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TO CUT OR NOT TO CUT?

EPISIOTOMY IN VACUUM EXTRACTION

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To cut or not to cut? Episiotomy in vacuum extraction

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

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“The main thing in life is to know your own mind” – Tove Jansson

To Liv,

POPULAR SCIENCE SUMMARY OF THE THESIS

Induction of labor is more common in older first-time mothers due to risks of prolonged pregnancy. If trial of labor is worthwhile has been discussed, considering the potential adverse outcomes in older women. In Sweden, 4-5% of first-time mothers with a spontaneous vaginal delivery (without help from vacuum extraction or forceps), are afflicted by an injury to the anal sphincter, so called obstetric anal sphincter injuries (OASIS). In first-time mothers delivered by vacuum the risk is almost tripled compared with spontaneous vaginal delivery. OASIS is the most prominent risk factor for anal incontinence. In order to try to prevent OASIS, an episiotomy may be performed. An episiotomy is a surgical cut in the vaginal opening performed in order to try to redirect a potential tear away from the anus. One adverse event of an episiotomy could be cutting deeper parts of the pelvic floor muscles, such as the levator ani muscle. This muscle is important for pelvic floor function. Injury to the levator ani muscle may increase the risk for pelvic floor dysfunction.

In **study I,** we explored if women 40 years or older had a higher risk of complications when trying to give birth, compared with women 25-29 years. Complications studied were the outcomes vacuum delivery, emergency cesarean section, OASIS and episiotomy. We used the Swedish Medical Birth Register. We compared nulliparous women ≥40 years (n=7796) with nulliparous women 25-29 years (n=264 262) after spontaneous onset and induction of labor between 1992-2011. Since women with induced labor differ from those with spontaneous labor we looked at these groups separately. We found that women ≥40 years had a higher risk of operative vaginal delivery compared to women 25-29 years both after spontaneous onset (22% vs 14%) and after induction of labor (23% vs 18%). Women ≥ 40 also had a higher risk for intrapartum cesarean section both after spontaneous onset of labor (15 % vs 5%) and after induction of labor (37% vs 20%) compared with women 25-29 years. The difference was less prominent in induced labor, probably because women with induced labor share risk factors in both age groups. There was no difference in risk of OASIS or episiotomy between age groups. Overall, 79% of women ≥40 years had a vaginal delivery compared with 93% of women 25-29 years.

In **study II,** we wanted to find out if OASIS could be prevented with an episiotomy in women with the highest risk to sustain OASIS i.e., first-time mothers with vacuum delivery. We aimed to mimic a randomized controlled trial using a so-called propensity score method, to balance differences between women who had an episiotomy and those who did not. We used the Swedish Medical Birth Register to find 63 654 first-time mothers who gave birth with vacuum delivery with or without episiotomy between 2000 and 2011. We calculated the average treatment effect, which is the estimated treatment effect if every first-time mother with vacuum delivery would receive an episiotomy. Our results showed that episiotomy could reduce OASIS from 15.5% to 11.8%. This was translated into "how many women will have an episiotomy to avoid *one* OASI?" We found that 27 women will have an episiotomy to prevent one OASI. This is a higher number than seen in other countries, which could mean that episiotomies in Sweden are not as preventive as in other countries.

With this in mind, we wanted to study the episiotomy use, technique, and attitudes among doctors in Sweden. We hypothesized that a low use, low skills, and negative perception of episiotomy could be one explanation. A certain level of use and a certain technique have both been shown to increase the protective effect. In **study III**, we e-mailed an electronic questionnaire to members of the Swedish Society of Obstetrics and Gynecology (SFOG). We asked them to name and depict the episiotomy they would perform in a clinical setting, on a picture of a crowning baby head. They were also asked to answer questions regarding attitudes and experience of episiotomy. We found that only 54% of doctors in Sweden drew what could be considered a protective episiotomy and that doctors in Sweden rated episiotomy as the least important measures to prevent OASIS in vacuum delivery.

In study **IV,** we wanted to assess if an episiotomy aimed at protecting the anal sphincter could injure deeper pelvic floor muscles, such as the levator ani muscle. We included 58 first-time mothers with a vacuum delivery and lateral episiotomy, and examined the pelvic floor muscles one year after delivery using endovaginal 3D ultrasound. Of these 58 women, 12 (21%) had a levator ani muscle injury. This is in accordance with previous findings. Two of these 12 women had an injury solely on the same side as the episiotomy. We therefore conclude that there was no excessive risk of cutting the levator ani muscle while performing a lateral episiotomy.

In conclusion, our research has shown that trial of labor is worthwhile in women having a first baby in their forties. Although they have a higher risk of cesarean section and vacuum delivery, they don't have a higher risk of OASIS or episiotomy compared with younger women. Episiotomy seems to have a protective effect on OASIS also in a Swedish setting in first-time mothers with vacuum delivery. However, we must perform more episiotomies compared with other European countries to achieve a protective effect. This could depend on a poor technique, which was supported by the depictions and self-reported use among doctors in Sweden. We believe that more training and education is needed. We could not find a strong association between episiotomy and levator ani muscle injury. Doctors' may perform lateral episiotomies most probably without affecting the levator ani muscle, until the effect of lateral episiotomy has been established.

ABSTRACT

BACKGROUND AND AIMS

Obstetric anal sphincter injury (OASIS) may cause anal incontinence, as well as sexual dysfunction and psychological trauma. Mediolateral and lateral episiotomy have been shown to be protective against OASIS in nulliparous women delivered by vacuum extraction (VE). The technique and trigonometric properties of an episiotomy may be important for its protective effect.

The aim of the thesis was to explore episiotomy in Sweden. Firstly, we aimed at investigating the effect of episiotomy in nulliparous women at VE. Secondly, we aimed at exploring the attitudes towards, and knowledge about, episiotomy among doctors. Finally, we wanted to find out if an episiotomy might cause injury to the levator ani muscles (LAM). The impact of advanced maternal age on delivery outcome was also explored.

METHODS AND MAIN RESULTS

Study I and II are register-based cohort studies based on data from the Swedish Medical Birth Register. In **study I** delivery outcome in women ≥40 years was explored. We compared nulliparous women ≥40 years (n=7796) with nulliparous women 25-29 years (n=264 262) after spontaneous onset and induction of labor between 1992-2011. The rate of OASIS, episiotomy, and low Apgar score was also investigated. We found a significantly higher rate of intrapartum cesarean section among women ≥40 years, both after spontaneous onset of labor (adjusted odds ratio (aOR) 3.07, 95%CI 2.81-3.35) and induction of labor (aOR 2.51, 95%CI 2.24-2.81). The risk of VE was also increased in women ≥40 years, both after spontaneous onset (aOR 1.71 95%CI 1.59-1.85), and induction of labor (aOR 1.45, 95%CI 1.28-1.65). We found no significant difference in rate of OASIS, episiotomy or low Apgar score. Overall, 79% of women ≥40 years had a vaginal delivery compared with 93% of women 25-29 years.

In **study II** nulliparous women delivered by VE between 2000-2011 were included. Women without episiotomy (n=43 853) were compared to women with a lateral or mediolateral episiotomy (n=19 801). After statistical balancing using propensity score, episiotomy was associated with a reduction in OASIS from 15.5% to 11.8%, ie an average treatment effect -3.7% (95% CI -4.3 to -3.0). The numbers needed to treat (NNT) to prevent one OASIS was 27. The third-degree perineal injuries alone were reduced from 14.0% to 10.9% (-3.1, 95% CI -3.7 to -2.4) with NNT 32. The fourth-degree perineal injuries alone were reduced from 1.6% to 1.0 % (-0.6%, 95% CI -0.8 to -0.4). Fourth-degree perineal injuries required NNT 172.

S**tudy III** was a web-based questionnaire sent to the members of the Swedish Society of Obstetrics and Gynecology with a registered email in 2019 (n=2140). The response rate was 25% (n=432). The questionnaire addressed different aspects of VE and episiotomy and contained a picture of a crowning fetal head in which the respondents were asked to depict

the episiotomy they would perform in the delivery room. The drawn episiotomies were translated into coordinates in a diagram. The episiotomies were categorized as lateral, mediolateral, midline or unclassifiable. In total, 57.8% (n=222) doctors reported performing episiotomy in less than 50% of VE deliveries. We found that only 54% of the doctors drew what could be considered a protective episiotomy. Furthermore, doctors in Sweden rated episiotomy as the least important measure to prevent OASIS in VE.

Study IV was a descriptive prospective cohort study, examining if lateral episiotomy causes an iatrogenic LAM injury. Sixty-three women delivered by VE who received a standardized lateral episiotomy were examined by 3D endovaginal ultrasound about one year after delivery. Five images were not possible to retrieve due to a broken hard drive, thus 58 women were included. Of these 58 women, 12 had a visible LAM injury (20.7%, 95%CI 10.9-32.9). This is a significantly lower proportion than the stipulated 50% ($p<0.001$) of women. Two (16.7%, 95% CI 2.1-48.4) of 12 women had an ipsilateral LAD ($p=0.02$, compared with the stipulated proportion of 50%).

CONCLUSION

In conclusion, trial of labor may be worthwhile in women ≥ 40 years. Episiotomy seems to have a protective effect of OASIS in a Swedish population of nulliparous women with VE. A small majority of doctors in Sweden could depict a protective episiotomy. Our studies support that doctors are able to continue performing lateral episiotomies without risk of cutting the LAM.

LIST OF SCIENTIFIC PAPERS

I. Delivery outcome after trial of labor in women 40 years or older – A nationwide population-based study.
Ankarcrona V, Altman D, Wikström A-K, Jacobsson B, Brismar Wendel S.
Acta Obstet Gynecol Scand. 2019 Sep;98(9):1195-1203.

II. Obstetric anal sphincter injury after episiotomy in vacuum extraction: an epidemiological study using an emulated randomized trial approach.
Ankarcrona V, Zhao H, Jacobsson B, Brismar Wendel S.
BJOG. 2021 Sep; 128(10):1663-1671.

III. Attitudes and knowledge regarding episiotomy use and technique in vacuum extraction: A web-based survey among doctors in Sweden.
Ankarcrona V, Hesselman S, Kopp Kallner H, Brismar Wendel S.
Eur J Obstet Gynecol Reprod Biol. 2022 Feb;269:62-70.

IV. Episiotomy in vacuum extraction, do we cut the levator ani muscle? A prospective cohort study.
Ankarcrona V, Karlström S, Sylvan S, Starck M, Jonsson M, Brismar Wendel S.
Accepted for publication in International Urogynecology Journal on March 14, 2022.

Scientific papers not included in the thesis

Lateral episiotomy versus no episiotomy to reduce obstetric anal sphincter injury in vacuum assisted delivery in nulliparous women; study protocol on a randomised controlled trial. Bergendahl S, **Ankarcrona V**, Leijonhufvud Å, Hesselman S, Karlström S, Kopp-Kallner H, Brismar Wendel S. BMJ Open. 2019, Vol.9(3), p.e025050.

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LIST OF ABBREVIATIONS

ATE	Average Treatment Effect
EAS	External Anal Sphincter
IAS	Internal Anal Sphincter
ICD	International Classification of Diseases
ICSI	Intra-Cytoplasmatic Sperm Injection
IPW	Inverse Probability Weighting
IUFD	Intra Uterine Fetal Death
IVF	In Vitro Fertilization
LAD	Levator Ani Deficiency
LAM	Levator Ani Muscle
LÖF	Landstingens Ömsesidiga Försäkring
MRI	Magentic Resonance Imaging
NNT	Numbers Needed to Treat
OASIS	Obstetric Anal Sphincter Injuries
POP	Pelvic Organ Prolapse
PS	Propensity Score
RCOG	Royal College of Obstetricians and Gynaecologists
SBF	Svenska Barnmorskeförbundet
SFOG	Swedish Society of Obstetrics and Gynecology
SMBR	Swedish Medical Birth Register
VE	Vacuum Extraction

1 INTRODUCTION

Episiotomy, by some researchers called *"the unkindest cut of all"*, is a surgical incision to enlarge the vaginal opening when the fetal presenting part is crowning to facilitate delivery (1-3).

1.1 HISTORY OF EPISIOTOMY

The first known episiotomy was described in Dublin in 1742 by the midwife and obstetrician Sir Fielding Ould (4). It was described as an emergency procedure to save the life of the unborn child (5). Since then, the use of episiotomy has passed through various clinical and political phases.

The first midline incision was described in 1799, followed by the bilateral incision in 1820, and the mediolateral episiotomy in 1847. Ten years later "episiotomy" was first mentioned in a published paper (5). When childbirth was hospitalized in the beginning of the 20th century, the episiotomy rate increased accordingly from 5% to 80% in the United States (6). In the Anglo-Saxon countries in the 1970s episiotomy was the most common surgical procedure during delivery. In the 1980s political feminist voices were raised in the US. The book "*Our bodies, ourselves: A book by and for women*" was published in 1973 selling over 1 million copies (5, 7). This gave rise to women questioning the evidence of routine episiotomy demanding scientific evidence, which in turn generated numerous evidence-based publications giving no grounds for routine episiotomy. Despite this, routine episiotomy continued to expand on different continents around the world to reach its peak in the 1990s (5).

1.2 EPISIOTOMY TODAY

As for today, restrictive use is recommended in spontaneous vaginal delivery. There is no difference in severe perineal trauma between women with or without episiotomy (1). Despite this, routine use is still applied in some European countries, as well as in Asia, parts of the middle East, and South/Central America (3, 8-10)

Episiotomy may be beneficial in preventing tears to the anal sphincter in operative vaginal delivery depending on type of episiotomy (11-13). This is salient as tears to the anal sphincter, also known as obstetric anal sphincter injury (OASIS) is a severe complication to vaginal delivery and the most important cause of anal incontinence in women (14). As stated by Dickinson et al:*"The achievement of a vaginal delivery at the expense of a woman's long-term fecal continence is not an obstetric success"(15).*

2 BACKGROUND

2.1 MODE OF ONSET OF LABOR

Labor can begin spontaneously or by induction. Induction of labor may be due to medical or psychological reasons. In Sweden today, 27% of the deliveries are induced with a variation of 13-38% between hospitals (16). This is an increase with 9% compared with 2015. A plausible explanation is the result from a multicenter randomized controlled trial (RCT) comparing induction of labor at 41+0 weeks compared to expectant management (17). The results indicated that the benefits of continued pregnancy after 41 gestational weeks were few (17). The national guidelines are not changed, but hospitals are asked to offer induction at 41+0 weeks on maternal request (17). Another reason for the increase may be that induction of labor is now recommended at an earlier gestational age in women with intercurrent or pregnancy induced medical diagnoses than before (18-20).

2.2 MODE OF DELIVERY

Childbirth can be vaginal or by cesarean section. Vaginal delivery without the help of instruments is usually called spontaneous vaginal delivery or normal birth. With the help of various instruments such as vacuum extraction (VE), forceps or spatula, it is called assisted/instrumental/operative vaginal birth. Cesarean sections are often categorized as planned/elective/antepartal/pre-labor when they are performed without trial of labor, or emergency/intrapartal when they are performed after trial of labor, depending on available data. However, pre-labor cesarean sections can also be emergency procedures.

In 2020, 71% of nulliparous women and 90% of multiparous women in Sweden experienced an uncomplicated vaginal delivery (16). Uncomplicated delivery is defined as spontaneous vaginal delivery without OASI, a 5 minutes Apgar score ≥7, and postpartum hemorrhage ≤1500 ml (16). The prevalence of operative vaginal delivery was 10% with a variation of 6-15% among nulliparous women (16). The prevalence of planned cesarean section was 7.9% and emergency cesarean section 8.8% (16). The total prevalence of pre-labor and intrapartum cesarean section in mixed parities was 17.8% with a variation of 13-25% within the country (16). The variation may be explained by different populations or different policies.

2.3 PELVIC FLOOR ANATOMY

Pelvic floor anatomy can be complex to understand due to its three-dimensional character. The perineal body is a tendinous convergence point of muscles between the vagina and the anorectum important to pelvic floor function (21). MRI images have shown that the superficial pelvic floor muscles (the bulbocavernosus muscle, the deep and superficial transverse perineal muscles (Figure 1), and the internal and external anal sphincter muscles) converge in the perineal body, along with the deep pelvic floor muscles (the puboperineal muscle and the puboanal muscle, which are part of the levator ani muscle) (21).

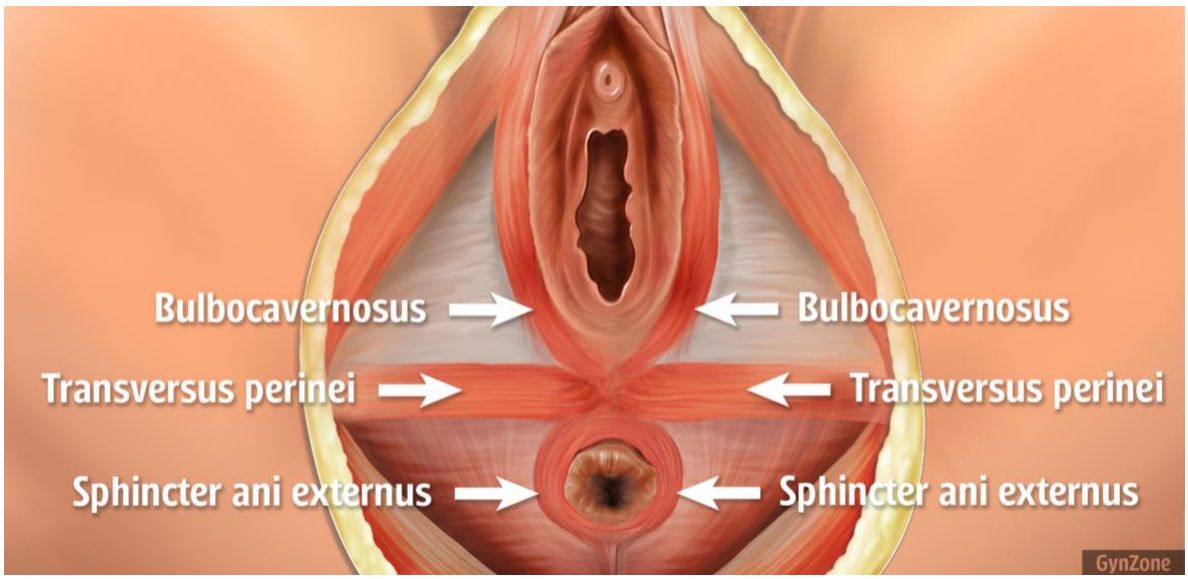


Figure 1. Superficial perineal muscles. © Gynzone. Reprinted with permission from Gynzone.

