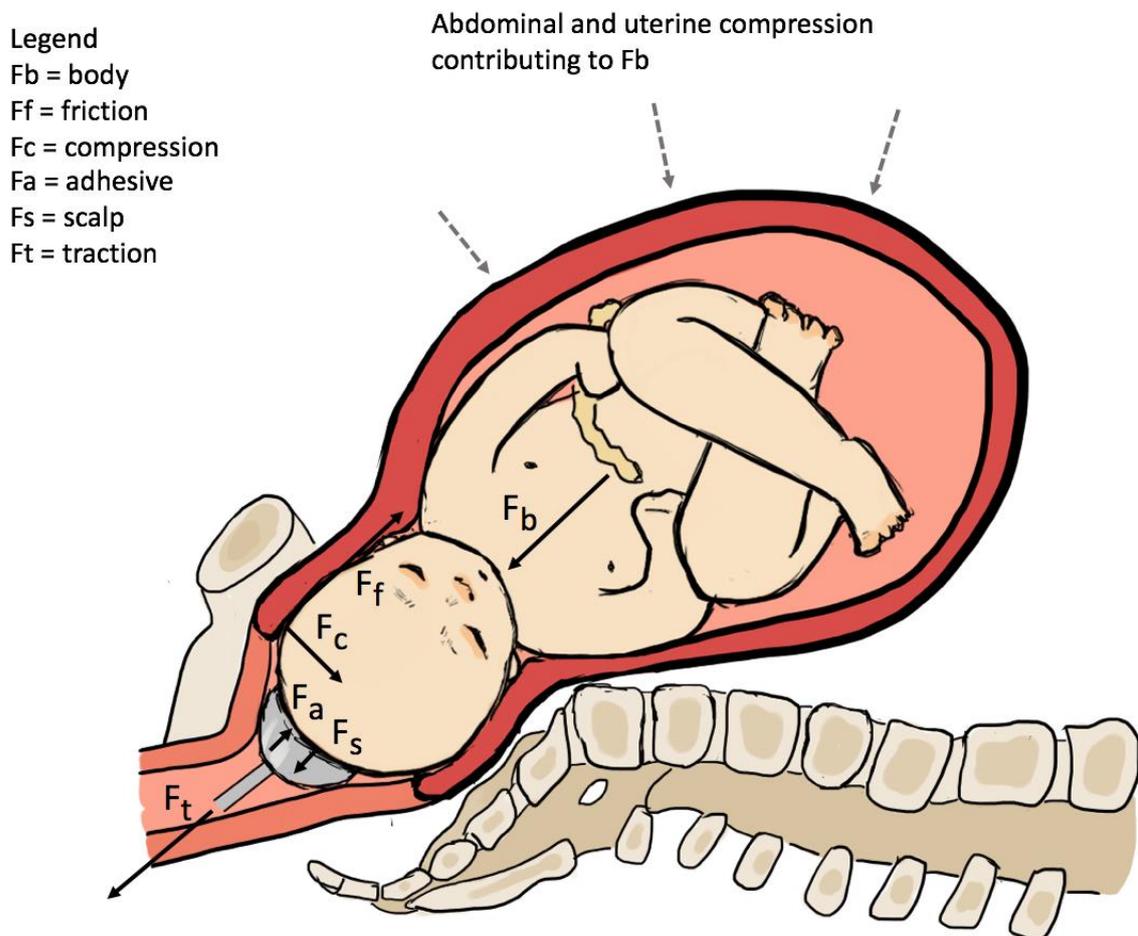


Figure 2.3 An illustration of possible forces acting on the fetal head during contractions and extraction. To achieve delivery, F_t must exceed F_f minus F_b ($F_b + F_t = F_f$ at standstill).

2.3.1 Traction force and pathophysiology

Malmström demonstrated that the scalp on which the negative pressure is imposed, is separate from the cranium beneath it, preventing any influence on pressure gradients across the skull from the actual cup *application*. However, the force on the scalp can cause a separation of the epicranial aponeurosis and the periosteum, resulting in bleeding into a space unlimited by firm structures. This is known as subgaleal hemorrhage. It has also been described how tearing at the scalp may cause a rupture in the emissary veins connecting extracranial space to intracranial tissue (4, 13, 68-70), and the idea that primary epicranial trauma can have intracranial effects is supported by the finding that infants with subgaleal hematomas often have concurrent subdural hematomas and other ICH (71). Subgaleal hematoma and different types of ICH that might result from trauma (subdural, epidural and subarachnoidal) (72) are therefore plausible injuries after vacuum extraction.

Nearly a century ago, Holland (69) investigated 168 intrapartal mortality cases, and found possibly strain-related dural lesions (falx cerebri and/or tentorium cerebelli) in nearly half of the instances. He proposed that the strain force was the most important stress factor during forceps delivery, and although vacuum was not yet in clinical use at the time, it is not unreasonable to assume that the moulding and strain may be similar. Indeed, the tentorial tears were confirmed in VE cases in a later post mortem review as well (12), although this type of lesion is not exclusive to operative vaginal delivery.

A pre-requisite to the moulding of the skull is the flexible skull structure of the fetus. The non-fixed sutures between the parietal bones enable moulding of the fetal head, typically from a round to a more oblong shape. This has long been recognized as a positive physiological character facilitating the fetal head passage through the birth canal, with possible negative side effects of excessive moulding (73).

It seems less likely that intraventricular hemorrhage should occur as a direct effect of excessive forces by traction, although coagulopathy and immature vessels in preterm infants may lower the threshold for any type of hemorrhage (74). It may be argued that the vessels of the premature brain may be sensitive to vacuum or traction induced changes in intracranial pressure as discussed in the section below, perhaps through ensuing changes in blood pressure. As presented in section 2.1, guidelines for operative vaginal delivery usually contain cautionary advice regarding prematurity, and perhaps preterm infants would display a different ICH panorama if obstetricians were less adherent to this

recommendation. Figure 2.3.1 illustrates central structures and possible lesions that may affect the fetal head during delivery.

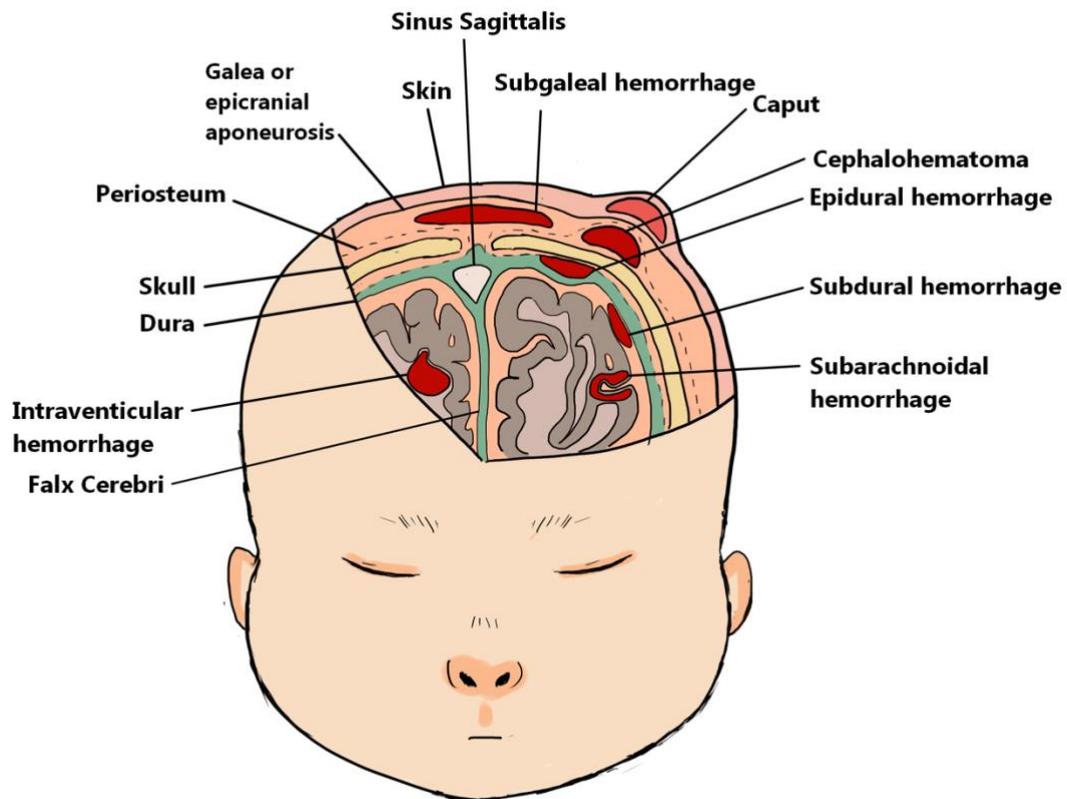


Figure 2.3.1 An illustration of the structures and possible lesion that may affect the fetal head during delivery.

2.3.2 Theoretical and experimental notions on the pressure on the fetal head

Attempts at theoretically modelling the intracranial pressure effect of traction force arrive at different results depending on a variety of assumptions reviewed by Kuit (75). Returning to basic physics and the *ideal gas law*, we are reminded that pressure and volume in a confined space make a constant equation, meaning that any lowering of volume yields a corresponding pressure increase. However, the intracranial content of a live fetus does not consist exclusively of fluids, making ideal physics less applicable. An element of inertia is therefore to be expected when the intracranial content is provoked, for example by contractions. Such an inertia is illustrated in one experimental case study (n=2) of intracranial pressure during delivery, where an intracranial pressure rise following a contraction was delayed by three seconds (76).

The relation between intracranial pressure and negative effect on fetal heart rate is inconsistent between two case studies (76, 77). Intracranial pressure effects from vacuum extraction are also unclear. In a post mortem study (n=18), intracranial pressure was unaffected (placement on posterior fontanelle) or decreased (placed on anterior fontanelle) by traction on an applied cup. Increased pressure was noted at sudden cup detachment and during forceps extraction (78).

Allowing some speculation on how intracranial lesions may arise, an increased volume (followed by a lowered intracranial pressure) might cause a strain on fixed structures, such as the falx cerebri and tentorium. Conversely, a volume decrease ensued by an intracranial pressure rise, might precede asphyxia through an impaired blood flow: cerebral perfusion pressure = mean arterial pressure – intracranial pressure, $CPP=MAP-ICP$. Issel (25) claimed that traction on a vacuum extraction cup would lead to increased compression of the skull by tightening of the central suture.

Conjoining the studies and theories presented above, it seems that some degree of compression of the head occurs with vacuum extraction, but whether this leads to a decreased volume or a constant volume with a different shape remains an open question. Consequently, the intracranial pressure effects are also uncertain. Among intrapartally deceased fetuses, Holland noted frequent compression of the cranial vault with overlapping bones, but still proposed that the ensuing decrease in volume is insignificant compared to the moulding and (dural) strain described in the previous section (69).

Malmström and his predecessors made efforts to measure intrauterine forces exerted on the fetus during spontaneous and assisted vaginal delivery. He developed a method for external and internal tocometry, and described *the propulsive forces* of spontaneous and vacuum expedited delivery (4). More recent studies found average and maximum pressure on the fetal head in the birth canal to be 0.17 and 0.61 kg/cm² respectively during spontaneous bearing down efforts. During vacuum extraction, measured average and maximum pressure in the birth canal was instead 0.32 and 0.77 kg/cm² respectively (79, 80). However, the relation between extracranially exerted forces, their possible effects on intracranial pressure as well as any clinical consequences remain to be shown.

An approximate conversion table of pressure units is presented below, table 2.3.2. Pressure in the birth canal from Moolgaokers (80) experiments*.

Table 2.3.2. Conversion table comparing observed and theoretical pressure: atmosphere, intracranial and birth canal. *Moolgaoker, 1979					
Pressure units	Atmosphere	Normal intracranial pressure	Standard induced vacuum	*Average (maximum) pressure in the birth canal: VE	*Average (maximum) pressure in the birth canal: spontaneous
mmHg	760	5-15	600	235	125
kg/cm ²	1.03	0.007-0.02	0.8	0.32(0.77)	0.17(0.61)
cmH ₂ O	1034	7-20	800	320(770)	170(610)
kPa (kN/m ²)	101	0.7-2	80	31(75)	17(60)

2.3.3 Traction force in clinical vacuum extraction

From the 1960s through the 1980s, a number of clinical studies on traction force in vacuum extraction were published. With the introduction of plastic cups during the 1990s, studies using rigid or soft non-metal cups became more common. To minimize the readers' confusion, it is worth mentioning that the international standard unit of force is Newton (N), but in the literature force is sometimes stated as its weight equivalent in kg or lb. There is no consensus as to what constitutes normal or excessive traction force, but an upper limit of approximately 220 Newton has been suggested (24, 25, 80, 81), corresponding to the calculated traction force allowed before cup detachment spontaneously would occur at recommended working pressure (negative pressure 0,8 kg/cm²) and large cup size 6 cm. A principally different rationale for a safety limit has also been proposed (25), based on a threshold effect: up to approximately 200 Newton Issel claimed that there is little compression of the fetal head, but after an approximate 200 Newton threshold, this changes rapidly. These findings combined have led to the widespread notion that vacuum extraction is safe because of the inherent limitations in possible traction force.

The applicable equation for cup adherence is: negative pressure x area of cup = maximum force

Example: $0,8 \times \pi 3^2 = 222N$ (large cup); $0,8 \times \pi 2,5^2 = 154N$ (medium cup)

However, experiments have shown that higher traction forces can be reached without cup detachment, and lowering the induced negative pressure and using a larger diameter cup

will increase the traction force needed to overcome the adhesive force of the cup. In a lab setting with fresh canine skin mounted on a solid sphere, Duchon et al compared maximum traction forces (until cup detachment) in different cups and at different vacuum levels. The combination of bird metal cup 50 mm at vacuum 80 kPa detached at just below 20 kg (81). Allowing time for formation of an optimal chignon will further raise the threshold for detachment (75). One clinical study of 120 metal cup extractions found a maximum peak of 350 N and total force (force by time) of up to 1310 Newtonminutes without suspected birth related morbidity (82). An approximate conversion table (table 2.3.3) of force units and weight equivalents is presented below, with a large size cup (60 mm diameter) and standard vacuum (80 mmHg) as example, theoretical and measured maximum (83).

	Newton (N)	Kilopond (kp)	Kilogram (kg)	Pound (lb)
Ref	9.8	1	1	2.2
Theoretical maximum	222	22.6	22.6	50
Measured maximum	350*	35	35	79

Another study of measured traction forces showed mid cavity maximum force of 280 N, and despite a limited sample size, Saling suggested the possibility of traction force as a cause of neonatal morbidity, and an increased frequency of cup detachment at traction forces exceeding 200N (80, 83-85). In the 1980s, Norwegian researchers investigated the relationship of exposure to measured traction force levels (easy, moderate and heavy) with neonatal outcome (defined as retinal hemorrhage and neurobehaviour. They found no correlation in their samples of approximately 50 deliveries. Low and mid cavity station were analyzed together, and constituted 81 percent of deliveries including high cavity station. Three deliveries required heavy traction force, defined as total force (force-time product) exceeding 60 kilopondminutes, corresponding to nearly 600 Newtonminutes, while the majority required less than 29 kilopondminutes. The failure rate was 19 percent (84).

Most recent studies on traction force in vacuum extraction have employed the Kiwi omni cup™, with its in-built gauge to enable traction force measurement. Vacca (86) observed

traction forces in 119 nulliparous women delivered by Kiwi omniscup extraction. Of these, 29 percent were mid cavity, and 79 percent required less than 25 lb traction force. Sequential delivery method was needed in nine percent. Similarly, a Canadian observational study (87) of plastic cup extractions and traction force investigated traction forces in relation to parity and fetal head station. Traction force level was analyzed in a binary mode: <25 lb vs >25 lb, with 86 percent requiring less than 25 lb. This small proportion of cases requiring higher levels of traction force is likely to reflect the case selection in this study: low or outlet fetal head station was predominant, with only 6.5 percent mid station. In 13 percent, delivery was not completed with vacuum extraction. Another study compared soft vs rigid plastic cups, and found that rigid plastic allowed a maximum traction force of nearly 20 kg, while the soft cup detached at a maximum of 15 kg (88).

Simulated settings have also been used to explore traction forces. To validate the obstetrician's subjective estimation of traction force level (minimal, average or maximal), 18 physicians performed fictive extractions (plastic cup) by a detailed protocol, and measured traction force levels. Since there were significant differences between all three groups, with an increasing force (kg) from minimal (6.5 ± 0.2) to average (8.7 ± 0.2) to maximal (10.5 ± 0.2); $p < 0.001$), the authors concluded that obstetricians make valid estimates of their exerted force levels (89).

In summary, the literature provides few final answers as to how traction force may affect the fetal head. There are some suggestions regarding the safety limits of exerted force, and theoretical as well as experimental models of their intracranial effects. Still, the sketching of a pathophysiological model needs to employ some level of speculation.

2.4 OTHER TECHNIQUE RELATED CONSIDERATIONS

The importance of correct cup application and selection of prognostically favorable cases for vacuum extraction is emphasized in the British and American OVD guidelines (17, 18). An Israeli cohort of 12,063 women compared maternal and neonatal outcome as a result of fetal head position, and found an increased risk of cup detachment (but unaffected risk of failed extraction), subgaleal hematoma and an APGAR score below seven at five minutes with occiput posterior position compared to the more anatomically favorable occiput anterior position (90).

In another cohort of 478 primiparous women undergoing an attempted operative vaginal delivery, nearly one third were found to have a suboptimal instrument placement, and this suboptimal technique was correlated with an increased risk of sequential mode of delivery and composite neonatal trauma, but no difference regarding admission to the neonatal intensive care unit (NICU) (91).

A recent hospital based study on more than one cup detachment as a risk factor for neonatal adverse outcome, found an OR of 45 regarding subarachnoid hemorrhage, but other ICH or subgaleal hematoma were not affected (92). A Malaysian cohort of 338 extractions reported an unprecedented incidence (21 percent) of subgaleal hematomas, and found cup placement far anterior to the flexion point to be a strong risk factor (67).

The use of intrapartal perineal ultrasound to assess difficulty and predict outcome in prolonged second stage is another possible route to increased safety in vacuum extraction. The method has been studied for diagnosing occiput posterior position (93, 94), and to predict progression and mode of delivery in prolonged second stage (21, 61, 95, 96). For example, in one small study (n=220) ultrasonography to some extent enabled prediction of duration of the extraction (97). Whether improved diagnostics lead to actual clinical advantages is not self-evident; a recent randomized trial comparing clinical and ultrasound assessment of fetal head position was stopped early because no decrease in failed extractions or subsequent ECS could be identified (98).