2.3.1 The bulbocavernosus muscle

The bulbocavernosus muscle runs from the clitoris, in/underneath the labia majora on both sides and attach in the perineal body. It consists of striated muscles and erectile tissue. During sexual arousal, the bulbocavernosus muscle may compress clitoral veins which leads to erection of the clitoris. It can also narrow the vaginal opening by contracting. Injury to the bulbocavernosus muscle may cause a sensation of a wide vagina (22).

2.3.2 The transverse perineal muscle

The transverse perineal muscle has a superficial part and a deep part (23). The muscle runs from the ischial tuberosities horizontally and attaches in the central part of the perineal body. The muscle fixates the perineal body to the pelvis and prevents downward descent of the rectum. An injury to the muscle may cause soiling, urge to pass stool, or a sensation of incomplete defecation (22).

2.3.3 The anal sphincter complex

2.3.3.1 The external anal sphincter

The external anal sphincter is circular and consists of striated muscle fibers and plays a crucial part in anal continence. Injury can lead to urgency, leakage, or difficulties to pass stool. The anal canal is surrounded by the anal sphincter. The external anal sphincter is laterally attached to the puboanal muscle, anteriorly attached to the perineal body, and needs support from the perineal body for optimal function (22).

2.3.3.2 The internal anal sphincter

The internal anal sphincter consists of smooth muscle fibers and is an elongation and thickening of the muscle layer in the intestinal wall, between the mucosa and serosa, underneath the external sphincter. It stretches about 3 cm up from the anal opening. Injury to

the internal anal sphincter may cause an inability to feel if there is need to pass stool or flatus. It can also cause soiling and flatus incontinence. Harm to both the external and internal anal sphincter muscles can lead to involuntary continuous soiling and mixed anal incontinence (22).

2.3.4 The levator ani muscle

The posterior wall of the vagina is supported by the rectovaginal fascia. The anterior wall of the vagina is supported by the vesicovaginal fascia. Injury to either of these fascias may lead to vaginal wall prolapse (24).

The lateral walls of the vagina are supported by the levator ani muscle (LAM), crucial for the structural and functional integrity of the pelvic floor. The LAM forms from the joining of three muscles: the puborectal, the pubococcygeal, also named pubovicseral (consisting of the pubovaginal, puboperineal, and puboanal muscle), and the iliococcygeal muscles (Figure 2) (25). The puboperineal muscle runs from the inferior pubic bone to the perineal body, the puboanal muscle to the anal canal, and the puborectal muscle runs in a loop around the rectum and creates the anorectal angle important for maintaining anal continence. On one hand, the LAM secures the abdominal and pelvic floor from gravity. On the other hand, the LAM must control disposal of feces and urine. It is also important for our reproductive needs such as sexual intercourse and vaginal birth, preferably without any adverse events.

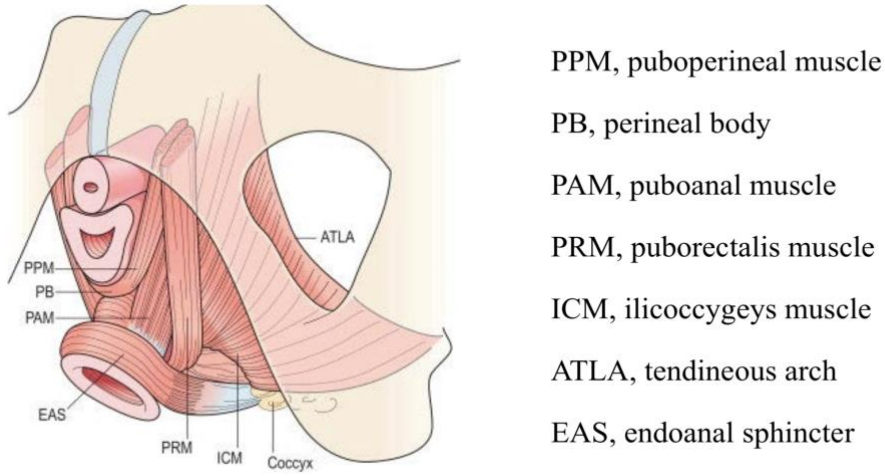


Figure 2. Deep perineal muscles. © DeLancey. Reprinted with permission from Professor DeLancey.

2.4 PERINEAL INJURY

In childbirth, tears to the perineum are classified according to their extent of tissue engagement. A first-degree injury is a superficial injury to the perineal skin, labia or vaginal mucosa and does not include any muscle tissue. Second-degree injuries engage the perineal muscles; the bulbocavernosus muscle, the transverse perineal muscle and/or the LAM, but not the anal sphincters (Figure 3). In 2020, a more delicate classification of second-degree tears was introduced in Sweden, enabling a better understanding of second-degree injuries (22).

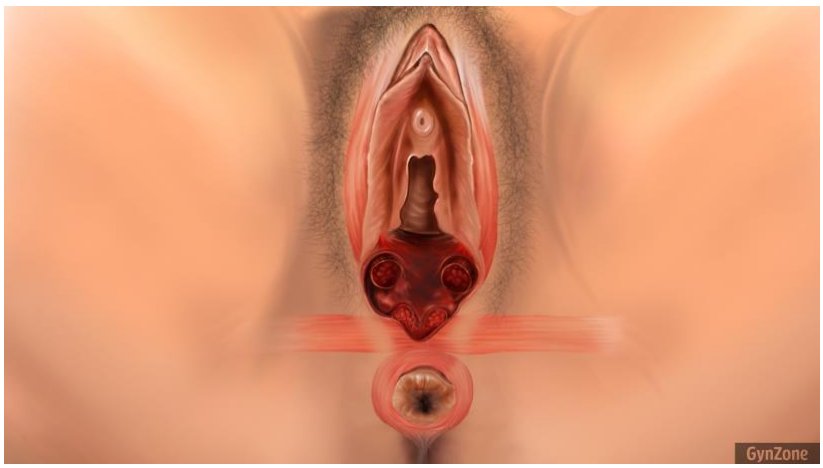


Figure 3. Second-degree perineal injury. © Gynzone. Reprinted with permission from Gynzone.

2.5 OBSTETRIC ANAL SPHINCTER INJURY (OASIS)

2.5.1 Definition of OASIS

Third-degree injuries involve injury to the anal sphincter complex to any extent, usually with injury to other perineal muscles as well (26). Fourth-degree injury involves the anorectal mucosa (Table 1). OASIS include both third- and fourth-degree injuries (Table 1) (27).

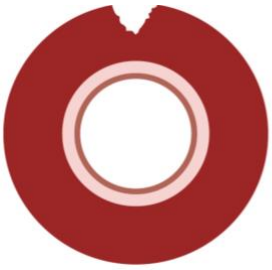
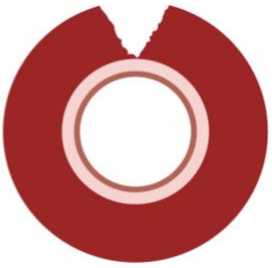
Grade 3a	Grade 3b	Grade 3c	Grade 4
≤50% of the external anal sphincter thickness torn.	≥50% of the external anal sphincter thickness torn.	Both anal sphincters torn	Injury to the perineum involving both sphincters and the anorectal mucosa.
			

Table 1. Classification of OASIS of different degrees according to Royal College of Obstetricians and Gynaecologists. © Gynzone. Reprinted with permission from Gynzone.

Swedish diagnosis codes have other suffixes than the internationally accepted definitions offered by the British Royal College of Obstetricians and Gynaecologists (RCOG) (Table 1). A third-degree tear affecting <50% of the external anal sphincter is diagnosed O70.2c, >50% O70.2d, both the external and internal sphincters O70.2e, while O70.2f is an isolated IAS injury. Fourth-degree tears are all tears affecting the rectal mucosa and are coded O70.3 (28). An isolated defect on the anorectal mucosa is called a buttonhole defect and is coded separately in the RCOG system (Figure 4) (29).

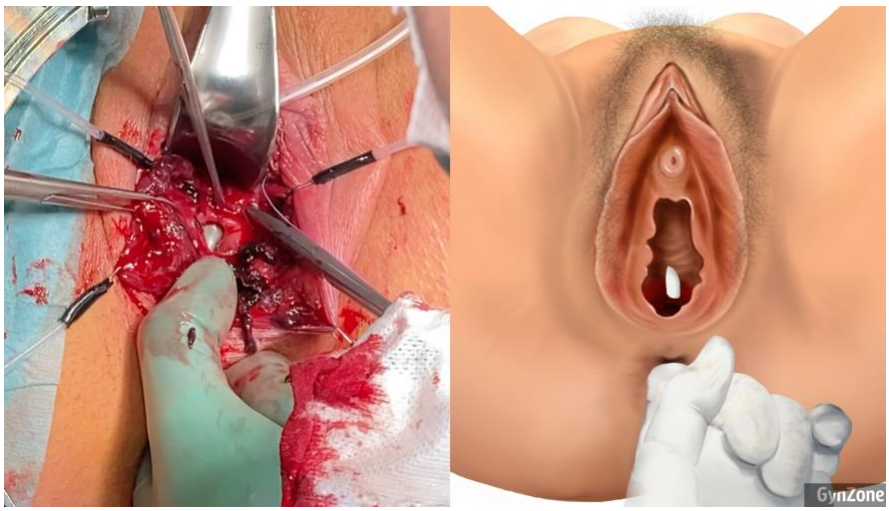


Figure 4. Buttonhole defect is an isolated defect in the anorectal mucosa. © Gynzone. Reprinted with permission from Gynzone.

2.5.2 Epidemiology

OASIS occurs in 2.1% of all spontaneous vaginal deliveries and in 10.2% of all VE in Sweden (16). The prevalence differs between 0.1% and 4% in spontaneous vaginal delivery and 0.5% to 15% in instrumental delivery (VE and forceps) in Europe (8). Nulliparous women are more often affected by OASIS. In Sweden in 2020, the prevalence of OASIS was 3.6% (1.3-6.7%) in spontaneous vaginal deliveries and 11.1% (0.7-22%) in VE among nulliparous women (16). The prevalence is based on clinical diagnosis at delivery and could be underestimated. A recently published meta-analysis showed that one in ten women have missed OASIS when examined with endoanal ultrasound postpartum (30).

2.5.3 Risk factors for OASIS

Risk factors associated with OASIS are operative vaginal delivery, nulliparity, birthweight ≥4000 g, occiput posterior position, Asian or African origin, a prolonged second stage of labor, and advanced maternal age (31-40).

Especially high and variable is the prevalence of OASIS in operative vaginal delivery (16). The variation may be due to background characteristics, preventive measures, labor management, diagnostic routines, or accuracy of registers. Nulliparity is an established risk factor and prevalence differs between countries (12, 41). Birthweight ≥4000 g and large head circumference are also established risk factors (34, 42, 43). Occiput posterior position of the fetal head is associated with OASIS in most studies (44-47). Prolonged second stage and its impact on the risk of OASIS is under debate. After adjusting for confounders for a prolonged second stage, such as birthweight, maternal height, labor dystocia, and fetal position, the association was no longer obvious in some publications (34, 44, 48), while one study of women with mixed parity found a discrete increased risk of OASIS after a prolonged second stage (46). Another study found an elevated risk in nulliparous women for each hour they spent in second stage of labor, but no additional risk was seen after three hours or more (49).

A third study also found that the odds for OASIS increased 1.5 times for every hour increase of second stage (50).

Whether the operator's skill in operative vaginal delivery has any impact on the risk of OASIS seems clinically apparent, but research studies are contradictory (34, 48, 51, 52). One study showed that there was no significant difference between residents, midwives, and consultants (34). Another study showed an increased risk if the operator was a resident compared to a consultant (51). A study by Bergendahl et al showed that the risk of OASIS was five times higher if the operator was a resident compared to a consultant working mainly in the delivery ward (52). None of the publications could demonstrate an association between OASIS and the fetal head station, number of pulls, cup detachment, or the indication for the VE.

2.5.4 Adverse outcomes of OASIS

OASIS is a severe complication to vaginal delivery. OASIS is the main cause of anal incontinence in women, and therefore important to avoid (14). Anal incontinence is reported in 9-40% of women with former OASIS and does not seem to improve over time (12, 53, 54). It may even increase with up to 50% 25 years after the injury (55). Furthermore, OASIS may cause chronic pain, sexual dysfunction, as well as psychological trauma (53, 54, 56-58).

2.6 LEVATOR ANI INJURY

2.6.1 The LAM during second stage of labor

Birth related trauma to the LAM was first described in 1943 by Dr. Gainey and then again in 1955 (59). It took 45 years before it evoked response among clinicians, and clinical preventions, diagnosis, and treatment began (59). The LAM is involved in defining the dimensions and biomechanical ability of the birth canal. Most skeletal muscles will snap if they are forced to stretch more than twice their length. The LAM may stretch up to four times its length during the late phase of second stage of labor (60). Stretching at the pubic bone attachment is especially straining when the occipito-bregmatic diameter of the fetal head passes through the LAM hiatus, known as crowning (Figure 5) (61, 62).

2.6.2 LAM avulsion

LAM injury may involve the muscle fibers attached to the perineal body and external anal sphincter muscle (62). While LAM injury close to the perineal body usually is visible and repairable, LAM avulsion at the pubic bone is rarely diagnosed at delivery. Magnetic resonance imaging (MRI) or three- or four-dimensional (3D/4D) ultrasound is often required for diagnosis (63). Repairing LAM avulsion has so far proven unsuccessful, therefore prevention is important (64). LAM avulsion has been reported in 1-52% of women after delivery depending on the setting and mode of delivery (65).

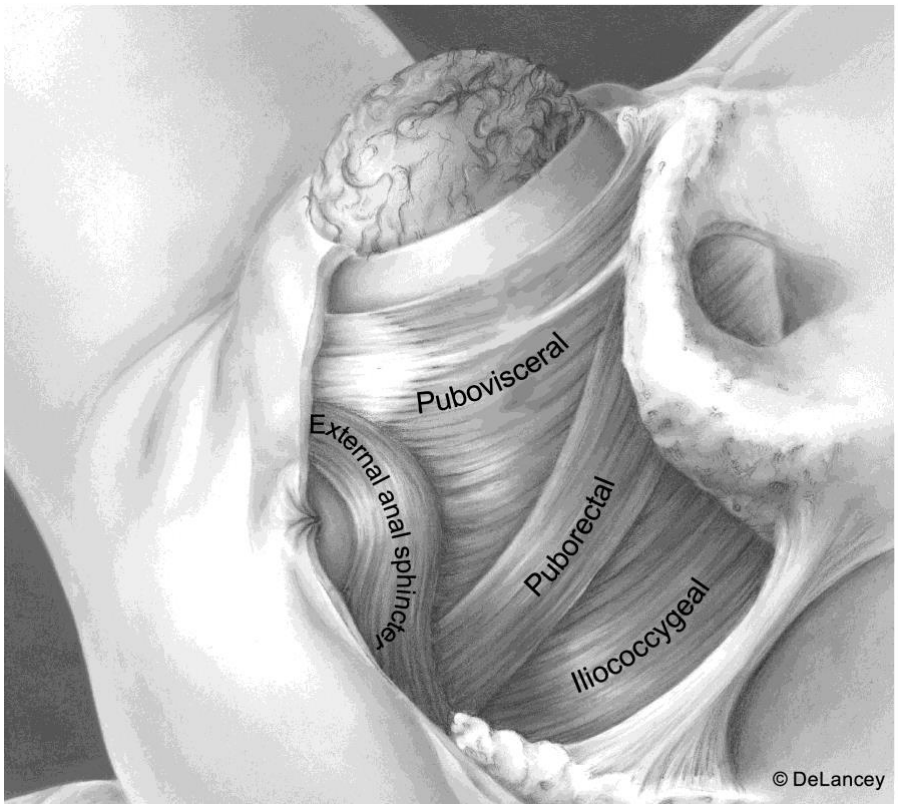


Figure 5. Levator ani muscle subdivisions and external anal sphincter at crowning of the fetal head showing the massive changes needed for the head to emerge. © DeLancey. Reprinted with permission from Professor Delancey.

LAM avulsion may appear as a result of the over-stretching of the muscles leading to a detachment of the puborectal muscle from its insertion to the inferior ramus of the pubic bone (66). Avulsion is in most cases a permanent injury, and it is the most important risk factor for pelvic organ prolapse (67, 68). LAM avulsion is also a risk factor for prolapse recurrence after surgery (69). Distension at childbirth may cause "ballooning", which is defined as an excessive distensibility of the LAM when doing the Valsalva maneuver (70). Clinical diagnosis of LAM injury may be difficult at delivery due to its occult nature, and palpation has been showed to underestimate avulsion in comparison to MRI and ultrasound (71). MRI or 3D/4D ultrasound are often required for diagnosis and show moderate agreement (72-74).