2.5 MATERNAL OUTCOME IN OPERATIVE VAGINAL DELIVERY

The increased incidence of obstetric anal sphincter tears (OASIS, also known as III and IV degree perineal tears) following instrumental vaginal delivery compared to spontaneous is well documented; twelve vs four percent in the official Swedish statistics 2016 (10). A Swedish systematic review concludes strong evidence that episiotomy in vacuum extraction prevents anal sphincter injury, although this also means inflicting a second degree perineal injury. In systematic reviews comparing forceps with vacuum extraction, III and IV degree perineal tears occur more frequently with forceps (23, 99). This increased risk of significant perineal laceration in forceps delivery compared to vacuum has also been replicated more recently (46).

Most studies have failed to detect a difference in long term general pelvic floor function between vacuum and forceps or between OVD and CS. For example, a cohort of fully dilated low deliveries (n=2518) found no long term difference in composite maternal outcome following attempted vacuum extraction, forceps or CS (47). However, bulge symptoms, the pathognomonic criterion of urogenital prolapse, seem to be more common after OVD (99-102). A large meta-analysis from 2014 concluded that stress urinary leakage was increased after vaginal delivery, but no specific long term effect of OVD (103). Recognizing that pelvic floor dysfunction is multifactorial, predictive models are being developed to better individualize delivery care (104).

2.6 SUMMARY

In summary, the clinical evidence that vacuum extraction *in general* causes severe adverse perinatal outcome is inconsistent and inconclusive; If this were the case, one would expect an unequivocal over-representation of morbidity in relation to other interventions. Searching the literature, data supporting such an indication-independent increase is found to run an even race with results favoring the opposite. Some plausible pathophysiological models of the head trauma of vacuum extraction have been discussed, but the knowledge gap regarding intracranial physiological and pathological effects specific to vacuum extraction is significant. Again, the issue of bias by indication pervades the whole endeavor. Subgaleal hematomas make a special case, occurring in some study populations almost exclusively after (failed) vacuum extraction. To address remaining concerns about the morbidity and mortality that may be caused by vacuum extraction, our approach is to study more *specific characteristics of difficult extractions*: mid and low cavity fetal head station, failed extractions, and application of high levels of traction force. This aspiration to study specific details of the vacuum extraction procedure is consistent with the requests by several reviewers of the field (16, 17), and the particular endeavor to analyze traction forces is in accordance with the earlier mechanical studies of the forces working on the fetal head (24, 25, 75, 76, 78, 80, 83, 85). Furthermore, previous studies on traction force are invariably small, and to study rare outcomes larger sample sizes are required.

3 AIMS

The main aim of this thesis was to investigate employed traction force; to explore its capacity to predict a difficult extraction; to evaluate its association to neonatal outcome, and thereby to evaluate traction force measurement as a means to increased perinatal safety in vacuum assisted delivery. We also wanted to provide a survey of failed extraction rates and an analysis of how they might be influenced by clinical education and ongoing traction force measurement studies.

Pre-specified hypotheses:

1. The risk of adverse neonatal outcome is increased following extractions employing high levels of traction force
2. Heavy extractions can be predicted early on in the procedure by measuring traction force
3. The frequency of failed extractions is decreased with educational efforts aimed at improving quality of care in operative vaginal delivery, and effected by highlighting vacuum deliveries by measuring traction force

The specific aims were:

To describe the initial frequency of failed vacuum extraction in low and mid vacuum assisted deliveries, and investigate whether the proportion is decreased after implementation of clinical training aimed specifically at vacuum extraction, and affected by the introduction of research based routine measurement of traction force (Paper I).

To describe levels of traction force in different categories of vacuum extraction regarding level of difficulty (minimal, average and strong), fetal head station (outlet, low, mid) and outcome (successful, aborted) (Paper II).

To design a predictive test for subjective category strong extraction, using a range of measured traction force variables (peak and total for each individual pull, differences between individual pulls, and accumulated forces during the whole extraction) (Paper III).

To evaluate high level traction force as a risk factor of adverse neonatal outcome (admission to neonatal intensive care unit) (Paper IV).

4 STUDY POPULATION AND METHODS

4.1 STUDY POPULATION AND STUDY DESIGN

All studied samples in this thesis are derived from a study population of women giving birth at Karolinska University hospital at Huddinge. In all studies except Paper II, outlet extractions were excluded due to the uncomplicated course of these extractions regarding failure, traction force level, and neonatal outcome. Universal inclusion criteria included term, singleton pregnancy. We defined term in accordance with the Royal College guidelines, suggesting insufficient evidence of the safety of VE up to 36+0 weeks of gestation (18), except for period 0 of study I, where term was defined as 37+0 completed weeks. Patient information was posted in the delivery ward, and informed consent was assumed in absence of active denial as approved by the ethical vetting board. None of the samples were randomly derived, but rather based on consecutive inclusion, either during pre-specified time periods (study I), or an arbitrary pre-specified sample size (Paper II-III) or a power calculated sample size (Paper IV). Since some of the study periods overlap, there are individuals who are included in more than one of the studies. Study II-IV were observational, and study III-IV included analytical aims, and in although these studies may be described as retrospective, the exposure data was registered prior to the outcome data, and the registrators of outcome data were blinded to the exposure. Study II had a descriptive main purpose. Study I was interventional, but performed retrospectively and analysed as a cross-sectional study comparing three prevalence periods.

Ethical approvals were obtained from the regional vetting board at Stockholm:
2014/1860-31; 2017/1411-32; 2012/1553-31/1; 2016/211-32.

Table 4.1 summarizes PICO (Population, Intervention, Comparison, Outcome) of all four studies.

Table 4.1 PICO (Population, Intervention, Comparison, Outcome) of studies I-IV				
	Study I	Study II	Study III	Study IV
Research question	Do educational efforts and increased monitoring change how we conduct the vacuum extraction procedure?	What is the distribution of measured traction force among different categories of vacuum extraction?	Can the risk of subjective category strong vacuum extraction be predicted early by measured traction force?	Is high level traction force associated with an increased risk of adverse neonatal outcome (admission to NICU)?
Hypothesis	Clinical training and increased monitoring effect the failed extraction rate	Non-applicable (descriptive)	Measured traction forces can predict subjective category strong extraction at second and third pull	High level traction force increases the risk of neonatal morbidity
Study design	Pre-post intervention	Descriptive observational cohort	Observational cohort, prediction	Analytical observational cohort
Study population	Hospital-based cohort, n=1074	Hospital-based cohort, n=200	Hospital-based cohort, n=277	Hospital-based cohort, n=331
Intervention/exposure	Clinical training and increased surveillance	Subjective category extraction	Measured traction force	High level measured traction force
Control group	Pre-intervention	Non-applicable (descriptive)	Subjective category non-heavy	Non high - level measured traction force
Outcome	Failed extraction rate	Measured traction force	Subjective category heavy	Adverse neonatal outcome (NICU admission)

4.2 DATA ACQUISITION AND DEFINITIONS

All clinical data were collected from the electronic individual medical records by the author, the main supervisor or one other experienced resident in the clinic. Exposure data was registered before outcome data in all analytical studies. In study IV, the exposure data remained unknown to the classifier of outcome data. Some variables, such as neonatal diagnoses, or diagnosis of failed vacuum extraction, were defined by their codes in the international classification of disease (ICD-10). However, most of the variables were double checked in the electronic individual medical records as measurements or text rather than diagnoses: for example, fetal head station is identified by reading the obstetricians' entered distance in cm from the ischial spines or pelvic floor. For classification of fetal head station in the studies, we used a four-scale international definition rather than the three-scale classification traditionally employed in Sweden, see figure 2.1. In the first traction force measurement study, we acquired data on cup placement. As presented in the background section, an incorrect placement of the cup will not guide the fetal head's smallest diameter through the narrowest parts of the pelvis, inducing an expected increased risk of excessive force or cup detachment. However, the data registration was very poor with 43 percent missing information, and therefore this variable was excluded in the subsequent studies. Indication of the VE procedure was binary, dystocia or fetal distress. The indication was not solely identified by reported diagnosis: in cases of a double diagnosis entry, the indication was classified from text entries by the obstetrician, scalp lactate, or a CTG with sign of fetal distress.

The traction force data was acquired using bespoke equipment developed within the research team in collaboration with engineers from the Royal institute of technology. The device consists of an intelligent handle attached to a regular (Bird™) metal cup. The handle contains a regularly calibrated load cell (105, 106), as well as instrumentation (battery, signal conditioning, processor and bluetooth transceiver) to allow transfer of the force measurement to a computer for recording, graphic presentation and calculation. The handle does not have the ability to measure direction of traction or oblique strain on the cup. Figure 4.2.1 shows the handle and computer pad, and figure 4.2.2 shows an example of traction force during an extraction.



Figure 4.2.1 Intelligent handle and computer pad.