2.6.3 Risk factors for LAM avulsion

Several epidemiological studies have shown that forceps delivery is associated with increased risk of LAM avulsion compared to spontaneous vaginal delivery (60, 75-79). The role of VE is more debated (60, 80-82). Prolonged second stage of labor, nulliparity, higher maternal age at delivery, large head circumference, and occiput posterior presentation are other risk factors (83, 84). Also, OASIS has been associated with LAM avulsion, likely because risk factors coincide and may simply represent a difficult vaginal delivery (85-87).

2.7 PERINEAL PROTECTION IN VAGINAL DELIVERY

Two principal views of perineal protection exist: "hands-on" and "hands-off/hands-poised". Hands-on or manual perineal support requires the birth attendant's hands supporting the perineum to slow down the emerging fetal head (88). Hands-off means avoiding touching the perineum and using verbal guiding to slow down the expulsion. Hands-poised is something in between, with the hands ready to intervene when deemed necessary. Perineal protection may also include warm compresses against the perineum or perineal massage (88). There is little difference between hands-on vs. hands-off/hands-poised techniques, while warm compresses and massage have proven to reduce perineal injury and OASIS in spontaneous vaginal delivery (88, 89). However, when looking at the hands-off/hands-poised group together, the actual treatment is difficult to detangle as hands-poised allows parts of the hands-on benefits (89).

A structured training program to decrease the rate of OASIS was implemented in a Norwegian hospital in 2005 (90). During second stage of labor doctors and midwives were taught to: 1/ place one hand on the fetal head at crowning in order to control the speed of expulsion, 2/ with the dominant hand support the perineum and pressing the outer parts of the perineum against the middle with the thumb and index finger to relieve pressure from the central part of the perineum ("the Finnish grip"), 3/ ask the birthing mother not to push, and when needed, 4/ perform a correct episiotomy (90). After implementation, the overall prevalence of OASIS decreased from 4.0% to 1.2% (90). A subgroup analysis of instrumental deliveries found a decrease from 16.3% to 4.9% (90).

Subsequently, this approach was implemented in more hospitals in Norway, as well as in other European countries and the United States (91-96). In Danish and Swedish hospitals, similar success rates were seen (92, 93), while the reduction of OASIS was smaller in other countries (94-96). Success in Scandinavian countries may be due to similar demography, obstetric care, and high OASIS rates to begin with (92, 93). More moderate or no effect in other studies could be due to smaller sample size, lower OASIS rates to begin with, higher detection rate of OASIS after implementation, or non-compliance to perineal protection or the implementation of episiotomy (94, 95, 97). International temporal trends in OASIS reveal that Norway is unique in keeping OASIS rates low (90, 98), likely helped by governmental support of the implementation (98, 99).

2.8 EPISIOTOMY

2.8.1 Classification of episiotomy

There are mainly three types of episiotomies: mediolateral, lateral, and median/midline. They are classified according to their point of incision and angle (Figure 6) (2). Mediolateral episiotomy is an incision in the posterior fourchette directed to either side of the midline with an ideal angle of 60° (2). Lateral episiotomy has the incision point on either side of the vaginal opening starting approximately two centimeters from the posterior fourchette, with an ideal angle of 60° (2). Median episiotomy starts in the midline and cuts straight down towards

the anus (2). Median episiotomy has been strongly associated with OASIS, why median episiotomy is not recommended (1, 13).

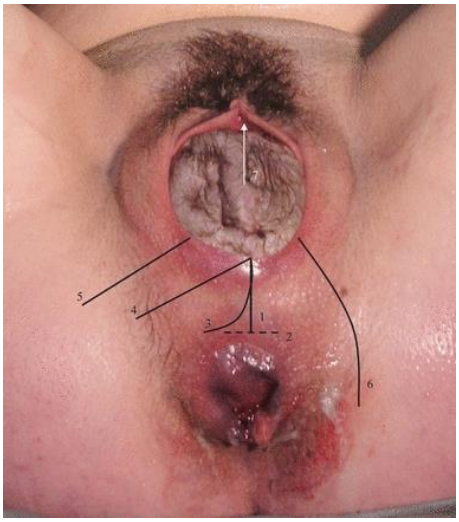


Figure 6. Different types of episiotomies.

1: Median episiotomy, 2: Modified median episiotomy, 3: 'J'-shaped episiotomy, 4: Mediolateral episiotomy, 5: Lateral episiotomy, 6: Radical lateral (Schuchardt incision), 7: Anterior episiotomy (white arrow). From Kalis V, Laine K, de Leeuw JW, Ismail KM, Tincello DG. Classification of episiotomy: towards a standardisation of terminology. BJOG 2012;119(5):522-6. Reprinted with permission from BJOG.

2.8.2 Trigonometric properties of episiotomy

The trigonometric properties: angle, incision point, and length of an episiotomy, may all be of importance to prevent tearing towards the anus (100-102).

2.8.2.1 Angle

An angle of approximately 60° to the midline when the head is crowning is preferable, because an angle too obtuse (<15) or too wide (>60°) increases the risk of OASIS (100, 101, 103-106). An incision angle of 60° at crowning seem to correspond to a suture angle of 43-50° (104, 106, 107). Incision angle and scar angle may differ 15-30° due to the distension of the perineum in transverse and vertical direction (Figure 7) (106).

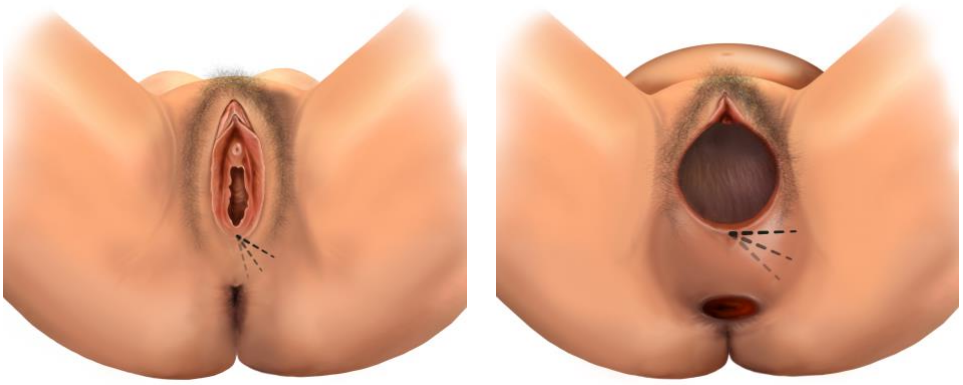


Figure 7. The angle of 60° increases at crowning. © Gynzone. Reprinted with permission from Gynzone.

Cutting the right angle has proven difficult (Figure 8). Doctors and midwives tend to cut an angle too obtuse (108-112). In an observational study by Bechard et al, 91% of midwives and

doctors reported a correct protective incision angle (110). Still only about half of the suture angles were correct (110). Cutting the right angle also needs practice: at least 10 episiotomies should be performed under supervision to get the angle right (111). The ischial tuberosity may serve as a landmark, or special scissors may aid in keeping the angle right (2, 113).

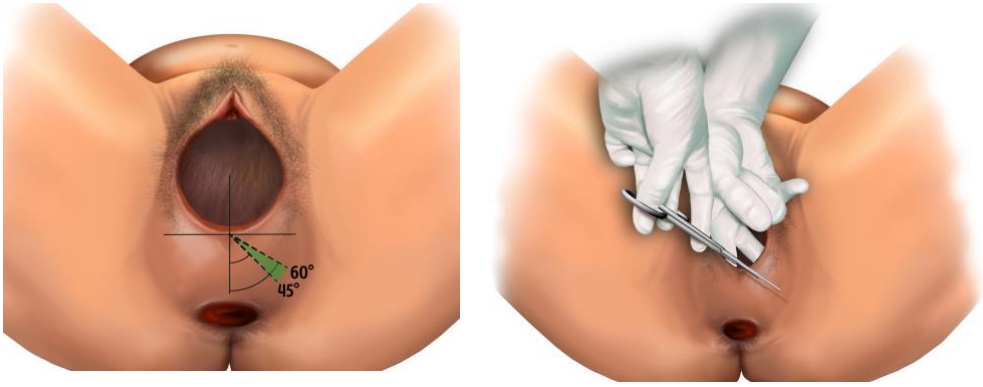


Figure 8. Direction of the cut in different angles. © Gynzone. Reprinted with permission from Gynzone.

2.8.2.2 Incision point

The incision point defines the main difference between a lateral and a mediolateral episiotomy (114). Stedenfeldt et al examined episiotomy scars in nulliparous women with or without OASIS after VE, and found that a scar incision point distance from the midline of >9 mm were more protective, which corresponds to a lateral episiotomy (100). In an RCT comparing lateral and mediolateral episiotomy in mixed first-time vaginal deliveries, no difference was seen in OASIS, but the OASIS prevalence was very low (<2%) (115).

2.8.2.3 Length

The episiotomy length needed to prevent OASIS is not well established. An increasing length could decrease the risk of OASIS (100). A scar length of >17 mm could be important to obtain the protective effect (100).

2.8.3 Confusion about terminology in episiotomy

The terminology regarding the definition of mediolateral and lateral episiotomy may be confusing. Most commonly, a lateral episiotomy is called a mediolateral episiotomy among doctors and midwives (2, 114, 116). Therefore, these two types are indistinguishable and interchangeable in almost all retrospective studies. Kalis et al have worked towards a standardized classification system in terms of incision point, angle, and length of episiotomy to facilitate robust and trustworthy evidence in research (2). Despite this, a joint terminology is not yet prevailing. On the other hand, the protective effect of episiotomy is not dependent on terminology. The most important factors are to keep away from the anal sphincter by a sufficient angle or distance (115).

2.8.4 Episiotomy in Sweden today

Until the 1990s, episiotomy was widely used in Sweden. Little reported protective effect in spontaneous vaginal delivery, increased early postpartum perineal pain, and impact on quality of life, especially sexual function, markedly decreased the use of episiotomy (1, 58, 117-119). The restrictive use of episiotomy in spontaneous vaginal delivery is supported by a Cochrane systematic review (1). Somewhat contradictory, there is an inverse correlation between the rate of episiotomy in a country and the country's rate of OASIS, even in spontaneous vaginal deliveries (8). In current practice, 7.3% of first-time mothers (0.8%-15.0%) with a spontaneous vaginal delivery will receive an episiotomy in Sweden (16). The restrictive use in spontaneous vaginal deliveries has also influenced practice in VE with an average rate of episiotomy at 33% (8%-80%) (16).

2.8.5 Selective vs routine use of episiotomy

There is no established definition of selective (restrictive) or routine use of episiotomy. In a Cochrane review of RCTs assessing selective or routine use, a selective policy is explained as *"only if needed"* and a routine policy is explained as *"part of routine management"* (1). Rates in the selective arm ranged from 8% to 59% (median 32%), and in the routine arm rates ranged from 51% to 100% (median 83%) (1). This should be kept in mind when discussing the effects of selective or routine episiotomy.

2.8.6 Episiotomy in spontaneous vaginal delivery

An episiotomy guarantees perineal trauma, and women may be subject to an unmotivated operation and pain. Therefore, it should be performed based on scientific evidence. Performing an episiotomy at crowning of the fetal head, rather than earlier, is associated with smaller vaginal tearing and smaller blood loss, which promotes restrictive use and not "just in case" (120). A systematic review on retrospective cohort studies (97.8% nulliparous women) indicated that mediolateral episiotomy compared to no episiotomy may be beneficial in prevention of OASIS (121). Subsequently, an updated Cochrane systematic review based on RCTs assessing selective or routine use in spontaneous vaginal deliveries showed that selective use resulted in 30% fewer women with severe perineal/vaginal injuries (1). No protective effect was seen in sub-analyses of nulliparous women only, or when excluding median episiotomies (1). Since this Cochrane review, selective use is universally recommended in spontaneous vaginal deliveries, although some countries still perform routine episiotomy, notably in nulliparous women (3, 8-10).

2.8.7 Episiotomy in vacuum extraction

2.8.7.1 Previous studies in favor of episiotomy

Lateral or mediolateral episiotomy has been associated with a reduced rate of OASIS in VE in nulliparous women in a several large register-based studies across Europe, which was presented in a meta-analysis in 2016 (12). The review and studies published after the review are summarized in Table 2.

Table 2. Summary of studies of episiotomy in VE in nulliparous women

Study	OASIS reduction	NNT	NNH
Lund 2016 (12)	OR 0.53 (95% CI 0.37-0.77)	18	
Shmueli 2017 (122)	1.9% vs 1.5%		250
van Bavel 2018 (105)	aOR 0.14 (95% CI 0.13-0.15) 14% vs 2.5%	8	
Marschalek 2018 (123)	aOR 0.72 (95% CI 0.70-0.75)	50	
Boujenah 2019 (47)	2.1% vs 0.8%	77	
Frenette 2019 (124)	aOR 1.12 (95% CI 1.02-1.22)		No Data
Gachon 2019 (125)	aOR 0.19 (95% CI 0.02-0.74) 1.1% vs 5.7%	22	
Schreiber 2020 (126)	3.2% vs 2.6%	167	
Ankarcrona 2021 (127)	ATE -3.66% (95% CI -4.31 to -3.01) 15.5% vs 11.8%	27	
Desplanches 2022 (128)	aOR 0.27 (95% CI 0.20-0.38) 3.4% vs 1.3%	48	

NNT = numbers needed to treat, NNH = numbers needed to harm, ATE = average treatment effect.

The prevalence of OASIS may just as well increase when restrictive use is implemented in a hospital where routine is the norm (125). A single-center Swedish study showed a decrease in OASIS from 15.1% to 3% during a 7-year period after introduction of an obstetric care bundle for the prevention of OASIS (93). During the study period, the rate of mediolateral and lateral episiotomies increased from 26% to 56% (93).

2.8.7.2 Previous studies not in favor of episiotomy

A meta-analysis of "no use" vs selective use of episiotomy was carried out in 2020 (129). Only two RCTs were eligible for the analysis (130, 131). Neither of the studies could show a difference in OASIS between "no use" vs selective use. This is probably explained by the rate of episiotomy being the same in the two study arms in both studies. As for today, no RCTs addressing routine episiotomy vs no episiotomy in nulliparous women in VE have been powered to show a difference.

2.8.7.3 Guidelines

There are few national obstetric guidelines in Sweden, and none regarding episiotomy. There are other publications proposing how to use episiotomy in VE: A report from Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) (132) and a web-based educational program produced by the Swedish Society of Obstetrics and Gynecology (SFOG), the Swedish Association of Midwives, and the Swedish National Patient Insurance Company (LÖF), aimed at reducing avoidable injuries to the baby and the mother (132). In both, it is recommended to *consider* episiotomy in nulliparous women in need of VE.

In comparison, several countries' national guidelines as well as experts in the field *recommend* that episiotomy should be performed in operative vaginal delivery (133, 134). On the other hand, the World Health Organization does not recommend routine use of

episiotomy in operative vaginal delivery (135). They emphasize that the role of episiotomy during operative vaginal delivery due to fetal distress remains to be established, while other indications such as protecting against OASIS are not mentioned (135).

2.8.8 Episiotomy and LAM avulsion

Association between episiotomy and LAM injury in nulliparous women has been shown in a large meta-analysis of cohort studies of mixed modes of vaginal delivery (136). In studies including only spontaneous vaginal deliveries, no association has been found (137, 138). It might not be the episiotomy per se that augments the risk for LAM avulsion, but instead the conditions necessitating episiotomy, but to date there is study that can account for the potential confounders.

2.8.9 Is there an optimal rate of episiotomy?

The optimal rate of episiotomy has not been settled. In a study of aggregated data from 20 European countries there was an inverse association between a countries rate of episiotomy and rate of OASIS (Figure 9) (8). The OASIS rate in Sweden is high compared to other European countries and may be related to the low rate of episiotomy (8).

In the meta-analysis by Lund et al 2016, episiotomy was found to be more protective when performed in more than 75% of the VE (OR 0.37, 95% CI 0.15-0.92) (12). A low rate of episiotomy may affect the skills of cutting a protective episiotomy which could partly explain the differences in NNT. In settings where routine episiotomy is used at operative delivery, non-use could be concurrent with other risk factors for OASIS, such as lack of time/imminent delivery, or unskilled operator. Apparently, operators judge the need for episiotomy very differently in different hospitals (125). It may simply not be possible to use episiotomy "as needed" since operators cannot predetermine who will sustain an OASIS or not.

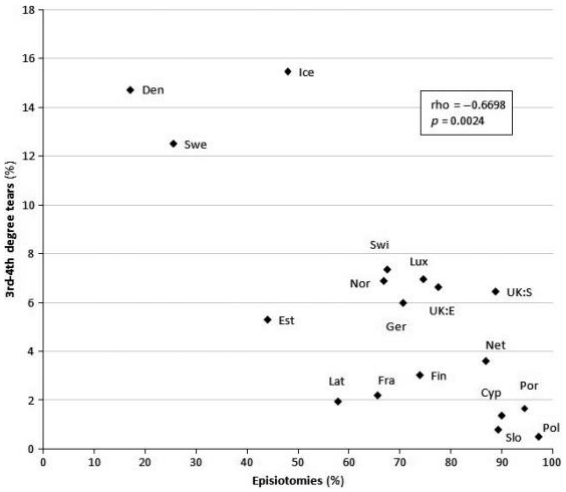


Figure 9. The relationship between proportion of episiotomies and proportion of 3rd and 4th degree tears, operative vaginal delivery, mixed parity. Blondel B, Alexander S, Bjarnadottir RI, Gissler M, Langhoff-Roos J, Novak-Antolic Z, et al. Variations in rates of severe perineal tears and episiotomies in 20 European countries: a study based on routine national data in Euro-Peristat Project. Acta obstetricia et gynecologica Scandinavica. 2016;95(7):746-54. Reprinted with permission from AOGS.

2.8.10 Post-episiotomy

2.8.10.1 Sexual function: episiotomy vs no episiotomy

In 2005, a systematic review investigated sexual health after routine vs restrictive episiotomy (139). There was no difference in the proportion of women who restarted their sexual activity or stopped experiencing dyspareunia three months postpartum (139). Mediolateral episiotomy was equivalent to a spontaneous second-degree tear in terms of resumption of sexual activity one year postpartum (140). A Cochrane systematic review from 2017 yet again confirmed little or no difference in dyspareunia postpartum between women randomized to episiotomy and those who were not (1). In 2020, a review came to similar conclusions (141).

2.8.10.2 Wound infection and dehiscence

Wound dehiscence is a gap of ≥5 mm between wound edges (142). Postpartum perineal wound infection and dehiscence occurs in 0.1-23.6% and 0.2-24.6% of vaginal births (143). An infected episiotomy is a common underlying cause (144, 145). However, no difference in wound infection between selective and routine episiotomy has been shown (1), and prophylactic antibiotics does not seem to decrease the risk of wound infection (146, 147).

2.8.11 Mediolateral vs lateral episiotomy

Karbanova et al conducted an RCT in 2010-2012 addressing peripartum outcomes of mediolateral vs lateral episiotomy (148). There was no significant difference in additional perineal or vaginal trauma in the continuation of the cut. The incidence of OASIS did not differ (1.5% vs 1.3%). Mediolateral episiotomy required less suturing material and took 2 minutes less to repair compared to lateral episiotomy (148).

No difference between lateral and mediolateral episiotomies has been found considering pain the first days postpartum (148). However, a mediolateral episiotomy with an angle of <40° has been associated with more perineal pain the first week postpartum compared to a wider angle (149). Nor has dyspareunia been related to the type of episiotomy (150, 151). In the RCT by Karbanova et al, no difference was seen in anal incontinence between the two types of episiotomies after six months (152).

2.8.12 Attitudes towards episiotomy

Episiotomy should be used selectively and restrictively, according to the Swedish National Board of Health and Welfare's State-of-the-Art of Normal Delivery (153). What this exactly means is not clear, although operative vaginal delivery could be such a selected situation. The current use of episiotomy in VE in Sweden is restrictive (33%) but varies widely from 8% to 80% which could reflect different interpretations of indication (16).

2.8.12.1 Attitudes in the Nordic countries

A Nordic survey among 297 doctors, including 53 Swedish consultants and one trainee, assessed use of, and perceived indications for, episiotomy (114). Only one doctor believed

that episiotomy was always incorrect. The rest thought that it was right on clinical indication. "Fetal distress" was the most accepted indication across countries. "Risk of OASIS" was considered an indication among 42-49% of Finnish and Norwegian doctors and 32% of Swedish doctors, in contrast to 8% of Danish doctors. "Instrumental delivery" was an indication according to 45-51% of Finnish and Norwegian doctors, but 17% of Swedish and 10% of Danish doctors. Accordingly, 90% of the doctors in Sweden and Denmark said they hardly ever used episiotomy, while doctors in Finland and Norway said they used episiotomy in ≥50% of their instrumental deliveries (114).

2.8.12.2 Attitudes worldwide

Outside Scandinavia, a handful of studies report on doctors' attitudes and perceptions regarding episiotomy in VE. In Vietnam and Jordan, routine episiotomy is practiced and favored by over 70% of doctors (154, 155). Reasons for routine use were reduction of OASIS, lack of training on how to minimize tears, traditions, and cultural aspects (154, 155). Similar reasons have been observed in China and Brazil (156, 157). An additional reason for routine episiotomy could be lack of time to wait for the perineum to stretch (156).

In the United Kingdom, a large survey to establish the current practice regarding operative vaginal delivery and episiotomy was performed prior to a planned RCT (158) of restrictive versus routine use of episiotomy in operative vaginal delivery (159). Over 1600 members (80%) of the Royal College of Obstetricians and Gynaecologists responded (159). Most doctors used routine episiotomy in forceps but were more restrictive in VE (159). In all, 45% of doctors believed that episiotomy decreased the risk of OASIS at VE and 66% at forceps (159). In Israel, a smaller survey showed that 58% of doctors considered VE an indication for episiotomy (160).

Less experienced doctors seem more likely to use routine episiotomy in both VE and forceps in both the United Kingdom and Israel (159, 160). In Israel, few doctors reported to base their practice of episiotomy on objective sources of information (medicine studies and professional literature), while most doctors admitted being informed through personal experience and senior colleagues (160). In the United States, doctors who have worked ever since episiotomy was routinely used, were less prone to adapt to a restrictive use (161). Given this, traditional routine use may be hard to change.

2.8.13 Episiotomy and consent: What is obstetric violence?

Both women and care givers experience lack of information and consent considering episiotomy (162). In a qualitative study in China, where routine use is practiced, women express lack of knowledge and consent (163). The effect of episiotomy was described as a "psychological shadow" and women felt they were doomed to suffer alone and not complain (163). With an episiotomy rate of 70%, China could have as many as 7.3 million unconsented episiotomies per year (163).

Episiotomy is performed during the last phase of second stage of labor, sometimes when there is no time to go through an accurate informed consent procedure. A review of legal cases showed that most episiotomy-related lawsuits originated from a routine use (164), although routine use is discouraged (1). Antenatal written information about episiotomy could reduce anxiety and increase acceptance among women (165). A further step is an episiotomy consent form proposed in 2019 but is not yet in use (166).

In 2018, a review article was published addressing the term "obstetric violence" (167). Opinions on obstetric violence among interviewed women differed between verbal, physiological, psychological, and sexual violence, as well as social discrimination, neglect of care, and inappropriate use of technologies (167). Of the included articles, 80% were published after 2015, mirroring that this issue is just recently being brought to the surface. More than half of the studies originated from South America and only a few from Europe (167). In 2014, WHO characterized any form of "disrespectful and abusive care during childbirth" as a human rights violation – including physical and verbal abuse, refusals of care and medication, and forcible or unconsented medical interventions (168). Based on this, the Lancet executed in 2016–2018 a cross-sectional study prospectively recruiting women ≥15 years of age in Ghana, Nigeria, Myanmar, and Guinea (169). The study was published in the Lancet in 2019 (169). Participants were observed by a researcher during labor and answered a questionnaire. In summary, more than one third experienced mistreatment and 75% did not consent to episiotomy (169). The same year, a literature review suggested routine episiotomy as an act of violence (170).

2.9 ADVANCED MATERNAL AGE

There is no global consensus of when a mother-to-be is of advanced age. This makes comparison or synthesis of the literature difficult, although ≥35 or ≥40 years is often used (171-175).

The proportion of women postponing childbirth until they reach the age of 40 years has tripled in Sweden in the last three decades, and now comprises 2.5% of all first-time mothers (176). This trend is similar across Europe, the United States, and Asia (174, 177, 178).

2.9.1 Trial of labor in advanced maternal age

Labor is more often induced in older women, due to accumulated and perceived risks of prolonged pregnancy (173, 175, 179-181). When comparing modes of labor onset, it is important to realize the difference between induction of labor vs spontaneous onset of labor, in contrast to induction of labor vs expectant management. Women with expectant management might enter spontaneous labor later, be induced for medical or psychosocial reasons or undergo pre-labor cesarean section. Consequently, at any point, the clinical decision is not between induction or spontaneous onset, but between induction and expectant management.

2.9.2 Evidence from observational studies

Multiple observational studies have reported that induction of labor is associated with increased intrapartum cesarean sections and other adverse maternal and perinatal outcomes, independent of maternal age (182-184). However, a Norwegian study of low-risk nulliparous women showed that the rates of operative vaginal delivery and intrapartum cesarean section were higher in women ≥40 years than in women 20-24 years, regardless of onset of labor (185). It has been suggested that the pure knowledge about an increased risk of intrapartum cesarean section in older women may lower the threshold for intervention (186).

Moreover, a systematic review showed that even in a selected population of women ≥35 years, induction of labor was not associated with increased intrapartum cesarean section compared with spontaneous onset (187). The meta-analysis included two retrospective cohort studies with nulliparous low-risk pregnancies and six RCTs including all parities with a blended risk. Induction of labor was performed using a variety of methods, including cervical ripening, amniotomy, and oxytocin (187).

2.9.3 Evidence from randomized controlled trials

An RCT conducted in the United Kingdom in 2016 (35/39 trial) compared elective induction of labor with expectant management in low-risk nulliparous women ≥35 years (172). There was no significant difference in intrapartum cesarean section (32%) or operative vaginal delivery (30%) between the two groups (172). In 2019, Grobman et al published the ARRIVE trial, a multicenter RCT comparing elective induction with expectant management in low-risk nulliparous women in the United States (188). The frequency of intrapartum cesarean section was significantly lower in the induction group (18.6%) than in the expectant management group (22.2%) also in women ≥35 years (188). Notably, both studies included low-risk women. An RCT conducted in Sweden designed to assess adverse perinatal outcome in induction of labor at 41+0 weeks compared with expectant management until 42+0 weeks showed no difference in intrapartum cesarean section or VE (17). The study was stopped early for safety reasons, due a significantly higher rate of perinatal mortality in the expectant management group (17). There were no outcome differences related to maternal age (17).

A Cochrane systematic review of 34 RCTs of induction at ≥37 weeks vs expectant management has concluded that there are lower cesarean rates without increasing rates of operative vaginal births in the induction group (189). All of this supports that it is not the induction that increases the rate of cesarean section in older mothers, but rather the reason for the induction.

2.9.4 OASIS and advanced maternal age

Advancing age in nulliparous women may increase the risk for OASIS even after adjusting for mode of delivery (40, 190). An Israeli study from 2022 studied risk factors for OASIS in women ≥35 years (191). The usual risk factors were found: higher birthweight/gestational

age, more epidurals, and operative vaginal delivery, but only birthweight and hypertensive disorder were positively associated with OASIS in the multivariate analysis (191).

2.9.5 Adverse neonatal outcome

Increasing maternal age has been associated with intrauterine growth restriction and stillbirth, which seems to be related to abnormal placentation (173, 186). The risk for placental dysfunction seem independent of age-related comorbidities, but also independent from protective factors such as high socioeconomic status, non-smoking, and attendance to antenatal care (192). However, intrauterine growth restriction in stillbirths is not more common in older women compared with younger women, suggesting that placental dysfunction may not be the only explanation (193). The risk of stillbirth ≥40 years is doubled compared with women <25 years (194). This is comparable to the risk of stillbirth in women who smoke, are obese or nulliparous, and less than women with preeclampsia and diabetes (195). Women ≥45 years may also have a higher risk of low Apgar score (196).

3 RESEARCH AIMS

The overall aim of this thesis is to add more and new knowledge to obstetric care in Sweden in our effort to reduce the risk of OASIS at VE in nulliparous women. We aim to do this by applying both clinical and epidemiological methodologies. If possible, we would like to increase the knowledge, understanding, and attitudes about episiotomy in VE.

3.1 AIMS OF THE STUDIES

3.1.1 Study I

To assess outcomes of trial of labor in nulliparous women ≥40 years compared with nulliparous women 25-29 years, specifically mode of delivery, risk of OASIS, risk of episiotomy, and risk of low Apgar score at five minutes, stratified for spontaneous and induced labor.

3.1.2 Study II

To emulate an RCT using propensity score methods to investigate if routine lateral or mediolateral episiotomy compared with no episiotomy reduces the prevalence of OASIS in VE in nulliparous women.

3.1.3 Study III

To explore the attitudes, use, and technique regarding episiotomy among doctors in Sweden, and their willingness to contribute to an RCT of lateral episiotomy or no episiotomy in VE in nulliparous women.

3.1.4 Study IV

To look at if a standardized lateral episiotomy may cause an iatrogenic injury to the levator ani muscle in VE in nulliparous women, and if the trigonometric properties have an impact on the risk of levator ani muscle injury.

4 MATERIALS AND METHODS

4.1 REFLECTION AND ETHICAL CONSIDERATION

All studies in this thesis have been ethically approved by the Regional Ethical Review Boards in Stockholm and/or Gothenburg.

Paper I: Gothenburg (2015/092-06, T885-15).

Paper II: Gothenburg (2015/092-06, T885-15) and Stockholm (2018/1627-31/2).

Paper III: Stockholm (2015/1238-31/2, 2017/1005-32, and 2018/2291-32).

Paper IV: Stockholm (2015/1238-31/2, 2017/1005-32, and 2018/775-32).

Considering **paper I and II**, there are ethical dilemmas common to all register-based studies. Data from medical records are forwarded to SMBR without patient consent, while research on this data is approved by ethical review boards and the National Board of Health and Welfare before delivery of data. Even though the data bases are pseudonymized and very large, it is hypothetically possible to identify individual women based on rare outcomes or demographic features, and date of delivery. Care must therefore be taken to present data by appropriately delimited groups. Research on register data can most often be defended by a positive risk-benefit relationship, as the risk of harm by threat to integrity is much lower, if data are handled correctly, than the benefit of increased knowledge for the population.

In **paper III**, a web-questionnaire was sent by email to all members of the Swedish Society of Obstetrics and Gynecology. Participation was voluntary and responses were anonymous. We made efforts to ensure personal data protection and reduce the risk of invasion of privacy. The research group did not have access to the identity of the respondents. A private company received the email address list, distributed, and collected the questionnaires on our request. The company was made accountable to keep email addresses protected from all unauthorized use.

Paper IV, a nested prospective cohort study within the EVA trial and the EVA trial itself, poses several ethical issues. The EVA trial is conducted according to Good Clinical Practice and the World Medical Association Declaration of Helsinki. Participation is voluntary and can be discontinued at any time without further explanation. Participation is dependent on signed informed consent, and thus ensuring a balanced, yet effective, and comprehensive information is the major challenge. Eligible women are given oral and written information and have the opportunity to ask questions before signing consent when the woman is receptive and has the time to consider her options and ask questions. The woman should not be in pain or distress, or lack resources to understand the information, for example by a language barrier. Care must be taken not to place pressure on the woman to participate, as she is dependent on healthcare providers and in a vulnerable situation and may feel pressure to be a “good patient”. In the EVA trial, concerns have been raised that study information, including details about VE, episiotomy, and tearing, will frighten women. To elucidate this

issue, a semi-structured qualitative interview study of 23 women who had received information about the EVA trial has been undertaken by our research group and found that women's experience varied widely but that women appreciated the information, especially when given in a calm situation (197). No woman felt intimidated or pushed to participate (197). Some voices have been raised against the proposed benefits of participation as participating women receive "unfair" benefits that ideally should be available for all women. Postpartum follow-up in the EVA trial is extensive and easily accessible compared to routine care. However, the follow-up is necessary to collect all relevant data. On the other hand, woman may feel pressured to follow the protocol once they signed informed consent. Care must be taken to capture reluctance. Participating women are not economically reimbursed. Nevertheless, there might be an economic incentive for antenatal midwifery units and hospitals to recruit women as they receive economic compensation for each signed consent and each randomized woman. To avoid undue pressure to collect informed consents or randomize women, compensation goes to the unit, not the midwife or doctor, and covers expenses for administration of the consent forms, extra time needed to inform women about the study, and for hospital follow-up.

Moreover, prior to trial start, hospitals participating in the EVA trial received education in performing a lateral episiotomy with correct trigonometric properties, but we are not able to control that episiotomy is performed correctly in the trial or in clinical practice. Performing an "unprotective" episiotomy may also be considered unethical. As described in the background, doctors' opinion and use of episiotomy at VE are highly variable. The woman about to give birth by VE is at a 8-80% risk of episiotomy depending on hospital (16). From previous observational research, OASIS seems to be more detrimental, both physically and psychologically than episiotomy, although episiotomy is not an entirely uncomplicated procedure and may entail sequelae (1). The balance to be settled is at what risk-benefit routine episiotomy is defensible. Numbers needed to treat varies widely in retrospective register studies (Table 2) which may be afflicted by methodological limitations. Appropriate RCTs will give us information to implement evidence-based practice. Yet again, to achieve this desirable evidence, we are dependent on the participation of individuals.

Finally, a dilemma is that we may do more harm than good for individual women. This is applicable to both women allocated to routine episiotomy and women allocated to no episiotomy. We will never know if the woman who had a routine episiotomy would not have sustained a tear, or if we could have protected a woman from OASIS if she had received an episiotomy. This is the actual research question and can only be determined on a group level.

4.2 PAPER I METHOD AND STATISTICAL ANALYSES

4.2.1 The Swedish Medical Birth Register

The Swedish Medical Birth Register (SMBR) holds recorded data on more than 98% of all births in Sweden since 1973, including demographic data, reproductive history, and perinatal outcomes. Starting with the first antenatal visit, normally between 8-12 weeks of gestation, information on parity, maternal weight, height, smoking habits, cohabitation status, assisted reproduction, chronic hypertension, and pre-gestational diabetes is prospectively collected by the midwife. The standardized records are identical throughout the country and passed on to SMBR. Onset of labor was introduced in SMBR in 1992 and episiotomy in 2000 (198). The SMBR has been evaluated three times and the latest validation was reviewed by the Center for Epidemiology at the National Board of Health and Welfare in 2003 (198). The validation contained two different approaches by cluster sampling. Firstly, data in the register were compared to data in the standardized records (checkboxes). Secondly, the registered medical diagnoses in SMBR were compared with a more extensive review of the content in medical records (198).