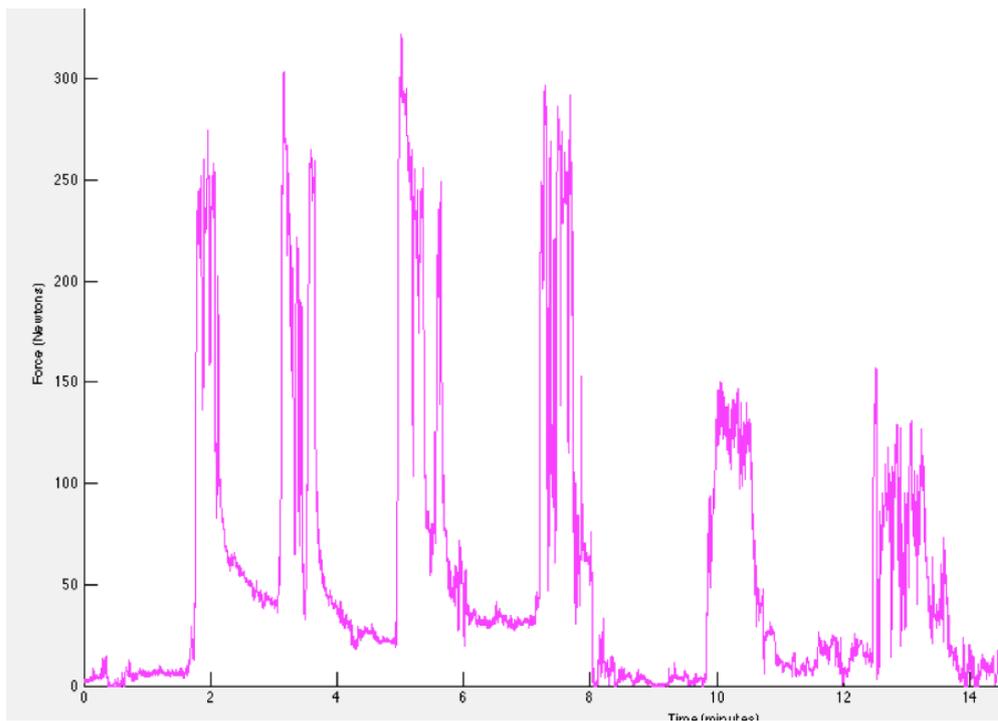


Figure 4.2.2 Example of a force curve: Y-axis force: 0-300 Newtons. X-axis time: 0-14 minutes. Pull 1-4 descending the head to outlet position. Pull 5-6: pelvic floor phase. The area under the curves constitutes the total traction force of the whole extraction.

4.3 STATISTICAL ANALYSES

All statistical analyses are performed with STATA (2014) ©, except for study II where Statistica (Statsoft Inc, Tulsa, US) was used. The plan and execution of statistical calculations were carried out by the author and the main supervisor (study I, II and IV), and in study III an external statistician provided the commands for the lasso regression (Least Absolute Shrinkage and Selection Operator) to select the best predictors (107, 108). We have chosen to make categorical variables from continuous data when there are clinically based definitions of cut offs, such as obesity or large for gestational age. The selection of variables to be included in the regression models (study I and IV) are based on reasoning within the research group and other clinically experienced research colleagues.

5 RESULTS IN SUMMARY

The main results of the separate studies are presented in further detail in the discussion chapter. This chapter includes a condense presentation of the results from each study, as well as a table (table 5) of traction force measurements by clinical characteristics and different categories of extraction.

Table 5 Median peak and total traction forces by clinical characteristics and different categories of vacuum extraction, outlet excluded. N =331				
	Total traction force Newtonminutes	Ranksum test	Peak traction force Newton	Ranksum test
Primiparous vs parous	243 vs 142	p <0.01	155 vs 191	p <0.01
Maternal BMI < 30 vs ≥30	223 vs 290	NS	185 vs 199	NS
Indication dystocia vs fetal distress	249 vs 205	NS	192 vs 179	p <0.01
Fetal head station mid vs low	283 vs 189	p <0.01	199 vs 176	p <0.01
Fetal head position occiput anterior vs occiput posterior	210 vs 332	p <0.01	187 vs 203	p <0.05
Cup detachment yes vs no	201 vs 358	p <0.01	185 vs 215	p <0.01
Birth weight <4500g vs ≥4500g	226 vs 249	NS	189 vs 191	NS
Subjective category heavy vs non-heavy	485 vs 181	p <0.01	219 vs 174	p <0.01
Failed vs successful extraction	357 vs 212	p <0.01	210 vs 186	p <0.01
Positive vs negative predictive test (at 3rd pull)	506 vs 176	p <0.01	232 vs 170	p <0.01

5.1 STUDY I MID AND LOW VACUUM ASSISTED DELIVERIES AND FAILED EXTRACTION: A HOSPITAL BASED PRE-POST INTERVENTION STUDY

During the study period following full implementation of a clinical education and team training programme, the rate of failed extraction decreased significantly. There was no evident effect of introduction of traction force measurements. The rates of failed extraction during the three study periods are shown in table 5.1.

Table 5.1 Primary outcome failed extraction rate during the study periods.						
	Period 0 n(%)	RR 0 vs 1 [CI]	Period 1 n(%)	RR 1 vs 2 [CI]	Period 2 n(%)	RR 0 vs 2 [CI]
Failed extraction, Crude	61(19)	0.41 p<0.001 [0.27-0.62]	28(8)	1.3 NS [0.81-2.08]	37(10)	0.73 p<0.001 [0.60-0.88]
Failed extraction, Adjusted		0.30 p<0.001 [0.19-0.49]		NA		0.62 p<0.001 [0.50-0.77]
Poisson regression. A p-value < 0.016 was considered significant (Bonferroni corrected 0.05 for 3 tests. 0.05/3). Adjusted model (parity and indication, maternal height < 1.55 m and BMI >30, fetal head station and position, duration first and second stage, nr pulls >6, duration >15 minutes and birthweight ≥4500)						

The secondary outcomes showed decreased procedural variables: more than two sequential delivery modes and more than one cup detachment. Neonatal secondary outcomes APGAR, NICU admission and asphyxia pH below 7.1 were unaffected, but there was an increase in asphyxia pH below 7.0.

5.2 STUDY II TRACTION FORCE DURING VACUUM EXTRACTION: A PROSPECTIVE OBSERVATIONAL STUDY

Measured traction force showed higher levels of total traction force compared to previous studies, and peak traction force frequently exceeded the proposed maximum level. Traction force levels were significantly different between subjective categories minimum, average and maximum extraction. Table 5.2 shows a comparison of peak (momentary) force (Newton) and total (time-force product) force in three subjective categories of extraction.

Table 5.2 Peak and total traction force employed for vacuum extraction (n=200)				
	A Minimum extraction	B Average extraction	C Excessive extraction	p-value
Peak traction force, N	176(5-360)	225(115-436)	241(164-452)	p<0.01 ^a p<0.001 ^b
Total traction force, N·min	127(0.7-511)	294(64-857)	506(160-1380)	p<0.001 ^a p<0.001 ^b p<0.01 ^c
^a A vs B, ^b A vs C, ^c B vs C (^{a,b,c} Mann-Whitney U-Test) p<0.001 with Kruskal-Wallis ANOVA by Ranks for Peak force and Total force Data shown is median (range)				

All categories of extraction showed a trend towards higher levels of traction force in the first pulls compared to the pelvic floor phase pulls. However, the heavy extractions displayed a non-significant decreasing force pattern. The difference in force level between consecutive pulls in heavy vs non-heavy (minimum plus average) extraction is presented in figure 5.2.

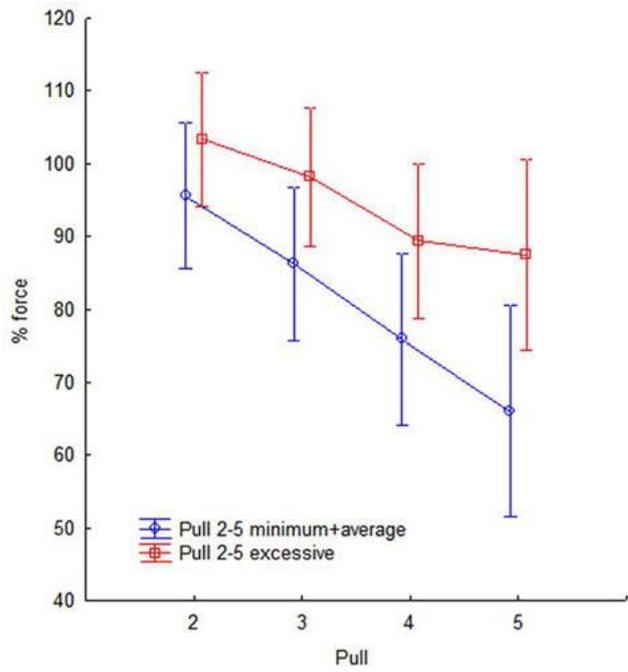


Figure 5.2 Pull force profile, pulls numbers 2–5, percentage force with respect to pull number 1 within each included extraction. Means, 95% CI of means; analysis of variance with repeated measurements, P < 0.05 within each group, P < 0.05 between groups at each pull; Student’s t test.

Furthermore, in a simulated setting obstetricians underestimated the traction force employed, compared to the clinically measured force levels.

5.3 STUDY III PREDICTIVE VALUE OF TRACTION FORCE MEASUREMENT IN VACUUM EXTRACTION: DEVELOPMENT OF A MULTIVARIATE PROGNOSTIC MODEL

The predictive tests based on a range of measured traction forces, enabled prediction of two thirds of heavy category extraction at the third pull, and exclusion of heavy category at the second pull. The AUROCs for the test at second and third pull respectively are shown in figure 5.3.

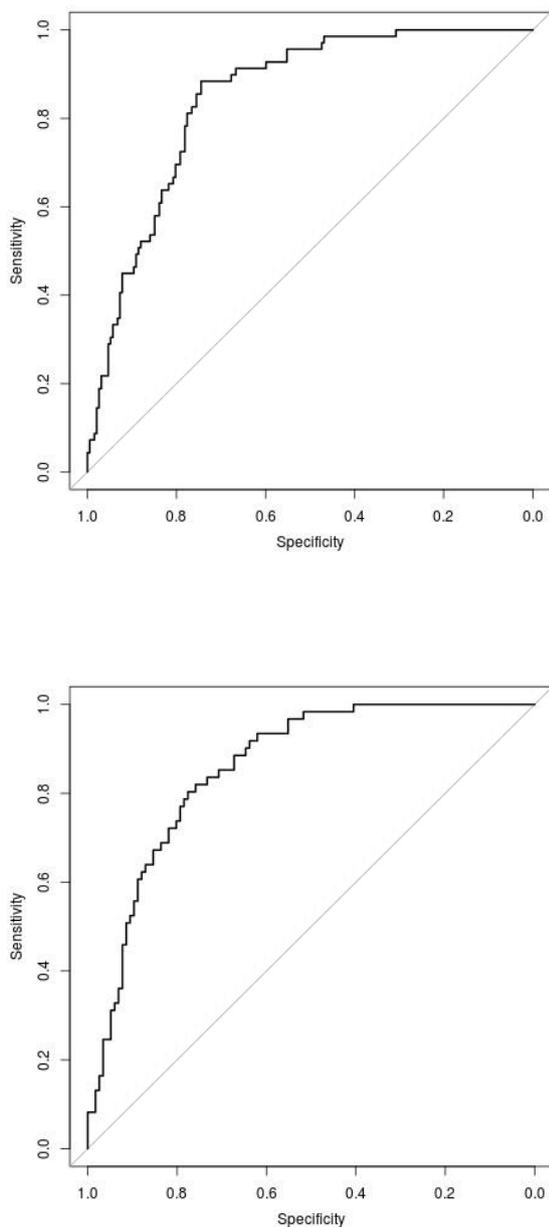


Figure 5.3. Top AUROC. Pull 1-2: AUC 0,85; specificity 0,76; sensitivity 0,87;PPV 0,56; NPV 0,94.
Bottom AUROC. Pull 1-3: Pull 1-3: AUC 0,86; specificity 0,87; sensitivity 0,70; PPV 0,65; NPV 0,89.

5.4 TRACTION FORCE AS A RISK FACTOR FOR ADVERSE NEONATAL OUTCOME IN VACUUM EXTRACTION: A HOSPITAL BASED COHORT STUDY OF MEASURED TRACTION FORCE IN MID AND LOW EXTRACTIONS

Adverse neonatal outcome was rare even among the high level force extractions. We found a possible association between exposure to total traction force >385 Newtonminutes and admission to the neonatal intensive care unit. No association was seen in asphyxia related secondary outcome. The crude and adjusted odds ratios are presented in table 5.4. Failed extraction and cup detachment had similar population attributable risks (PAR) as high level traction force: 20, 24 and 28 percent respectively.

Table 5.4 Primary outcome infant admission to the NICU by exposure high level of traction force >385 Nminutes. Crude and adjusted OR			
	Crude OR [CI]	Adjusted model 1	Adjusted model 2
Total traction force >385 Nmin (75th%)	2.7 [1.16-6.29] p 0.021	2.7 [1.09-6.66] p 0.033	2.1[0.76-5,64] p 0.154 NS
Model 1: Adjusted for indication, birthweight >4500g and failed extraction Model 2: Adjusted for indication, birthweight >4500g, failed extraction, cup detachment, duration of extraction >15 minutes and number of pulls >6			

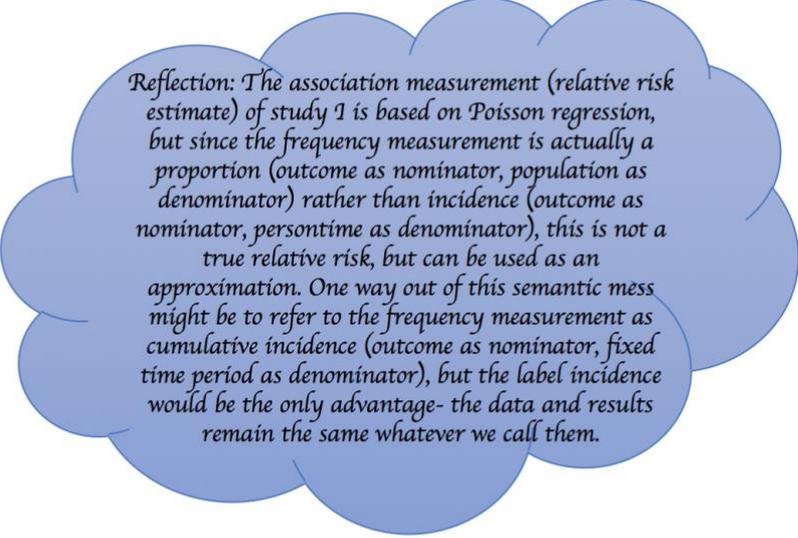
6 RESULTS AND DISCUSSION

6.1 METHODOLOGICAL CONSIDERATIONS

6.1.1 Main findings and interpretation

Measuring traction forces may contribute to increased perinatal safety in vacuum delivery. The most novel findings are the high levels of traction force that can be applied before cup detachment, and the possible association between high level traction force and the risk of admission to NICU. We also found some support that clinical training may lead to improvement of quality indicators, operationalized as rates of failed extraction. Finally, in a simulated setting, obstetricians seem to underestimate the magnitude of employed traction force.

In study I, we demonstrated a large and robust decrease in the relative risk (RR 0.3) of failed extraction during the time period characterized by full implementation of clinical training aimed at improving safety and quality of care in vacuum extraction delivery. This is in accordance with our pre-specified hypothesis. The relative risk in the last time period, during the traction force measurement studies, showed that some of the decrease remained, compared to the naïve period (RR 0.62), but there was no further decrease between the training period and traction force measurement period.



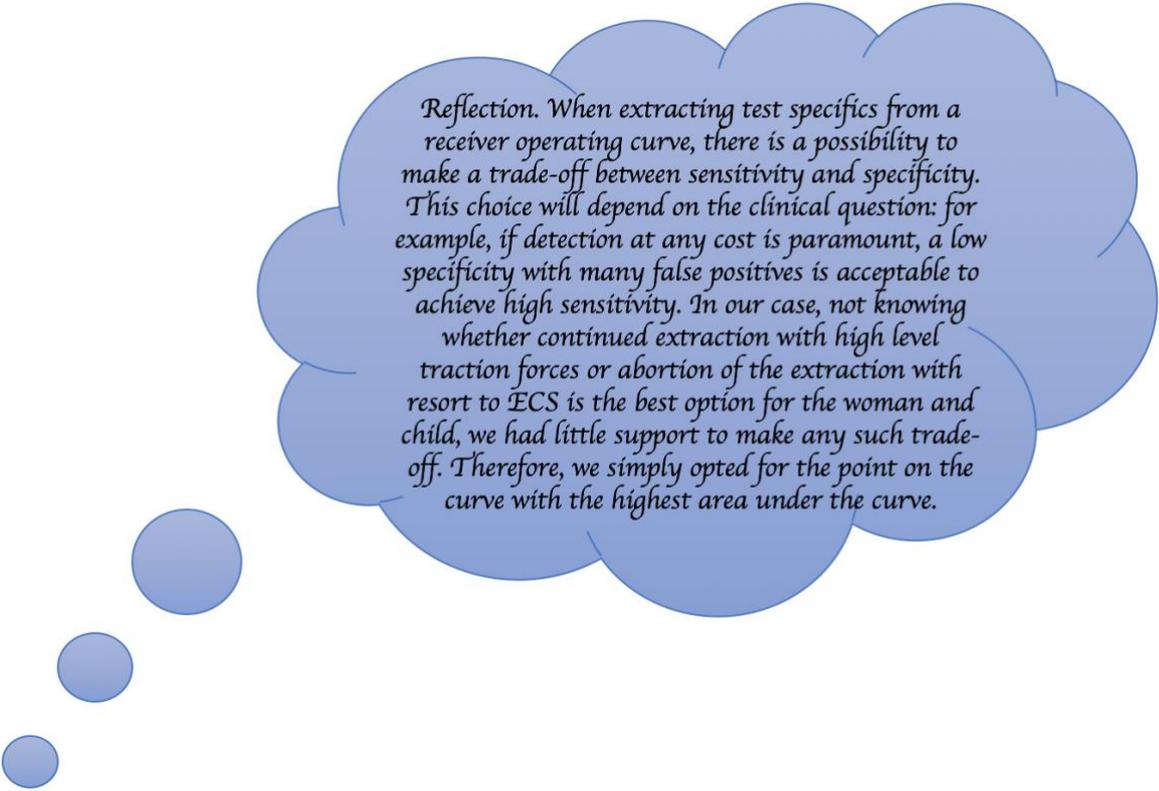
Reflection: The association measurement (relative risk estimate) of study I is based on Poisson regression, but since the frequency measurement is actually a proportion (outcome as nominator, population as denominator) rather than incidence (outcome as nominator, person-time as denominator), this is not a true relative risk, but can be used as an approximation. One way out of this semantic mess might be to refer to the frequency measurement as cumulative incidence (outcome as nominator, fixed time period as denominator), but the label incidence would be the only advantage- the data and results remain the same whatever we call them.