4.2.2 Method

Paper I is a nationwide population-based study based on SMBR from January 1, 1992 to December 31, 2011. We included all nulliparous women with a singleton, live fetus in vertex presentation, who gave birth at term and our final cohort consisted of 272 058 women (Figure I:1). We excluded multiparous women, and all women with either unknown or mixed mode of onset of labor, unknown maternal age, or women with a pre-labor cesarean section.

We identified presence of preeclampsia, hypertension, diabetes, pre-labor rupture of membranes, labor dystocia, and intrapartum fetal distress using International Classification of Diseases versions 9 and 10 (ICD-9 and ICD-10) codes for these diagnoses (Appendix I:1). Preeclampsia and hypertensive disease were collapsed into one covariate and different kinds of diabetes into another. Information on epidural anesthesia was collected from the standardized obstetrical record (checkboxes) in the SMBR.

Our exposure was maternal age ≥40 years. Maternal age 25-29 years was used as reference as 27.2 years was the median age during our study period. The exposure group and the reference group were stratified according to mode of labor onset; spontaneous versus induction, and comparisons were made within each stratum.

The primary outcome was mode of delivery categorized as intrapartum cesarean section, operative vaginal delivery, and spontaneous vaginal delivery. Our secondary outcomes were OASIS, episiotomy, and 5-minutes Apgar score <7, which was defined as a low Apgar score. We computed a combined variable to ensure that all cases of OASIS were included in our cohort. This variable should contain at least one of the following: an ICD-9 or ICD-10 code for OASIS in the medical record, checkboxes marked for injury to the “sphincter” or “rectum”, or a procedure code for anal sphincter repair.

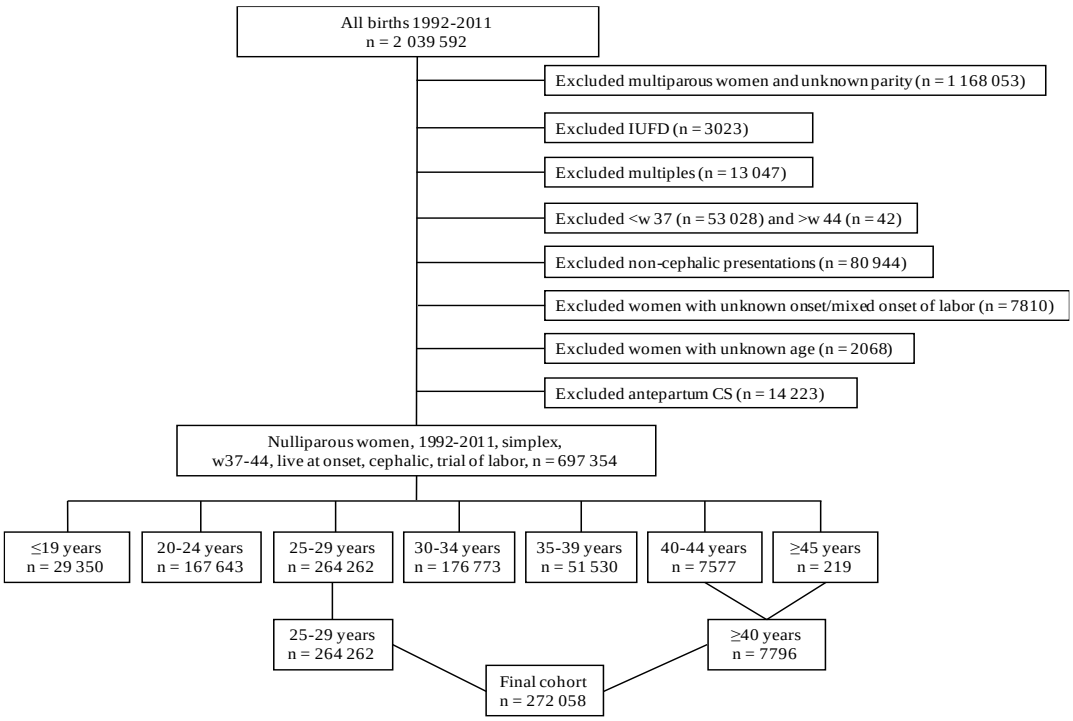


Figure I:1. Flowchart of the study cohort.

To ensure inclusion of all cases with episiotomy, we used data from checkboxes and procedure codes registered after delivery. Apgar scores were collected from the standardized neonatal record.

Maternal BMI was categorized according to WHO's definition of obesity (<30 or ≥30 kg/m^2), and maternal height was categorized into <160 cm or ≥160 cm, since an increased risk of intrapartum cesarean section and operative vaginal delivery has been observed below this cut-off (199). Smoking included any smoking during pregnancy and reproduction included in vitro fertilization (IVF) or intra-cytoplasmatic sperm injection (ICSI).

In SMBR, gestational age at birth, birthweight, and head circumference is collected from the standardized neonatal record. Gestational age at birth was given using a hierarchy of estimated date of delivery by embryo transfer, early second trimester ultrasound, or last menstrual period. Gestational age was categorized into week intervals (week 37-38, 39-40, 41, ≥42). We separated 41 from 42 weeks, since nulliparous women ≥40 years are recommended induction of labor at 41 weeks in some parts of Sweden. Birthweight was categorized into 500 g intervals (<2999 g, 3000-3499 g, 3500-3999 g, 4000-4499 g, ≥4500 g). Head circumference was dichotomized into <38 cm or ≥38 cm. This cut-off represented the 95th percentile in our material.

4.2.3 Statistical analyses

Prevalence and risks of intrapartum cesarean section, operative vaginal delivery, OASIS, and a low Apgar score were calculated for the exposure group and refences group both after spontaneous onset and induction of labor. Risks were calculated by unconditional logistic

regression and presented with crude odds ratios (OR) and adjusted odds ratios (aOR) with 95% confidence intervals (95% CI).

Firstly, we calculated prevalence of characteristics in women in our exposure group and our reference group, compared by tests of proportions (Chi^2). Missing data was missing at random and evenly distributed in both groups. In the next step, to identify confounders, we calculated the crude OR and the prevalence of intrapartum cesarean section for covariates with significant differences between age groups.

Finally, in the multivariate regression analyses, adjustments were made for covariates with significant differences in risk of intrapartum cesarean section. The aOR for OASIS was calculated for women with vaginal births only and stratified for spontaneous vaginal delivery and operative vaginal delivery The aOR for a low Apgar score was calculated using the same covariates, also stratified for mode of delivery. Statistical analyses were performed using SPSS statistics version 24.0 (IBM, Armonk, USA).

4.3 PAPER II METHOD AND STATISTICAL ANALYSES

4.3.1 Method

Paper II was a retrospective nationwide population-based study on nulliparous women in gestational week ≥34+0 with a singleton, live, non-malformed fetus in cephalic presentation delivered with VE, with a lateral or mediolateral episiotomy or no episiotomy. Data was collected from SMBR from January 1, 2000 through December 31, 2011. The SMBR has been described in the method of **paper I**.

The SMBR does not specify which kind of vacuum cup is used for extraction, but metallic cups are most common in Sweden. Episiotomy was introduced in SMBR in 2000. Episiotomy was identified using marked checkboxes indicating left, right, or median episiotomy, or procedure code (TMA00). Median or non-specified episiotomies were excluded from analyses. The extraction of the study population in is shown in Figure II:1.

The maternal and delivery baseline characteristics were categorized as follows: maternal age (<19, 20-24, 25-29, 30-24, 35-39, ≥40 years), maternal continent of birth (Europe and United States of America, Canada, New Zeeland and Australia as one category, and Asia, Africa, and Latin America as separate categories), maternal height (<160 cm or ≥160 cm), maternal BMI (<18.5, 18.5-24.9, 25.0-29.9, 30.0-34.9, ≥35.0), smoking (yes or no at any timepoint during pregnancy), cohabitation (yes or no), diabetes (pregestational and gestational, yes or no), preeclampsia or hypertension (pregestational and gestational, yes or no), Crohn's disease or ulcerative colitis (yes or no), female genital mutilation (yes or no).

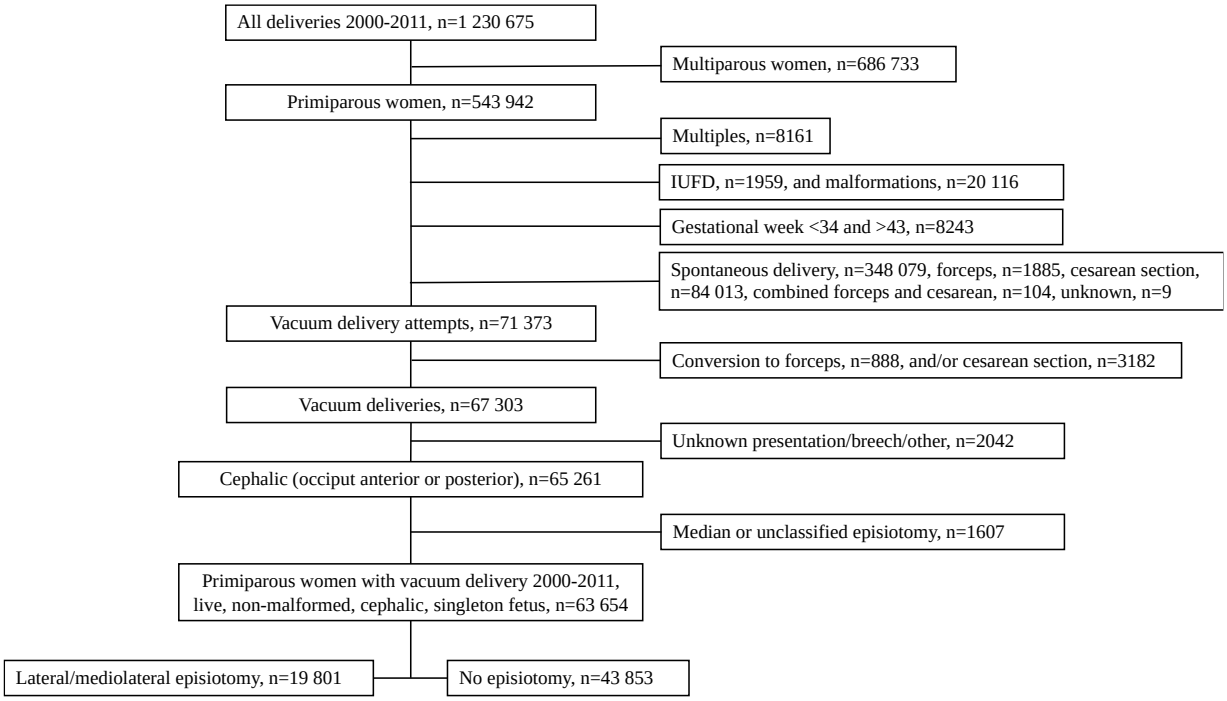


Figure II:1 Flowchart of study population.

Delivery characteristics were categorized as follows: onset of labor (spontaneous or induction), gestational age (34-36 weeks, 37-40 weeks, or ≥41 weeks), epidural anesthesia (yes or no), labor dystocia (yes or no), intra-partum fetal distress (yes or no), fetal head station at VE (outlet, mid-cavity, unspecified), and fetal head position (occiput anterior or occiput posterior).

Neonatal characteristics were categorized as follows: Fetal head circumference (<38 cm or ≥38 cm, which corresponds to the 95th percentile), neonatal sex (boy/girl), birthweight (<3000 g, 3000-3499 g, 3500-3999 g, 4000-4499 g, ≥4500 g). Apgar at 1 minute (≥4 and <4) served as a proxy for severely abnormal CTG during the VE, shoulder dystocia (yes or no), and year of delivery. Hospital of delivery was limited to hospitals with at least 100 VE during the study period.

Missing data on continent of birth of the woman giving birth, maternal height, BMI, smoking, cohabitation, fetal head station, and head circumference were categorized as “unspecified” to avoid exclusion of women with frequently missing data. For all other covariates missing data occurred in less than 1% of the treated or nontreated women, and these observations were not included in the analysis.

Our primary outcome was OASIS, defined by ICD-10 codes, marked checkboxes, or the procedure code indicating repair of a third- or fourth-degree perineal injury (MBC33). The secondary outcome was a fourth-degree perineal injury defined by ICD-10 code (O70.3) or a marked checkbox (injury to the rectum). For ICD-10 codes added to characteristics and outcomes, see supplementary Table SII:1.

4.3.2 Statistical analyses

Chi^2 tests were performed to determine if there was a statistical difference in maternal or delivery characteristics between women with and without episiotomy and women with and without OASIS. Thereafter, we calculated the propensity score for each woman. In the model, we included characteristics that could potentially influence treatment or outcome if they had a p-value <0.20 in the bivariate analyses. Then, we calculated the average treatment effect (ATE), which can be described as an estimated treatment effect in a population if everyone would receive the treatment. We used a doubly robust method, combining inverse probability weighting (IPW), and the outcome regression method. We also examined the data using IPW alone, as well as regression adjustment. In regression adjustment the propensity score is included as an independent variable together with the exposure (200). We checked for the positivity assumption by examining propensity scores overlap between the two treatment groups (not shown). We also checked for the balance of baseline characteristics after inverse probability weighting of each observation (supplementary Table SII:2 and SII:3). The results are presented as the ATE of episiotomy on OASIS with 95% CI and numbers needed to treat (NNT) calculated as 100/ATE. Statistical analyses were made using STATA 16.1 (StataCorp, College Station, Texas, USA).

4.3.2.1 Propensity score

The propensity score is a balancing score (i.e. a value between 0-1) and mimics the probability of a treatment assignment conditional on observed baseline characteristics (201). Standard regression models to control for confounding by indication on the association between episiotomy and OASIS may be unsatisfactory. The propensity score can be used to emulate an RCT as, conditional on the propensity score, the distribution of baseline covariates will be similar between the exposed and unexposed. This was comprehensively explained by Shah et al: "*Two patients with the same propensity score have an equal estimated probability of exposure. If one was exposed and the other unexposed, the exposure allocation could be considered random, conditional on the observed confounders. Therefore, like in a randomized trial, there is balance of the confounders between exposure groups after adjusting for the propensity score"(202)***.** Propensity scoring aims to emulate randomization of subjects as occurs in RCTs. Nonetheless, unlike randomization to treatment groups, the balancing achieved by propensity scoring is based only on identified confounders rather than all possible confounders. Thus, if essential factors are not identified, or are omitted, the accuracy of the propensity scoring method will be weakened.

The propensity score is most commonly estimated by using logistic regression with the exposure, in our case episiotomy, as a dependent variable, meaning that episiotomy serves as the outcome in the regression analyses. Instead of controlling for confounding by adjusting for the association between covariates and the outcome, we can control confounding by using the propensity score as defined above. The modeling constraints, the effect of assumptions, and the risk of bias due to residual and unmeasured confounding that are present in regression analyses, still applies when using the propensity score (200). The propensity score is not a

panacea for confounding issues in observational research. In theory, propensity score methods are neither better nor worse than regression methods based on the same assumptions. Both approaches can only adjust for measured and included covariates (200). Propensity score methods and classic multivariate regression models have also shown similar results in a systematic review (202). The propensity score methods gave slightly weaker associations, as they were not used optimally in the majority of the included articles (202).

In observational studies, the treatment is often influenced by the caregiver and the subject, leading to treated and untreated being systematically different, which may lead to confounding of the treatment effect (203). Nevertheless, when using the propensity score, it is challenging to decide which variables to control for when trying to remove the effect of treatment selection bias. The variables can be described in terms of their relationship either to the outcome, the treatment, or both. The true confounder model includes variables related to both treatment and outcome and has been shown to increase statistical power and lead to the best unbiased results in Monte Carlo simulations. This is the model used in our analyses (203).

4.3.2.2 Doubly robust method

The maternal and delivery characteristics contributing to OASIS often correspond to the risks leading to episiotomy. Therefore, causal inference versus confounding may be difficult to disentangle. The doubly robust method allowed us to adjust for characteristics irrespective of their relation to the treatment or outcome. The doubly robust method combines two approaches to estimate causal effect of a treatment or exposure on an outcome. In our study this was the case with the effect of episiotomy on the risk of OASIS. Subsequently, the double robust model will provide correct reasoning when either the treatment selection model (propensity score model) or the outcome regression model is correct (204).

4.3.2.3 Inverse probability weighting

The IPW is one way to control for confounding using the propensity score (PS). In this method a pseudo-population is created in which covariates leading to confounding are balanced between the exposed and unexposed (200). The pseudo-population is composed by giving each individual a weight. For the exposed the weight is 1/PS and for the unexposed 1/(1-PS). This creates a pseudo-population assigned to each of the two treatment groups, with balanced patient characteristics.

4.4 PAPER III METHOD AND STATISTICAL ANALYSES

4.4.1 Method

Paper III was a web-based questionnaire study among members of SFOG with a registered email in the member register 2019 (n=2140). Participation was voluntary and answers were anonymous. Participants were asked to answer the questionnaire on a computer rather than a smartphone, to be able to depict an episiotomy (Figure III:1).