The procedural secondary outcome variables *more than one cup detachment* and *more than one sequential delivery mode* also showed a decreased frequency, and this co-variation of the primary and secondary procedural variables is in accordance with the pre-specified hypothesis. In concrete terms, the latter means fewer instances of VE attempt *plus* obstetric forceps attempt *plus* ECS. Since the neonatal secondary variables showed no improved outcome, the interpretation that team training and increased attention increases patient safety remains debatable. On the other hand, asphyxia indicators such as APGAR score below seven at five minutes, and pH below seven, are poor predictors of neonatal brain damage (109), and might therefore not be the most relevant clinical outcome to study. We concluded that although the study design infers residual confounding and a regression towards the mean, some of the effect is likely due to the educational efforts. One strength of the evaluation of the clinical training is that the implemented team training fulfilled most criteria of evidence based effective methods in obstetrics (110).

The most important finding of study II is arguably that the theoretical and experimental maximum adherence capacity of the cup is frequently surpassed with good margins: nearly one third of the extractions exhibit a maximum traction force of 220 N or more, in most cases without cup detachment. Our measured maximum momentary traction force of 452 N exceeds the 350 N from previous studies (83). This constitutes further evidence against the idea of a self-limiting traction force as a built-in safety mechanism suggested (25, 111). It also illustrates the gap between experimental situations on models and clinical application with physiological conditions that apparently are difficult to mimic in a lab setting. Some secondary results also warrant mentioning: A higher frequency of hypoxic ischemic encephalopathy was seen in heavy category extractions (3/42) compared to non-heavy category (1/151). Furthermore, in heavy category extractions, there was no decrease in force level between subsequent pulls (contractions), whereas non-heavy extractions showed such a declining pattern. Finally, in the simulation part of study II, obstetricians seemed to systematically underestimate their level of applied traction force. In a previous simulation study (89), the authors came to the opposite conclusion, namely that obstetricians make valid estimations of their applied force since they employed increasing levels of force when simulating an easy, average and maximum pull, respectively. Our comparison of easy, average and maximum category displayed similar results, but the interpretation that obstetricians underestimate the force is instead based on the group level differences

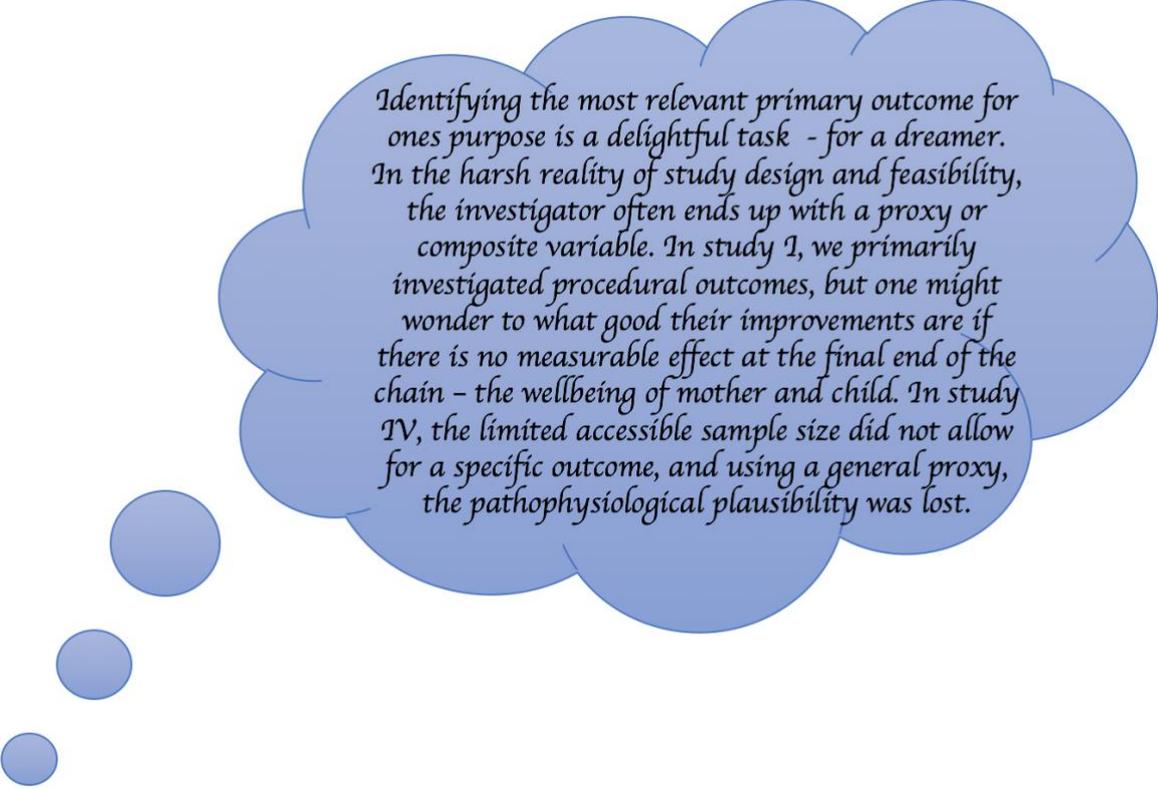
between self-estimated force, the simulated setting force, and the measured force in the clinic.

In study III, we found an improved positive prediction capacity of the test applied at the third pull (PPV 0.65, NPV 0.89) compared to the second pull (PPV 0.56, NPV 0.94). It may be too early to use traction force measurement to predict a subjective category strong extraction at the second pull (contraction). For the test to be of maximum clinical use, the detection of an imminent heavy extraction should arguably occur as early as possible. The NPV can be used with good accuracy at the second pull, but this is perhaps of less clinical importance. Whether the low PPV at the second pull makes the test less applicable remains to be seen in external validation studies; prediction studies are often afflicted by a bias of the test sample, and need validation in a new sample (112). The likelihood ratio (LR: sensitivity/1-specificity) of the test at the second pull is 3.6 and at the third pull 5.4. An approximate interpretation of LR states that a value of 3 or 5 adds around 20 or 30 percent respectively of probability of the disease compared to the clinical estimation (113). If this test should prove accurate in external validation, it may be used as a guide to early conversion of a heavy extraction to a non-catastrophic ECS.



Reflection. When extracting test specifics from a receiver operating curve, there is a possibility to make a trade-off between sensitivity and specificity. This choice will depend on the clinical question: for example, if detection at any cost is paramount, a low specificity with many false positives is acceptable to achieve high sensitivity. In our case, not knowing whether continued extraction with high level traction forces or abortion of the extraction with resort to ECS is the best option for the woman and child, we had little support to make any such trade-off. Therefore, we simply opted for the point on the curve with the highest area under the curve.

The most novel finding in study IV is the possible association between high level of traction force ($\geq 385\text{Nmin}$) and adverse neonatal outcome (NICU), OR 2.5. The secondary outcome severeNICU (n=6), including only selected relevant diagnoses (subgaleal hematoma, HIE, seizures, ICH and death) rather than *all* NICU, showed a stronger association (OR 6.1), and although the cases are too few to allow for any conclusions, it may be argued that the estimate may be more accurate; the unspecific character of the NICU outcome is bound to dilute the effect estimate. The optimal primary outcome would have been a more specific one, perhaps head trauma such as hemorrhages. However, symptomatic brain damage is fortunately a rare complication, and to test the hypothesis of traction force would require a much larger sample size.



Identifying the most relevant primary outcome for ones purpose is a delightful task - for a dreamer. In the harsh reality of study design and feasibility, the investigator often ends up with a proxy or composite variable. In study I, we primarily investigated procedural outcomes, but one might wonder to what good their improvements are if there is no measurable effect at the final end of the chain - the wellbeing of mother and child. In study IV, the limited accessible sample size did not allow for a specific outcome, and using a general proxy, the pathophysiological plausibility was lost.

The pre-specified model selected for multivariate analysis in study IV includes adjustment for indication, failed extraction and large for gestational age. We defined these variables as confounders, since they might influence the exposure as well as the outcome. In our understanding, the causal paths explaining adverse neonatal outcome in vacuum extraction are still obscured by lack of knowledge, and whether covariates have been handled optimally in this study remains an open question. Therefore, a second model was also shown, adjusting for co-variates that we actually consider to be mediators of the traction

force effect. As expected, the hypothesis test failed to reject the null hypothesis when including duration and number of pulls, since these variables are contributing to the exposure variable *total* force, which is actually determined partly by time.

6.1.2 Problems of generalizability

The study population for this entire thesis is hospital based, and the most apparent limitation to this study design is the issue of generalizability, or external validity. Compared to a population based study, the risk of exposure-outcome associations in a hospital based cohort not being representative to the population outside of the study base is obvious. However, the traction force measurement exposure that is present in all four studies, is unique to this research project, and therefore no other study population was plausible. One approach to make up for this shortcoming would be to identify and compensate for the characteristics where the hospital population is different from the general population. From the Swedish pregnancy registry[©], we know that during 2014-2107 Karolinska Huddinge was the fifth largest labor and delivery ward in Sweden, and during 2015 displayed similar rates of VE (5.7 percent) as the national rate (6 percent) and a slightly higher frequency of ECS, but we lack information regarding most socioeconomic factors (114).

The next level to reflect upon after the selected study population is the studied sample extracted from the population. In our case, there is no randomization at this stage. The closest thing to a common characteristic of the sampling in the four studies is convenience sampling, and this poses a problem if and only if the sampling itself incurs a dependency in exposure or outcome status. We have therefore considered the possibility that sampling only those women who underwent VE *with* traction force measurement could further decrease the generalizability. To counteract this, or at least to be better equipped to elaborate on the matter, we could have gathered *clinical characteristics* data on all VE, not exclusively the ones where we had exposure information.

The external validity can be disputed in the *simulated* traction force measurements that formed a secondary part of study II: we concluded that obstetricians generally underestimate their applied traction forces based on participants' estimation and simulation in a simplified environment without a model fetus or pelvis, and some of the participants spontaneously commented on the limitations of the unrealistic setting.

6.1.3 Problems of accuracy

Interval validity threats in hospital based cohorts include the risk of bias in the comparison group – selection bias: comparing cases to non-cases, where the non-cases are admitted to the hospital due to some other disease, may lead to a selection not independent from the exposure. In our case, with cohorts of exposed and unexposed rather than cases and controls, this could be inferred by volunteer bias: lower risk of outcome in those who accept participation, or among those whom the *obstetrician* chose to include for participation. Furthermore, it is plausible that some obstetricians might refrain from employing high levels of traction force in a situation where the fetus is already compromised, thus inducing an outcome dependent selection of controls (low level of traction force).

Selection bias is easily confused with dependent misclassification. Misclassification occurs later in the process, when information on exposure or outcome is being acquired. Particularly in study IV, where we studied the association of high levels of traction force and adverse neonatal outcome (NICU), misclassification would be a great risk if the neonatologist assessing the newborn would have access to exposure information: a slightly impassive or apathetic infant would certainly be more likely to end up in NICU care if the neonatologist knew that the vacuum delivery had been extremely heavy. We avoided this blunt example by not passing on any information on the exposure status to the pediatric staff.

In study II, where we investigated levels of traction force and compared measured forces in different subjective categories (minimal, average and strong), there is a less obvious example, and one where we do not know to what extent a dependent misclassification might have occurred: it was instructed that the measured traction forces should not be revealed to the obstetrician, but they were available on a small screen in the delivery room. As described above, the assistant nurse in the delivery team was handling the force measurement equipment, and she had simultaneous access to the traction forces. It is not unreasonable to assume that the obstetrician indirectly could interpret the assistant nurse's oral or facial expression in high level force cases, and thereby inflicting a risk of labelling the extraction *subjective* category strong *because* of the assumed high *measured* levels. This situation could also be described as a reversed causality.

Confounding is perhaps the most frequently discussed source of bias. The most popular ways to control confounding factors is through matching, randomization or adjustment in regression models. Common causes of bias are *failure* to adjust for a confounder, or to

inaccurately adjust for a collider, that is, a common effect of exposure and outcome (115). In study I, one might suspect an induction of collider bias, since the adjusted association estimates are stronger than the crude ones. However, we have considered the variables included in the regression models, and the only plausible *effects of the outcome* would be shorter and fewer pulls, but excluding these from the model results in the same estimates. In study IV, with an aim to make a causal claim, handling co-variates was a delicate problem; To the best of our knowledge, there is not sufficient evidence on covariance in the field to safely define the etiological associations. Despite our cautious approach to pre-specify a model for adjustment, there is still an uncertainty whether we have chosen the least biased way to handle the co-variates.

6.1.4 Statistics

There is an abundance of options regarding statistical methods, and although some are dictated by common rules, such as non-parametric tests for skewed data or correction for multiple comparison, many choices remain, and they can influence the results. For instance, when analyzing the variable *number of pulls* as a continuous variable, there is a significant difference in base line characteristics between the cases vs controls in study IV. Yet, for clinical relevance, perhaps the dichotomous separation of more than six pulls (y/n) is more relevant, since this distinction in the procedural performance is part of clinical guideline recommendations. However, as a binary variable, the difference in number of pulls is not significant between the groups, and to report that exclusively therefore seems dishonest. The variable “duration” (of extraction) displayed a similar but reversed situation: no significant difference at baseline using the raw variable, but binary according to clinical guidelines (more than 15 minutes y/n) differed. In the clinical characteristics table of study IV, showing both versions of the variable seems uncontroversial, maybe even interesting, but for the multivariate analyses, this choice required some intellectual effort.

In study I we chose to use Poisson regression instead of logistic regression, since Poisson with robust variance or Cox with fixed time is recommended in statistical literature in cross-sectional material (116, 117). Using logistic regression, the effect might be over-estimated, as is the case when the outcome is more frequent than about ten percent. We therefore had two reasons *not* to go for logistic regression in study I. This choice of a less renowned method is contrary to the wise common sense advice regarding statistics – to stick to simple and well known methods for reasons of transparency.

For the prediction model in study III we also chose a less well known regression method, advised by a co-writer statistician. The lasso model (Least Absolute Shrinkage and Selection Operator) helps weighting variables and sorting out those with the best prediction capacity, with less bias than unconstrained stepwise regression (107). All traction force variables were included in the model, without any attempts to distinguish the most relevant exposure. This work procedure illustrates a principal difference between prediction studies and etiological studies; In prediction studies, whether a variable is a confounder, mediator or independent risk factor is irrelevant. All that matters is its predictive capacity.

Conversely, in study IV with its causal claims, selecting the variables to be included in the regression model is of paramount importance; excluding a variable that is actually a confounder will make the estimate biased in favor of the hypothesis (type I error), while erroneously including a variable that is actually a mediator will typically bias the estimate in favor of the null hypothesis (type II error). The difficulty here is not primarily mathematical, since epidemiologists have long argued against machine selection of co-variates and instead favoring context specific knowledge based criteria for modeling (118). In a field of insufficient clinical knowledge of the nature of the associations, the latter approach proved difficult, with opinions differing depending on which sources or experts we consulted. Perhaps the most central problem of accuracy in study IV is that the exposure variable *total* traction force consists of force *and* time, and therefore cannot be separated from duration and number of pulls, which in turn may be independent risk factors.

7 CONCLUSIONS

Our data suggest possible etiological associations and areas for clinical implementation of measured traction force as a means to improve safety in vacuum extraction. Furthermore, we showed in study I that recurring clinically based team training addressed at vacuum extraction may improve procedural outcome, although methodological limitations call for caution regarding any causal claim. Also, measuring traction force did not seem to deter obstetricians from low and mid cavity VE. The results from study II showed that higher levels of traction force are used in metal cup extractions compared to previous studies of the rigid plastic kiwi™ cup, and that the momentary peak force frequently exceeds the suggested maximum limit of 220 Newton. Study III showed that a test based on measured traction forces can predict two thirds of subjective category heavy extractions. Whether implementation of the test could lead to improved clinical outcome needs to be validated in a clinical trial. In study IV, we found a possible association of high level *total* (time force product) traction force to adverse neonatal outcome. However, the possible causal links between the exposure and outcome and the remaining independent variables are unclear. Furthermore, previous notions on traction force safety limits are based on *peak* traction force, whereas our studies show no support for either built-in safety limits, nor adverse outcome based on momentary maximum force. A larger study powered to investigate a more precise outcome than NICU admission could yield more information regarding possible causation. The results of all three analytical studies are afflicted by uncertainties, and should not prompt any alterations to clinical guidelines or practice, but the described associations warrant further studies. One possible gain of traction force measurement *with feedback* might be an avoidance of cup detachments, by using measured traction force levels to guide the obstetrician to a controlled early abortion of heavy extractions. Measuring traction forces could also be used as a pedagogical tool, and as an objective documentation in audit cases.

8 SUGGESTIONS FOR FURTHER RESEARCH

To further investigate the possible causal relationship between high levels of traction force and adverse neonatal outcome, there are two principally different plausible paths to explore: The most straight forward idea, as discussed above, would be a sufficient sample size to allow an arguably more traction force specific outcome, such as different types of head trauma and hemorrhage. This would require a multicenter approach that our research group, so far, has lacked the organizational muscles to pursue. The other possibility would be an enhanced study design, with an alternative definition of the traction force exposure – namely one that separates for example the time factor from the force. The absent association of *peak* traction force to any neonatal outcome suggests that this latter idea may prove a difficult task.

A pilot study of an intended larger randomised study evaluating intra-operative traction force feed back to the obstetrician based on the predictive test from study III has been conducted, preliminary results not available. The hypothesis here is that feed back on high level traction force improves severe adverse neonatal outcome, without directly addressing the etiological issue of effects of traction force.

Another approach concerns the clinical dilemma of which is the lesser evil in a difficult situation: to abort an attempted vacuum in favor of emergency cesarean section; to continue a heavy extraction beyond guideline recommendations; to go straight for cesarean section when the odds are against successful extraction. By comparing neonatal and maternal outcome between high level traction force mid extractions, failed and successful, and cesarean section at fully dilated cervix *without* a prior attempt at vacuum extraction, one might hope to add a piece of evidence to the obstetricians decision.

Other members of our research group are currently carrying out longitudinal studies in children born by mid cavity vacuum extraction. Such follow-up projects might help decide which perinatal complications after vacuum extraction can be considered harmless after the acute phase, and conversely, whether long term disability may occur years after a seemingly healthy neonatal period.

In a different line of complications of vacuum extraction, another clinical research group at the Karolinska institute are combining clinical and traction force data with perianal ultrasound diagnostics to learn more about uro-genital maternal complications.