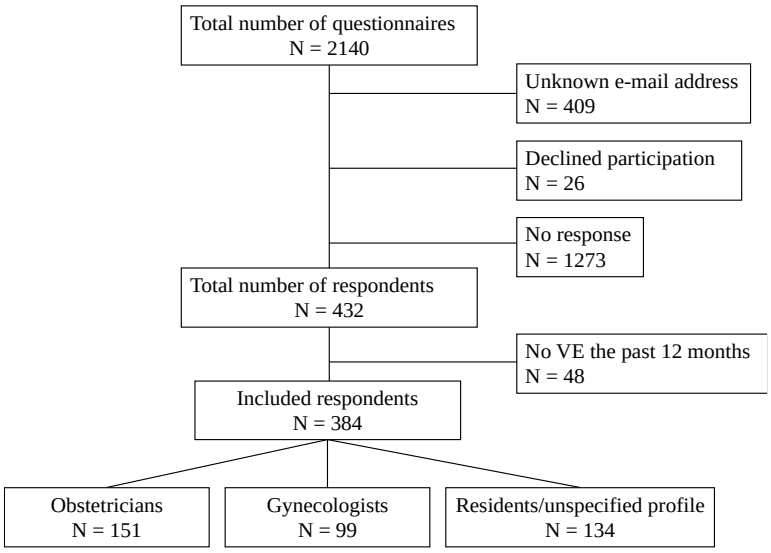


Figure III:1 Flowchart of study participants.

The questionnaire included 25 closed answer questions (see supplementary information). It addressed the characteristics of the respondent, their clinical profile (obstetrician, gynecologist or resident/working in both fields as in a smaller hospital = unspecified) and their clinical role at VE, their attitude towards episiotomy, how often and in which situations they would consider performing an episiotomy. They were also asked to rank given perceived protective measures against OASIS in VE in nulliparous women and finally they were asked to draw the episiotomy they would perform in a clinical situation on a two-dimensional picture with a crowning fetal head with a cup attached to it, on the computer screen (Figure III:2).

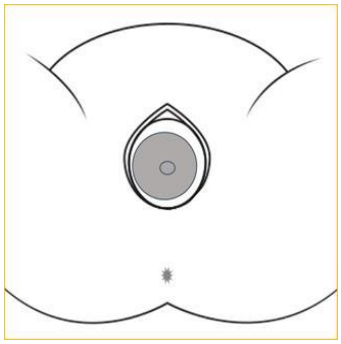


Figure III:2. Two-dimensional schematic picture of a crowning fetal head with a vacuum cup attached. Adapted from Fodstad K, Staff AC, Laine K. Episiotomy preferences, indication, and classification--a survey among Nordic doctors. Acta Obstet Gynecol Scand. 2016;95(5):587-95.

They were also asked to name their episiotomy lateral, mediolateral or midline. At the end they were asked if they would consider participating in an RCT of lateral episiotomy or no episiotomy in VE in nulliparous women, either as a doctor or as a trial participant and what they considered an acceptable NNT to avoid OASIS in a woman (205).

The drawn episiotomies were translated into coordinates in a diagram with the origin of the grid at the posterior fourchette of the vaginal orifice. The episiotomy angle was calculated

from the midline. The length was calculated in millimeters with the distance between the posterior fourchette and anus as reference (40 mm). The incision point was calculated as the straight distance in millimeters from the origin at the posterior fourchette to the incision point. In the analysis the episiotomies were categorized as lateral, mediolateral, midline or unclassifiable according to the classification done by Kalis et al (2). Episiotomies with defined trigonometric properties of a lateral or mediolateral episiotomy including a length of at least 30 mm were considered protective, and the remainder of episiotomies were considered non-protective.

4.4.2 Statistical analyses

Differences in proportion between clinical profiles were calculated by Chi^2 tests. Independent Kruskal-Wallis test were calculated for difference in median for all trigonometric factors of the episiotomy. The odds of drawing a protective episiotomy were calculated using univariate logistic regression for different doctor characteristics and a directed acyclic graph (DAG) was drawn to assess covariates (Figure III:3). A multivariate backward stepwise conditional logistic regression was used to reduce the risk of overadjustment when analyzing the effect of clinical profile. The ranking of preventive measures against OASIS at VE were dichotomized into most and second most important (rank 1-2) versus other ranks (rank 3-5). We used simple tests of column proportions to compare doctors who considered each protective measure most and second most important. Analyses were performed using SPSS (IBM SPSS version 26.0, Armonk, NY: IBM Corp).

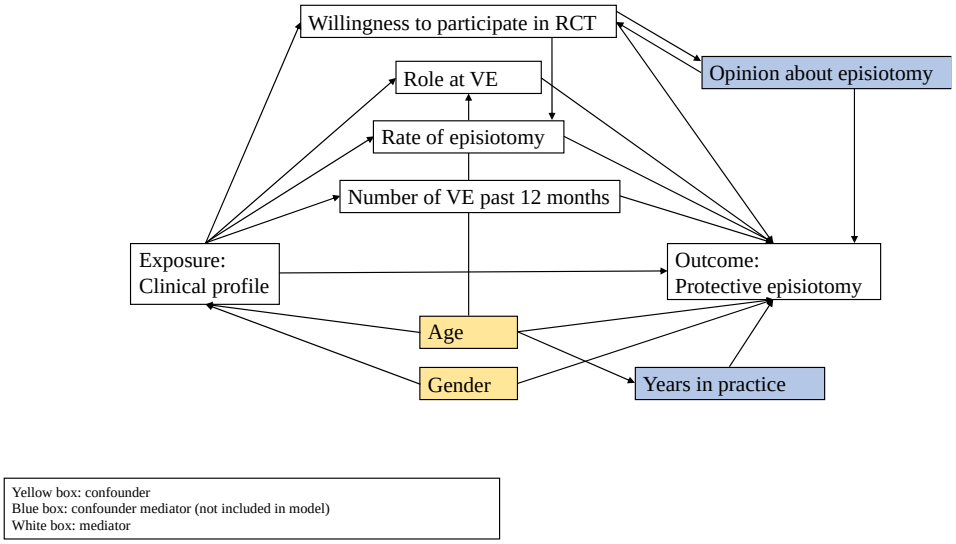


Figure III:3. Directed acyclic graph of the effect of clinical profile on protective episiotomy

4.5 PAPER IV METHOD AND STATISTICAL ANALYSES

4.5.1 Method

Paper IV was a descriptive prospective cohort study, nested within the EVA trial which is an RCT of lateral episiotomy versus no episiotomy in nulliparous women delivered with VE (www.clinicaltrials.gov, NCT02643108) (205). We examined if a lateral episiotomy may

cause an iatrogenic LAM injury on the same side as the episiotomy. Sixty-three women who had received a standardized lateral episiotomy were scheduled for a 3D endovaginal and endoanal ultrasound assessment at the Pelvic Floor Centers at Karolinska University Hospital Huddinge, Danderyd Hospital in Stockholm, and Uppsala University Hospital about one year after delivery. The ultrasound assessments were performed by three different doctors (one on each site). The images were then examined by one well experienced (more than 1000 similar examinations) examiner blinded to if the patient had received an episiotomy or not. Women participating in the EVA trial are allocated to a standardized lateral episiotomy (performed at crowning 1-3 cm from the midline, at a 60° angle, and 3-5 cm long) or no episiotomy. The episiotomy is placed either side of the vaginal opening according to the doctor's preference. Hospitals participating in the EVA trial have received education in performing a lateral episiotomy to ensure that it is performed with the right trigonometric properties.

4.5.1.1 Pelvic exam with episiotomy scar measurement and 3D endovaginal and endoanal ultrasound

Participants in the study had a pelvic exam by one of the investigators in an out-patient setting. The first step was to measure the episiotomy scar. The patient was placed in dorsal lithotomy position, with hips flexed and abducted. Measurements of the scar were taken on the perineal skin using a ruler and protractor. The scar angle against the midline, the length, and the incision point distance from the posterior fourchette were measured. Measuring scars after episiotomy has been described as a proxy for the trigonometric properties of the episiotomy as performed in the delivery room (100, 137).

The next step was the ultrasound examination performed by one of three investigators, all with training in 3D ultrasound examination. The patient remained in the same position as for the scar measurement. No preparation was required, no rectal or vaginal contrast was used, and the patient was asked to have a comfortable volume of urine in the bladder. The probe was inserted into the vagina and anus in a neutral position. BK Medical Flex focus (BK Medical, Peabody, MA, USA) with a transducer equipped with 8838 9 Hz/12 MHz and a high-resolution 3D capability was used. The transducer has a built-in 6 cm linear array that rotates 360^0 inside it and was set at 12 MHz. The 8838 transducer has an internal automated motorized system that allows an acquisition of 300 aligned transaxial 2D images over a distance of 60 mm every 0.2 mm in 60 seconds, without any movement of the probe within the cavity. The endovaginal ultrasound 3D volumes were analyzed off-clinic on a personal computer using the 3D viewing software (BK Medical, Peabody, MA, USA).

Each subgroup of the LAM, namely the pubovaginal/puboperineal/puboanal (PA), puborectal (PR), and iliococcygeal/pubococcygeal (PV) muscles (Table IV:1), was evaluated in its specific axial plane where the full length of the muscle could be visualized and scored on each side, based on thickness and detachment from the pubic bone (206). Scoring of LAM injuries were done according to Levator Ani Deficiency (LAD) score as described previously by Ronstmina et al (207). No deficiency gave zero points, a minor deficiency (<50% muscle loss) one point, a major deficiency (>50% muscle loss) two points, and a total avulsion (total

absence of the muscle) gave three points. Each total side score could range from zero, indicating no deficiency, to a maximum score of nine. For the entire LAM, the LAD score may thus range from 0 to 18. Scores were categorized as a mild (0 to 6), moderate (7 to 12), or severe (≥13) deficiency.

Table IV:1. Nomenclature of portions of the levator ani muscle

	Inner portion	**Middle portion**	**Outer portion**
Shobeiri[a, b]	Puboperineal+puboanal = Puboanal (PA)	Ileococcygeal+pubococcygeal = Pubovisceral (PV)	Puborectal (PR)
DeLancey[c]	Pubovaginal, puboperineal, puboanal = Pubovisceral (former pubococcygeal)	Ileococcygeal	Puborectal

[a] Shobeiri SA, LeClaire E, Nihira MA, Quiroz LH, O'Donoghue D. Appearance of the levator ani muscle subdivisions in endovaginal three-dimensional ultrasonography. Obstet Gynecol 2009 Jul;114(1):66-72.
[b] Javadian P, O'Leary D, Rostaminia G, North J, Wagner J, Quiroz LH, Shobeiri SA. How does 3D endovaginal ultrasound compare to magnetic resonance imaging in the evaluation of levator ani anatomy? Neurourol Urodyn. 2017 Feb;36(2):409-413.
[c] Kearney R, Sawhney R, DeLancey JOL. Levator ani muscle anatomy evaluated by origin-insertion pairs. Obstet Gynecol. 2004 Jul;104(1):168-73. doi: 10.1097/01.AOG.0000128906.61529.6b.

4.5.1.2 Perinatal data

Maternal, delivery, and neonatal characteristics were chosen due to their association with LAM injury (83, 137, 208, 209). Data on maternal age (<35 or ≥35 years), height (<160 or ≥160 cm), BMI (<25 or ≥25 kg/m^2), country of birth (Europe/USA, Africa, Asia or other), female genital mutilation (no or yes), epidural (no or yes), prolonged second stage of labor (<3 or ≥3 hours) (49), fetal head position (occiput anterior or occiput posterior), fetal head station (outlet or mid-cavity), number of pulls (<4 or ≥4), and cup detachment (no or yes) serve as proxies for complicated labor, neonatal head circumference (<35 or ≥35 cm) (83), birthweight (<3000, 3000-3999 or ≥4000 g) were collected from patient medical records. The side of the episiotomy was verified in the medical records.

4.5.2 Statistical analyses

Fifty-eight women had valid endovaginal ultrasound images. The images from five study participants were not possible to analyze due to loss of data caused by hardware problems. Characteristics of the women with and without LAD were described in numbers and proportions and compared by Chi^2 tests. Episiotomy scars were categorized by angle, length, and incision point. Episiotomy scars with an angle of 15-60° to the midline, a length of ≥18 mm, and an incision point of at least ≥10 mm from the posterior fourchette were considered protective in relation to OASIS (100).

This study was an a priori planned safety analysis within the EVA trial. We hypothesized that if a standardized lateral episiotomy causes LAD on any side, the LAD prevalence would be at least 50%. Using test of one proportion, comparing our observed outcome with the stipulated outcome 50%, we would reject our hypothesis with a LAD prevalence of up to 37% ($p<0.05$)

with the current sample size of 58 women. Moreover, if a lateral episiotomy does not cause injury to the LAM, and LAD occur randomly on the left or right side, there would be equal proportions of LAD on both sides irrespective of the side of the episiotomy. Test of one proportion was used to test the hypothesis that the stipulated prevalence of LAD on the same side as the episiotomy would be at least 50% if the trauma was related to the episiotomy. The ability to reject this hypothesis with our sample would depend on the LAD prevalence. Post hoc analysis revealed that we could reject our hypothesis up to a prevalence of 21.7% (2.6 cases of 12, which in reality would correspond to three women).

5 RESULTS

5.1 PAPER I

We included 7796 nulliparous women ≥40 years and 264 262 nulliparous women 25-29 years. Overall, 79% of women ≥40 years reached a vaginal delivery compared with 93% of women 25-29 years. Induction of labor and pre-labor medical conditions were more common in women ≥40 years (Table I:1).

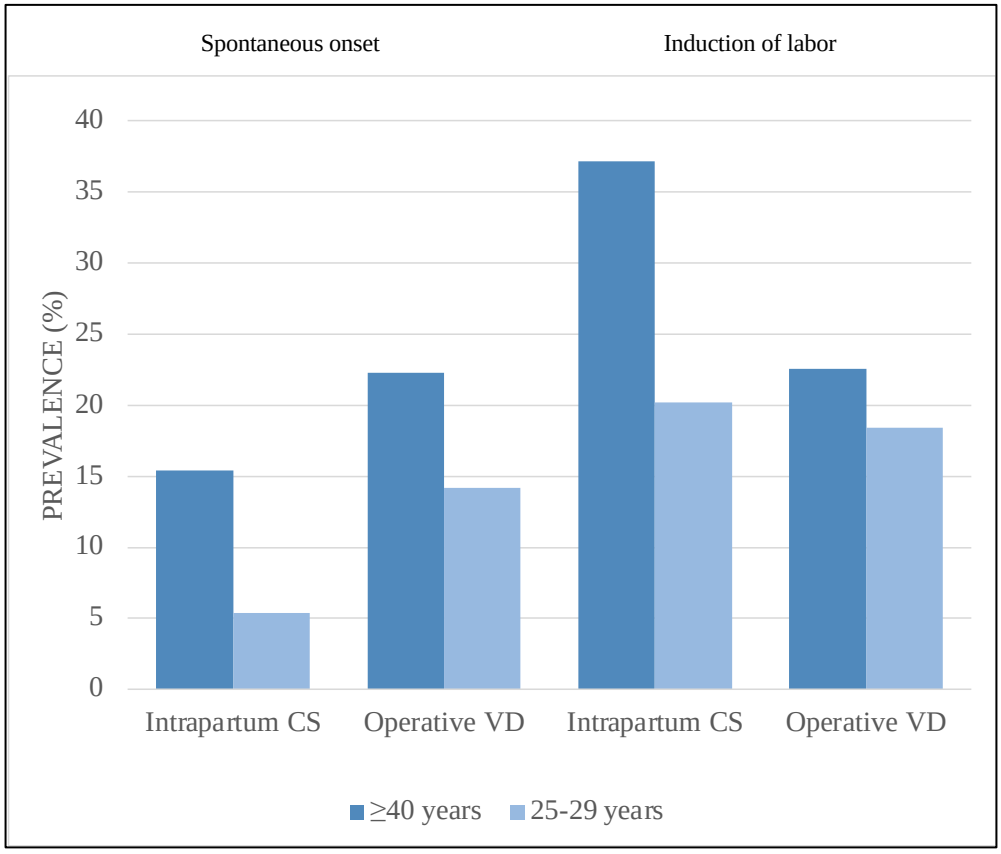


Figure I:1. Prevalence of intrapartum cesarean section (CS) and operative vaginal delivery (VD) in women ≥40 years and 25-29 years stratified for mode of onset.

We found an increased risk of intrapartum cesarean section in women ≥40 years compared with women 25-29 years, both after spontaneous onset of labor (aOR 3.07, 95% CI 2.81-3.35), and induction (aOR 2.51, 95% CI 2.24-2.81) (Figure I:1, Table I:2). The difference was less prominent in the induction group.

At the time for intrapartum cesarean section, a diagnosis of fetal distress was present in about 40% of the deliveries and equally distributed in both groups, while labor dystocia was less common in women ≥40 years (45%) compared with women 25-29 years (49%), p= 0.002 data not shown.

Table I:1. Characteristics in women ≥40 years and 25-29 years stratified for spontaneous onset and induction of labor.