9 SVENSK SAMMANFATTNING

9.1 INTRODUKTION

Förlossning med sugklocka är näst kejsarsnitt den vanligaste operativa åtgärden för att avsluta en pågående förlossning vid värksvaghet eller hotande fosterasfyxi. Komplikationer hos nyfödda såsom skallblödningar eller kramper är ovanliga i storleksordningen enstaka promille respektive procent, men risken är ökad vid alla operativa förlossningssätt (kejsarsnitt, sugklocka och tång) jämfört med spontant vaginalt förlopp. Huruvida det finns en riskökning vid sugklocka jämfört med framförallt akut kejsarsnitt är oklart. En del av riskökningen jämfört med spontan vaginal förlossning beror sannolikt på det avvikande förlossningsförlopp som lett fram till den operativa åtgärden. Kunskapsläget är bristfälligt avseende vilka egenskaper hos ingreppet som skulle kunna leda till skador på fostret, men det finns studier som talar för att misslyckad sugklocka (som åtföljts av akut kejsarsnitt), ofrivilligt klocksläpp samt en alltför lång operationstid skulle kunna leda till skador. Det finns även studier som undersökt dragkraft utan att hitta något samband med sjuklighet hos nyfödda. Dragkraftsstudierna är dock mycket små, med deltagarantal på färre än hundra kvinnor, och därmed mycket liten chans att upptäcka en ökad risk för ovanliga komplikationer.

9.2 SYFTE

Det övergripande syftet med detta projekt var att undersöka om objektiv mätning av anlagd dragkraft kan förbättra säkerheten vid sugklockeförlossning. Målet med delstudie I var att beskriva hur frekvensen av sugklocka och misslyckad sugklocka förändrades över tid, samt att undersöka hur dessa utfall påverkades av utbildningsinsatser samt forskningsprojektets pågående dragkraftmätningar. I delstudie II var målet att kartlägga hur stora dragkrafter som används vid olika typer av (metall)sugklockeförlossningar. Studie III syftade till att utröna om en hotande tung sugklocka kan upptäckas tidigt i förloppet med hjälp av uppmätta dragkrafter, och därmed göra riskbedömningen under pågående sugklockeprocedur mer objektiv. Vi utformade därför ett prediktivt test där prediktorerna var olika dragkraftsvariabler och utfallet postoperativt skattad *tung* sugklocka. Med studie IV ville vi undersöka höga nivåer av dragkraft som riskfaktor för sjuklighet hos nyfödda.

9.3 RESULTAT

9.3.1 Delstudie I

I delstudie I undersökte vi tre olika tidsperioder på Karolinska sjukhuset i Huddinge med avseende på förekomst av förlossning med sugklocka i allmänhet, samt medelhög och misslyckad sugklocka i synnerhet. Kohorten utgjordes av 1074 fullgångna förlossningar med medelhög sugklocka. Exponeringen utgjordes av förändringar under de respektive tidsperioderna, där period 0 definierades som naiv, period 1 karakteriserades av införande av utbildningsprogram med inriktning mot sugklocka, och under period 2 pågick mätning och dokumentation av dragkraft. Vi fann att andelen sugklocka bland samtliga förlossningar minskade, i likhet med trenden på nationell nivå. Förekomsten av misslyckad sugklocka minskade signifikant från den första tidsperioden jämfört med de två andra (RR 0,3 respektive 0,6). Minskningen skedde under utbildningsperioden, och parallellt med en ökning av andelen medelhöga sugklockor (36%, 45% och 60% under respektive period). Vi tolkade den minskade risken för misslyckad sugklocka som ett möjligt resultat av utbildningsinsatser. En fortsatt hög andel medelhöga sugklockor tyder på att operatörerna inte låtit sig avskräckas från potentiellt svåra sugklockor av dragkraftsmätningarna. Studiedesignen har dock begränsande metodologiska problem, exempelvis avseende regression mot medelvärdet samt oidentifierade störfaktorer.

9.3.2 Delstudie II

Delstudie II är huvudsakligen en beskrivande kartläggning (n=200) av vilka dragkrafter som används vid metallsugklocka, men vi utförde också jämförande analyser mellan olika kategorier av sugklocka. Utrustningen som vi använde har utvecklats inom ramen för forskningsprojektet och består av ett handtag utrustat med dragkraftsmätare, trådlös överföring samt inbyggd strömförsörjning. Handtaget kopplas till ordinarie metallsugklocka (Bird 50 mm, undertryck 80 kPa). Krafterna mättes i Newton (momentan maxkraft) eller produkten Newtonminuter (totalkraft). Bland resultaten återfinns signifikanta medianskillnader i totalkraft mellan de olika subjektiva svårighetsgraderna lätt, medelsvår och tung (127, 294 respektive 506 Newtonminuter), samt en frånvaro av minskning av dragkraften för varje värk vid tung sugklocka. Signifikant skillnad sågs även mellan framstupa och vidöppen bjudning (191 respektive 355 Newtonminuter). Som bifynd fann vi även en överrepresentation av neonatal sjuklighet i form av hypoxisk ischemisk encefalopati vid subjektiv kategori tung sugklocka (3/42) jämfört med icke-tung (1/151). I

en sidostudie fann vi också att sugklockeanvändare verkar underskatta hur stor dragkraft som används i kliniken.

9.3.3 Delstudie III

Deltagarna i studie III var 277 kvinnor förlösta med medelhög sugklocka. Eftersom syftet var att skapa ett prediktivt test kallas motsvarigheten till exponeringsvariabler för *prediktorer*, och dessa utgjordes av ett batteri av uppmätta dragkrafter: momentan maxkraft och totalkraft per drag under drag ett till tre, procentuell skillnad mellan dragen, samt ackumulerad totalkraft under drag ett och två respektive drag ett till tre. Med hjälp av regressionsmodellen lasso (least absolute shrinkage and selection operator), som väljer ut och viktar exponeringsvariabler, utformades en algoritm av dragkraftsvariabler som gav den bästa prediktionen av en hotande tung sugklocka. Testets egenskaper vid respektive drag:

Drag 2: Areal under kurvan 0,85; sensitivitet 0,87; specificitet 0,76; PPV 0,56; NPV 0,94; likelihood ratio 3,6

Drag 3: Areal under kurvan 0,86; sensitivitet 0,70; specificitet 0,87; PPV 0,65; NPV 0,89; likelihood ratio 5,4

Eftersom syftet var att undersöka om just uppmätt dragkraft kunde tidigt upptäcka en tung medelhög sugklocka vägdes inga andra oberoende variabler in i modellen, och inga antaganden om orsaksamband gjordes.

9.3.4 Delstudie IV

Till delstudie IV samlade vi in dragkraftdata från 331 kvinnor förlösta med medelhög sugklocka i fullgången tid medelst samma utrustning som i studie II och III. Exponeringen utgjordes av den 75e percentilen av totalkraft under extraktionen, det vill säga den fjärdedel av fallen med största uppmätta dragkraft gånger tid. Utfallet vi undersökte var inläggning på neonatal intensivvårdsavdelning, NICU. De kliniska bakgrundsvariablerna som skiljde sig signifikant åt mellan NICU-fallen respektive icke-NICU var fosterhuvudets station i förlossningskanalen, duration och antal drag i extraktionen, ofrivilliga klocksläpp samt misslyckad (avbruten) extraktion. Efter justering för de på förhand specificerade störfaktorerna indikation, stort barn samt misslyckad extraktion var odds ratio 2,5 [1,03-6,25]. Ingen association kunde ses efter justering för lång duration, stort antal drag och

klocksläpp, men vi tolkade dessa variabler som mediatorer (duration, antal drag, klocksläpp).

9.4 SLUTSATSER

Vi har visat att det finns möjliga samband och tillämpningar av uppmätt dragkraft som skulle kunna förbättra patientsäkerheten vid medelhög sugklocka. Vidare har vi i delstudie I påvisat ett möjligt samband mellan riktade utbildningsinsatser och utfall vid medelhög sugklocka, även om metodologiska svagheter förhindrar säkra slutsatser om kausala samband. Resultaten från delstudie II visade att dragkrafter vid metallsugklocka är generellt sett högre än vid exempelvis kiwi™, och att momentan maxkraft ofta överstiger föreslagen maximal kraft om ca 220 Newton. Studie III visade att det i viss mån är möjligt att diagnosticera och utesluta tunga sugklockor med hjälp av ett test baserat på uppmätta dragkrafter. Huruvida tillämpning av testet kan leda till ett förbättrat neonatalt utfall bör utvärderas i klinisk prövning. I studie IV fann vi ett möjligt samband mellan hög nivå av dragkraft och intensivvårdsbehov hos nyfödda. Viss osäkerhet finns avseende de kausala förhållandena mellan övriga oberoende variabler å ena sidan, och exponering respektive utfall å andra sidan. En större studie med möjlighet att undersöka ett mer precist utfall än NICU skulle sannolikt ge bättre information om ett eventuellt kausalsamband. Resultaten är behäftade med osäkerheter och bör i nuläget ej föranleda några förändringar i riktlinjer eller liknande, men de möjliga sambanden utgör skäl för att vidare studera området. En möjlig tillämpning skulle kunna vara återkoppling till operatören när dragkraften når en nivå som kan predicera en tung sugklocka, som en vägledning till kontrollerat avbruten sugklocka i stället för oförutsett klocksläpp. Vi har också sett att utrustningen tolereras väl av användarna, och torde kunna användas som pedagogiskt instrument, samt som objektiv dokumentation vid exempelvis svåra fall som leder till granskning.

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