			≥40 years n=7796 n (%)	25-29 years n=264 262 n (%)	p-value
Maternal characteristics	BMI	≥30	662 (8.5)	17 103 (6.5)	<0.001
		<30	5947 (76.2)	213 719 (80.0)	
		Missing	1187 (15.3)	33 440 (13.5)	
	Height (cm)	<160	786 (10.0)	26 936 (10.2)	0.84
		≥160	6359 (81.6)	219 567 (83.0)	
		Missing	651 (8.4)	17 759 (6.8)	
	Smoking	Yes	640 (8.2)	20 707 (7.8)	0.08
		No	6633 (85.0)	231 254 (87.5)	
		Missing	523 (6.8)	12 301 (4.7)	
	Single/no cohabitation	Yes	1119 (14.4)	10 089 (3.8)	<0.001
		No	6084 (78.0)	240 427 (91.0)	
		Missing	593 (7.6)	13 746 (5.2)	
	Country of birth	Nordic	6447 (83.0)	226 834 (86.0)	<0.001
		Non-Nordic	1224 (15.7)	33 739 (12.8)	
		Missing	125 (1.3)	3689 (1.2)	
	Year of delivery	≥1997	6596 (84.6)	192 811 (73.0)	<0.001
		<1997	1200 (15.4)	71 451 (27.0)	
	Assisted reproduction		1161 (14.9)	4404 (1.7)	<0.001
	Hypertension/preeclampsia		626 (8.0)	11 978 (4.5)	<0.001
	Diabetes (all types)		207 (2.7)	2582 (1.0)	<0.001
Delivery characteristics	Spontaneous onset		5794 (74.3)	236 510 (89.5)	<0.001
	Induction of labor		2002 (25.7)	27 752 (10.5)	<0.001
	Pre-labor rupture of membranes		928 (11.9)	19 796 (7.5)	<0.001
	Epidural anesthesia		3639 (46.7)	115 115 (43.6)	<0.001
	Gestational week	37-38	1096 (14.1)	42 436 (16.1)	<0.001
		39-40	3954 (50.7)	143 358 (54.2)	
		41	1898 (24.3)	54 988 (20.8)	
		≥42	848 (10.9)	23 480 (8.9)	
	Neonatal sex	Boy	3994 (51.2)	135 701 (51.4)	0.99
		Girl	3802 (48.8)	128 552 (48.6)	
		Missing	0	9	
	Birthweight (g)	<2999	1114 (14.3)	29 589 (11.2)	<0.001
		3000-3499	2926 (37.5)	95 570 (36.2)	
		3500-3999	2581 (33.1)	96 852 (36.7)	
		4000-4499	993 (12.7)	35 078 (13.3)	
		≥4500	170 (2.2)	6694 (2.5)	
		Missing	12 (0.02)	479 (0.1)	
	Head circumference (cm)	≥38	313 (4.0)	8807 (3.3)	0.002
		<38	7244 (93)	245 324 (92.8)	
		Missing	239 (3.0)	10 131 (3.9)	

Column percentages are presented. Covariates with p-value <0.05 are further analyzed in Appendix I:2.

The risk of operative vaginal delivery was also increased in women ≥40 years, both after spontaneous onset (aOR 1.71, 95% CI 1.59-1.85) and induction (aOR 1.45, 95% CI 1.28-1.65) compared with women 25-29 years (Figure I:1, Table I:2). Again, diagnoses of intrapartum fetal distress at operative vaginal delivery were more common in women ≥40 years than in the women 25-29 years (45% vs 40%, p<0.001), while labor dystocia diagnoses were equally common, about 52%.

Table I:2. Mode of delivery in women ≥40 years and 25-29 years stratified for spontaneous onset and induction of labor.

		≥40 years n=7796	**25-29 years n=264 262**
		Spontaneous onset n=5794	n= 236 510
Intrapartum CS	Prevalence, n (%)	890 (15.4)	12 888 (5.4)
	OR (95% CI)	3.15 (2.93-3.39)	1.0 (ref)
	aOR (95% CI)	3.07 (2.81-3.35)	1.0 (ref)
Operative VD	Prevalence, n (%)	1291 (22.3)	33 551 (14.2)
	OR (95% CI)	1.73 (1.63-1.85)	1.0 (ref)
	aOR (95% CI)	1.71 (1.59-1.85)	1.0 (ref)
Spontaneous VD	Prevalence, n (%)	3613 (62.4)	190 071 (80.4)
	OR (95% CI)	0.41 (0.38-0.43)	1.0 (ref)
	aOR (95% CI)	0.40 (0.38-0.43)	1.0 (ref)
		Induction of labor n=2002	n=27 752
Intrapartum CS	Prevalence, n (%)	744 (37.2)	5611 (20.2)
	OR (95% CI)	2.33 (2.12-2.57)	1.0 (ref)
	aOR (95% CI)	2.51 (2.24-2.81)	1.0 (ref)
Operative VD	Prevalence, n (%)	453 (22.6)	5101 (18.4)
	OR (95% CI)	1.30 (1.16-1.45)	1.0 (ref)
	aOR (95% CI)	1.45 (1.28-1.65)	1.0 (ref)
Spontaneous VD	Prevalence, n (%)	805 (40.2)	17 040 (61.4)
	OR (95% CI)	0.43 (0.39-0.46)	1.0 (ref)
	aOR (95% CI)	0.37 (0.33-0.41)	1.0 (ref)

Column percentages are presented.
Adjustment was made for potential confounders (Appendix I:2: BMI, cohabitation status, country of birth, year of delivery, assisted reproduction, hypertensive disease/preeclampsia, diabetes, pre-labor rupture of membranes, epidural anesthesia, gestational week, birthweight, and head circumference).

OASIS was not increased in women ≥40 years compared with women 25-29 years, in neither mode of onset (Table I:3). OASIS was more common in both age groups in operative vaginal delivery. Episiotomy was more common in women ≥40 years compared with women 25-29 years in spontaneous vaginal delivery after spontaneous onset, but not after induction (Table I:3).

There was no significant difference in 5-minutes Apgar score <7 between women ≥40 years and women 25-29 years in either onset of labor (Table I:4).

Table I:3. Perineal injury in women ≥40 years and 25-29 years stratified for onset of labor and mode of vaginal delivery.

			≥40 years n=6162	**25-29 years n=245 763**
			Spontaneous onset n=4904	n=223 622
Operative VD	OASIS	Prevalence, n (%)	145/1291 (11.2)	4625/33 551 (13.8)
		OR (95% CI)	0.79 (0.66-0.94)	1.0 (ref)
		aOR (95% CI)	0.89 (0.73-1.09)	1.0 (ref)
	Episiotomy	Prevalence, n (%)	358/1291 (27.7)	8428/33 551 (25.1)
		OR (95% CI)	1.14 (1.01-1.30)	1.0 (ref)
		aOR (95% CI)	1.11 (0.95-1.28)	1.0 (ref)
Spontaneous VD	OASIS	Prevalence, n (%)	166/3613 (4.6)	9507/190 071 (5.0)
		OR (95% CI)	0.92 (0.78-1.07)	1.0 (ref)
		aOR (95% CI)	0.86 (0.71-1.04)	1.0 (ref)
	Episiotomy	Prevalence, n (%)	424/3613 (11.7)	14 880/190 071 (7.8)
		OR (95% CI)	1.57 (1.41-1.74)	1.0 (ref)
		aOR (95% CI)	1.39 (1.23-1.56)	1.0 (ref)
			Induction of labor n=1258	n=22 141
Operative VD	OASIS	Prevalence, n (%)	61/453 (13.5)	704/5101 (13.8)
		OR (95%CI)	0.97 (0.73-1.29)	1.0 (ref)
		aOR (95%CI)	0.91 (0.65-1.26)	1.0 (ref)
	Episiotomy	Prevalence, n (%)	118/453 (26.0)	1348/5101 (26.4)
		OR (95%CI)	0.98 (0.79-1.22)	1.0 (ref)
		aOR (95%CI)	0.90 (0.70-1.17)	1.0 (ref)
Spontaneous VD	OASIS	Prevalence, n (%)	44/805 (5.5)	865/17 040 (5.1)
		OR (95%CI)	1.08 (0.79-1.48)	1.0 (ref)
		aOR (95%CI)	1.08 (0.75-1.56)	1.0 (ref)
	Episiotomy	Prevalence, n (%)	91/805 (11.3)	1591/17 040 (9.3)
		OR (95%CI)	1.24 (0.99-1.55)	1.0 (ref)
		aOR (95%CI)	1.10 (0.84-1.43)	1.0 (ref)

Adjustment was made for potential confounders (Appendix I:2: BMI, cohabitation status, country of birth, year of delivery, assisted reproduction, hypertensive disease/preeclampsia, diabetes, pre-labor rupture of membranes, epidural anesthesia, gestational week, birthweight, and head circumference).

Table I:4. 5-minutes Apgar score <7 in women ≥40 years and 25-29 years stratified for spontaneous onset and induction of labor.

	≥40 years n=7796	**25-29 years n=264 262**
	Spontaneous onset n=5794	n= 236 510
Prevalence, n (%)	84 (1.5)	2218 (0.9)
OR (95% CI)	1.55 (1.25-1.93)	1.0 (ref)
aOR (95% CI)	1.12 (0.85-1.47)	1.0 (ref)
	Induction of labor n=2002	n=27 752
Prevalence, n (%)	35 (1.8)	478 (1.7)
OR (95% CI)	1.01 (0.72-1.43)	1.0 (ref)
aOR (95% CI)	0.80 (0.51-1.25)	1.0 (ref)

Adjustment was made for potential confounders (Appendix I:2: BMI, cohabitation status, country of birth, year of delivery, assisted reproduction, hypertensive disease/preeclampsia, diabetes, pre-labor rupture of membranes, epidural anesthesia, gestational week, birthweight, head circumference, *and* mode of delivery).

5.2 PAPER II

We extracted 63 654 nulliparous women with a singleton live birth delivered with VE without an episiotomy (68.5%, n=43 853) or with a lateral or mediolateral episiotomy (31.5%, n=19 801) (Figure II:1). Women without and with episiotomy differed significantly in almost every measurable aspect, as shown in Tables II:1 and II:2.

Table II:1. Maternal characteristics

	Exposure			Outcome		
	No episiotomy N=43853 n (row %)	**Episiotomy N=19801 n (row %)**	**p-value [a]**	**No OASIS N=54626 n (row %)**	**OASIS N= 9028 n (row %)**	**p-value [a]**
Maternal age						
<19 years	875 (68.5)	402 (31.5)	<0.001	1198 (93.8)	79 (6.2)	<0.001
20-24 years	6791 (67.3)	3301 (32.7)		8978 (89.0)	1114 (11.0)	
25-29 years	15400 (68.2)	7169 (31.8)		19189 (85.0)	3380 (15.0)	
30-34 years	14591 (69.6)	6363 (30.4)		17728 (84.6)	3226 (15.4)	
35-39 years	5145 (70.9)	2112 (29.1)		6235 (85.9)	1022 (14.1)	
≥40	858 (69.3)	380 (30.7)		1073 (86.7)	165 (13.3)	
Missing	193 (72.3)	74 (27.7)		225 (84.3)	42 (15.7)	
Continent of birth						
Europe, USA, Ca, NZ, Australia	38273 (68.7)	17399 (31.3)	<0.001	47904 (86.0)	7768 (14.0)	<0.001
Asia	3871 (70.7)	1603 (29.3)		615 (90.7)	63 (9.3)	
Africa	662 (61.0)	422 (39.0)		4577 (83.6)	897 (16.4)	
Latin America	533 (78.6)	145 (21.4)		890 (82.1)	194 (17.9)	
Unspecified	514 (68.9)	232 (31.1)		640 (85.8)	106 (14.2)	
Maternal height						
<160 cm	5490 (67.2)	2676 (32.8)	0.002	6905 (84.6)	1261 (15.4)	<0.001
≥160 cm	35557 (69.0)	16008 (31.0)		44349 (86.0)	7216 (14.0)	
Unspecified	2806 (71.5)	1117 (28.5)		3372 (86.0)	551 (14.0)	
Maternal BMI						
<18.5	996 (66.1)	510 (33.9)	0.18	1287 (85.5)	219 (14.5)	<0.001
18.5-24.9	25465 (68.8)	11535 (31.2)		31817 (86.0)	5183 (14.0)	
25.0-29.9	8864 (68.9)	3997 (31.1)		10951 (85.1)	1910 (14.9)	
30.0-34.9	2330 (69.5)	1023 (30.5)		2869 (85.6)	484 (14.4)	
≥35.0	872 (69.8)	378 (30.2)		1108 (88.6)	142 (11.4)	
Unspecified	5326 (69.9)	2358 (30.1)		6594 (85.8)	1090 (14.2)	
Smoking						
Yes	2627 (68.8)	1191 (31.2)	0.86	3418 (89.5)	400 (10.5)	<0.001
No	37330 (68.7)	17035 (31.3)		46483 (85.5)	7882 (14.5)	
Unspecified	3896 (71.8)	1575 (28.2)		4725 (86.4)	746 (13.6)	
Cohabitation						
Yes	38652 (68.5)	17800 (31.5)	0.003	48343 (85.6)	8109 (14.4)	<0.001
No	2808 (70.7)	1162 (29.3)		3529 (88.9)	441 (11.1)	
Unspecified	2393 (74.0)	839 (26.0)		2754 (85.2)	478 (14.8)	
Diabetes, all types						
Yes	588 (66.0)	303 (34.0)	0.06	762 (85.5)	129 (14.5)	0.80
No	43265 (68.9)	19496 (31.1)		53864 (85.8)	8899 (14.2)	
Preeclampsia/hypertension						
Yes	2444 (69.8)	1051 (30.2)	0.17	3030 (86.7)	465 (13.3)	0.13
No	41409 (68.8)	18750 (31.2)		51596 (85.8)	8563 (14.2)	
Crohn's/Ulcerative colitis						
Yes	339 (67.4)	164 (32.6)	0.47	442 (87.9)	61 (12.1)	0.19
No	43514 (68.9)	19637 (31.1)		54184 (85.8)	8967 (14.2)	
Female genital mutilation						
Yes	42 (43.4)	55 (56.7)	<0.001	72 (74.2)	25 (25.8)	0.001
No	43811 (68.9)	19746 (31.1)		54554 (85.8)	9003 (14.2)	

[a] Test of proportions (Chi^2)

Table II:2. Delivery characteristics

	Exposure			Outcome		
	No episiotomy N=43 853 n (row %)	**Episiotomy N=19 801 n (row %)**	**p-value [a]**	**No OASIS N=54 626 n (row %)**	**OASIS N=9028 n (row %)**	**p-value [a]**
Episiotomy						
Yes	0	19801	n/a	17361 (87.7)	2440 (12.3)	<0.001
No	43853	0		37265 (85.0)	6588 (15.0)	
Onset of labor						
Spontaneous	36758 (69.0)	16549 (31.0)	0.42	45772 (85.9)	7535 (14.1)	0.55
Induction	6897 (68.3)	3165 (31.7)		8617 (85.6)	1445 (14.4)	
Missing	198 (69.5)	87 (30.5)		237 (83.2)	48 (16.8)	
Gestational age						
34-36 w	1111 (71.1)	452 (28.9)	<0.001	1461 (93.5)	102 (6.5)	<0.001
37-40 w	26815 (70.0)	11498 (30.0)		33225 (86.7)	5088 (13.3)	
≥41 w	15927 (67.0)	7851 (33.0)		19940 (83.9)	3838 (16.1)	
Neonatal sex						
Boy	24110 (67.9)	11396 (32.1)	<0.001	30283 (85.3)	5223 (14.7)	<0.001
Girl	19742 (70.1)	8404 (29.9)		24341 (86.5)	3805 (13.5)	
Missing	1 (50)	1 (50)		2 (0)	0	
Epidural						
Yes	28392 (70.2)	12059 (29.8)	<0.001	34729 (85.9)	5722 (14.1)	0.72
No	15461 (66.6)	7742 (33.4)		19897 (85.8)	3306 (14.2)	
Labor dystocia						
Yes	27403 (68.4)	12526 (31.4)	0.06	33867 (84.8)	6062 (15.2)	<0.001
No	16450 (69.3)	7275 (30.7)		20759 (87.5)	2966 (12.5)	
Intrapartum fetal distress						
Yes	19050 (69.9)	8275 (30.1)	<0.001	24078 (88.1)	3247 (11.9)	<0.001
No	24803 (68.3)	11526 (31.7)		30548 (84.1)	5781 (15.9)	
Fetal head station						
Outlet	21097 (69.7)	8748 (30.3)	<0.001	25818 (86.5)	4027 (13.5)	<0.001
Mid-cavity	14519 (65.7)	7577 (34.3)		18591 (84.1)	3505 (15.9)	
Unspecified	8237 (70.3)	3476 (29.7)		10217 (87.2)	1496 (12.8)	
Head position						
Occiput ant	41075 (71.2)	17460 (28.8)	<0.001	50414 (86.1)	8121 (13.9)	<0.001
Occiput post	2778 (54.4)	2341 (45.6)		4212 (82.3)	907 (17.7)	
Head circumference						
<38 cm	39851 (69.7)	17332 (30.3)	<0.001	49314 (86.2)	7869 (13.8)	<0.001
≥38 cm	2830 (66.9)	1400 (33.1)		3372 (79.7)	858 (20.3)	
Unspecified	1172 (52.3)	1069 (47.7)		1940 (86.6)	301 (13.4)	
Birthweight						
<3000 g	5371 (72.6)	2027 (27.4)	<0.001	6875 (92.9)	523 (7.1)	<0.001
3000-3499 g	14789 (71.1)	6014 (28.9)		18593 (89.4)	2210 (10.6)	
3500-3999 g	15991 (68.2)	7467 (31.8)		19875 (84.7)	3583 (15.3)	
4000-4499 g	6442 (64.5)	3544 (35.5)		7869 (78.8)	2117 (21.2)	
≥4500 g	1195 (62.9)	704 (37.1)		1318 (69.4)	581 (30.6)	
Missing	65 (59.9)	45 (40.1)		96 (87.3)	14 (12.7)	
Apgar at 1 minute						
≥4	42545 (69.2)	18915 (30.8)	<0.001	52727 (85.8)	8733 (14.2)	0.16
<4	1237 (59.8)	830 (40.2)		1796 (86.9)	271 (13.1)	
Missing	71 (55.9)	56 (44.1)		103 (81.1)	24 (18.9)	
Shoulder dystocia						
Yes	303 (58.5)	215 (41.5)	<0.001	342 (66.0)	176 (34.0)	<0.001
No	43550 (69.0)	19586 (31.0)		54284 (86.0)	8852 (14.0)	
Year of delivery [b]			<0.001			<0.001
Hospital of delivery [c]			<0.001			<0.001

[a] Test of proportions (Chi^2)

[b, c] See supplementary information (Tables [b] II:S4 and [c] II:S5)

Women with the exposure episiotomy were more often of African origin and subject to female genital mutilation. Their babies were more often born in occiput posterior position, with a birthweight over 4500 g, an unspecified head circumference, and an Apgar score <4. Shoulder dystocia was also more frequent in this group (Tables II:1 and II:2).

Women with the outcome OASIS were older, more often of Latin American or African origin, lower BMI, non-smokers, cohabitated with the other parent, subject to female genital mutilation, and no episiotomy. Their babies were more often born ≥41weeks, of male sex, in occiput posterior position, with a birthweight over 4500 g, head circumference ≥38 cm, and the birth complicated by labor dystocia, mid-cavity VE, and shoulder dystocia (Tables II:1 and II:2). Year of delivery and hospital of delivery influenced both the prevalence of episiotomy and OASIS (supplementary Tables SII:4 and SII:5).

The prevalence of OASIS was 15.02% in women without episiotomy and 12.32% in women with episiotomy in the crude population (Table II:3). Most OASIS were third-degree perineal injuries, while fourth-degree perineal injuries were rare (Table II:3). In the unadjusted analysis, episiotomy was associated with an average treatment effect (ATE) of -2.70% (95% CI -3.27 to -2.13), corresponding to the expected reduction in OASIS if all women had received an episiotomy (Table II:3). Numbers needed to treat (NNT) would be 37 to avoid one OASIS.

After statistical balancing, episiotomy was associated with an ATE of -3.66% (95% CI -4.31 to -3.01) (Table II:3). NNT to prevent one OASIS would be 27. Looking at third-degree perineal injuries alone, the ATE was -3.08% (95% CI -3.71 to -2.42) and NNT 32. In fourth-degree perineal injuries alone the ATE was -0.58% (95% CI -0.79 to -0.37) and NNT of 172 (Table II:3).

Table II:3. Unadjusted analysis and causal inference results using different methods

	No episiotomy	Episiotomy	ATE (95% CI)	NNT
Unadjusted Analysis	**n=43 853**	**n=19 801**		
OASIS	15.02%	12.32%	-2.70 (-3.27 to -2.13)	37
4th degree perineal injury	1.51%	0.99%	-0.52 (-0.70 to -0.35)	192
3rd degree perineal injury	13.51%	11.89%	-2.18 (-2.72 to -1.63)	46
Adjusted analyses	**No episiotomy**	**Episiotomy**	**ATE (95% CI)**	**NNT**
Doubly robust				
OASIS	15.50%	11.84%	-3.66 (-4.31 to -3.01)	27
4th degree perineal injury	1.58%	1.00%	-0.58 (-0.79 to -0.37)	172
3rd degree perineal injury	13.95%	10.87%	-3.08 (-3.71 to -2.45)	32
IPW				
OASIS	15.57%	11.95%	-3.62 (-4.28 to -2.97)	28
4th degree perineal injury	1.59%	1.01%	-0.58 (-0.79 to -0.37)	172
3rd degree perineal injury	13.98%	10.93%	-3.05 (-3.68 to -2.42)	33
RA				
OASIS	15.51%	11.82%	-3.69 (-4.32 to -3.06)	27
4th degree perineal injury	1.58%	1.00%	-0.58 (-0.78 to -0.37)	172
3rd degree perineal injury	13.93%	10.82%	-3.11 (-3.72 to -2.50)	32

ATE = average treatment effect, CI = Confidence Interval, NNT = numbers needed to treat, OASIS = obstetric anal sphincter injury, IPW = inverse treatment probability weighting, RA = regression adjustment

5.3 PAPER III

Of 2140 sent questionnaires, 409 bounced back due to unknown email addresses and 432 were completed (response rate 25.0%). We excluded 48 responding doctors who reported no VE in the past year, resulting in 384 doctors in the final.

There were significant differences in almost all characteristics between obstetricians, gynecologists, and residents/unspecified subspeciality, but the reported use of episiotomy in VE was similar across all clinical profiles (Table III:1). Altogether, 222 (57.8%) doctors reported that they use episiotomy in less than 50% of VE and 77 (20.1%) doctors reported that they use episiotomy in ≥75% of VE (Table III:1).

Table III:1. Doctors' self-reported characteristics and use of VE, forceps, and episiotomy in Sweden.

		Obstetricians N=151		**Gynecologists N=99**		**Residents/unspec N=134**		**p**
		n	%	n	%	n	%	
Gender	Female	118	78.1	75	75.8	118	88.1	0.032
	Male	33	21.9	24	24.2	16	11.9	
Age (years)	≤39	20	13.2	25	25.3	105	78.3	<0.001
	40-49	61	40.4	38	38.4	19	14.2	
	50-59	46	30.5	25	25.3	5	3.7	
	≥60	24	15.9	11	11.1	5	3.7	
Years in practice	0-5	1	0.7	2	2.0	99	73.9	<0.001
	6-10	31	20.5	28	28.3	13	9.7	
	11-15	28	18.5	25	25.3	8	6.0	
	16-20	25	16.6	17	17.2	5	3.7	
	>20	66	43.7	27	27.3	9	6.7	
Role at VE	Supervising role	89	58.9	45	45.5	8	6.0	<0.001
	Independent	61	40.4	53	53.5	61	45.5	
	Trainee	1	0.7	1	1.0	65	48.5	
Role at forceps	Supervising role	5	3.3	1	1.0	1	0.7	0.009
	Independent	26	17.2	10	10.1	7	5.2	
	Trainee	1	0.7	4	4.0	5	3.7	
	Do not perform	119	78.8	84	84.8	121	90.3	
Number of VE past 12 months	1-5	37	24.5	43	43.4	60	44.8	0.004
	6-10	58	38.4	34	34.3	47	35.1	
	11-20	45	29.8	18	18.2	21	15.7	
	≥21	11	7.3	4	4.0	6	4.4	
Number of forceps past 12 months	0	130	86.1	94	94.9	126	94.0	0.041
	1-5	18	11.9	5	5.1	8	6.0	
	6-10	0	0	0	0	0	0	
	11-20	3	2.0	0	0	0	0	
	≥21	0	0	0	0	0	0	
Rate of episiotomy in VE	0-24%	53	35.1	36	36.4	51	38.1	0.351
	25-49%	33	21.9	15	15.2	34	25.4	
	50-74%	34	22.5	22	22.2	29	21.6	
	≥75%	31	20.5	26	26.3	20	14.9	
Rate of episiotomy in forceps	0-24%	16	10.6	15	15.2	26	19.4	<0.001
	25-49%	15	9.9	13	13.1	21	15.7	
	50-74%	25	16.6	18	18.2	41	30.6	
	≥75%	95	62.9	53	53.5	46	34.3	

Unspec = unspecified subspeciality.

In all, 308 pictures were analyzed, as 72 did not draw an episiotomy and four pictures were deemed invalid (extreme outliers) (Figure III:4).

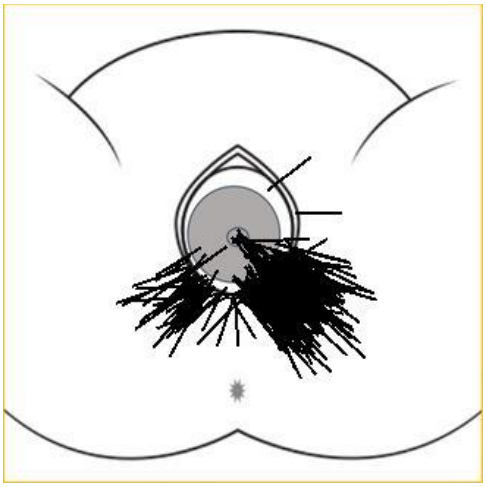


Figure III:4. Two-dimensional schematic picture of a crowning fetal head with a vacuum cup attached showing the distribution of depicted episiotomies. Adapted from Fodstad K, Staff AC, Laine K. Episiotomy preferences, indication, and classification--a survey among Nordic doctors. Acta Obstet Gynecol Scand. 2016;95(5):587-95.

The average episiotomy corresponded well to a lateral episiotomy (angle 53°, incision point from the midline 21 mm, and length 36 mm), but the ranges were wide for all trigonometric properties across clinical profiles. This resulted in only 167 (54.2%) drawn episiotomies with properties typical for a protective episiotomy (Table III:2 and 4). Terminology was also mixed-up, as half of the lateral episiotomies were called mediolateral by the doctors (Table III:3).

Table III:2. Episiotomy trigonometric properties in illustrations of technique among doctors in Sweden.

	Obstetricians N=132[a]		**Gynecologists N=81[b]**		**Residents/unspec N=95[c]**		**P**
	Median	Range	Median	Range	Median	Range	
Angle (°)	54.5	19.4-92.2	51.7	21.4-92.1	52.9	23.2-119.9	0.246
Distance (mm)	20.6	0.6-58.2	20.9	2.1-41.8	20.7	0.9-37.2	0.843
Length (mm)	37.4	16.2-71.6	36.8	17.1-59.9	33.5	11.8-70.0	0.023
	n	%	n	%	n	%	
Angle 45-80°	93	70.5	54	66.7	66	69.5	0.842
Distance ≥10 mm	107	81.1	72	88.9	83	87.4	0.224
Length ≥30 mm	98	74.2	60	74.1	57	60.0	0.044

Unspec = unspecified subspeciality.
Angle (to the midline), Distance (from posterior fourchette to start of incision) and Length (from start to end of incision) are presented as continuous variables with median and range, and as number of doctors with column proportions.
[a] 132 of 151 obstetricians drew a valid picture, 1 invalid
[b] 81 of 99 gynecologists drew a valid picture, 2 invalid
[c] 95 of 134 residents/unspecified drew a valid picture, 1 invalid

Table III:3. Doctors' definition of illustrated episiotomy vs. consensus type of episiotomy in Sweden.

Consensus type of episiotomy	Doctors' definition of illustrated episiotomy									P
	Midline		Mediolateral		Lateral		No opinion		Total	
	n	%	n	%	n	%	n	%	N	
Obstetricians										0.034
Midline	0	0	2	2.7	0	0	0	0	2	
Mediolateral	0	0	12	16.4	1	1.8	0	0	13	
Lateral	0	0	33	45.2	39	70.9	2	50.0	74	
Other	0	0	26	35.6	15	27.3	2	50.0	43	
Total	0	0	73	100	55	100	4	100	132	
Gynecologists										0.294
Midline	0	0	0	0	0	0	0	0	0	
Mediolateral	0	0	5	11.1	1	3.2	1	25.0	7	
Lateral	0	0	22	48.9	22	71.0	2	50.0	46	
Other	1	100	18	40.0	8	25.8	1	25.0	28	
Total	1	100	45	100	31	100	4	100	81	
Residents/unspec										0.532
Midline	0	0	0	0	0	0	0	0	0	
Mediolateral	0	0	6	11.8	0	0	1	14.3	7	
Lateral	1	50.0	29	56.9	22	62.9	4	57.1	56	
Other	1	50.0	16	31.4	13	37.1	2	28.6	32	
Total	2	100	51	100	35	100	7	100	95	

Column percentages: consensus types as the proportion of the types. Unspec = unspecified subspeciality.

Episiotomy was not considered an important protective intervention against OASIS at VE (Figure III:5). Most doctors rated slow birth as the most important preventive measure.

In their role as a doctor, 240 (62.5%) doctors were positive to, or already involved in, an ongoing RCT assessing lateral episiotomy vs. no episiotomy in VE in nulliparous women (Table III:5). These doctors had a threefold increased probability to draw a protective episiotomy (Table III:4). The greatest concern regarding the trial was causing unnecessary injury to the perineum, by either an unnecessary episiotomy or an unnecessary OASIS. Most doctors considered an NNT of 14 or lower as an acceptable number of episiotomies to prevent one OASIS (Table III:5).

Table III:4. Non-protective and protective episiotomy and self-reported characteristics among doctors in Sweden.

	Non-protective episiotomy N=167[a]		Protective episiotomy N=141[a]		Univariate analysis OR (95% CI)	Multivariate analysis[c] aOR (95% CI)
	n	%[b]	n	%[b]		
Profile						
Obstetrician	69	52.3	63	47.7	1.0 (reference)	x
Gynecologist	44	54.3	37	45.7	0.92 (0.53-1.60)	x
Resident/unspec	54	56.8	41	43.2	0.83 (0.49-1.41)	x
Gender						
Female	127	51.0	122	49.0	1.0 (reference)	1.0 (reference)
Male	40	67.8	19	32.2	0.49 (0.27-0.90)	0.57 (0.31-1.08)
Age (years)						
≤39	62	55.4	50	44.6	1.0 (reference)	x
40-49	51	52.6	46	47.4	1.12 (0.65-1.93)	x
50-59	33	49.3	34	50.7	1.28 (0.70-2.34)	x
≥60	21	65.6	11	34.4	0.65 (0.29-1.47)	x
Years of practice						
0-5	40	56.3	31	43.7	1.0 (reference)	x
6-10	33	52.4	30	47.6	1.17 (0.59-2.32)	x
11-15	27	58.7	19	41.3	0.91 (0.43-1.93)	x
16-20	21	51.2	20	48.8	1.23 (0.57-2.66)	x
>20	46	52.9	41	47.1	1.15 (0.61-2.16)	x
Role at VE						
Supervising role	60	50.8	58	49.2	1.0 (reference)	x
Independent	85	58.2	61	41.8	0.74 (0.46-1.21)	x
Trainee	22	50.0	22	50.0	1.03 (0.52-2.07)	x
Number of VE past 12 months						
1-5	50	46.7	57	53.3	1.0 (reference)	1.0 (reference)
6-10	69	58.5	49	41.5	0.62 (0.37-1.06)	0.48 (0.27-0.86)
11-20	39	56.5	30	43.5	0.68 (0.37-1.24)	0.59 (0.31-1.12)
≥21	9	64.3	5	35.7	0.49 (0.15-1.55)	0.37 (0.11-1.26)
Opinion about episiotomy effect on OASIS at VE						
Increases risk	6	66.7	3	33.3	1.0 (reference)	x
No difference	34	54.8	28	45.2	1.65 (0.38-7.19)	x
Decreases risk	91	51.4	86	48.6	1.89 (0.46-7.80)	x
No opinion	36	60.0	24	40.0	1.33 (0.30-5.85)	x
Rate of episiotomy in VE						
<25%	63	56.3	49	43.8	1.0 (reference)	1.0 (reference)
25-49%	33	50.8	32	49.2	1.25 (0.68-2.30)	1.03 (0.54-1.97)
50-74%	44	66.7	22	33.3	0.64 (0.34-1.21)	0.44 (0.22-0.88)
≥75%	27	41.5	38	58.5	1.81 (0.98-3.36)	1.70 (0.89-3.28)
Willingness to participate in RCT						
No	77	66.4	39	33.6	1.0 (reference)	1.0 (reference)
Yes	59	52.2	54	47.8	1.81 (1.06-3.08)	2.09 (1.20-3.66)
Already participating	31	39.2	48	60.8	3.06 (1.69-5.53)	3.69 (1.94-7.02)

Unspec = unspecified subspeciality. RCT = randomized controlled trial, in this case an RCT of lateral episiotomy or no episiotomy in vacuum extraction in nulliparous women.

[a] Doctors with a valid picture and at least one VE the past 12 months (n=308).

[b] Row percentages.

[c] Model based on backward stepwise conditional logistic regression including gender, number of VE past 12 months, rate of episiotomy in VE, and willingness to participate in RCT.

Table III:5. Doctors' perceptions about a randomized controlled trial of lateral episiotomy or no episiotomy in vacuum extraction in nulliparous women in Sweden.

	Obstetricians N=151		Gynecologists N=99		Residents/unspec N=134		P
	n	%[a]	n	%[a]	n	%[a]	
Numbers needed to treat							0.092
A routine episiotomy is never acceptable	10	6.6	6	6.1	3	2.2	
NNT ≤14	100	66.2	72	72.7	111	82.8	
NNT 15-49	36	23.8	18	18.2	18	13.4	
NNT ≥50	5	3.3	3	3.0	2	1.5	
Willingness to participate as doctor							0.036
Yes	58	38.4	25	25.3	61	45.5	
No	54	35.8	45	45.5	45	33.6	
Hospital already involved	39	25.8	29	29.3	28	20.9	
Willingness to participate as a patient/recommend a birthing partner							0.370
Yes	58	38.4	31	31.3	44	32.4	
No	57	37.7	50	50.5	60	44.8	
Do not know or do not wish to answer	36	23.8	18	18.2	30	22.4	
Fears or objections about RCT							
No specific fears or objections	36	23.8	24	24.2	21	15.7	0.162
Increased fear of vaginal birth	21	13.9	8	8.1	24	17.9	0.099
Increased rate of episiotomy	37	24.5	25	25.3	34	25.4	0.984
Episiotomy is not preventive	6	4.0	8	8.1	6	4.5	0.322
Episiotomy is worse than OASIS	9	6.0	6	6.1	7	5.2	0.952
Unnecessary harm (episiotomy/OASIS)	86	57.0	47	47.5	89	66.4	0.015
I rarely cause OASIS	36	23.8	14	14.1	20	14.9	0.071
I/others can judge when epi is necessary	41	27.2	31	31.3	43	32.1	0.624
Other fears or objections	12	7.9	5	5.1	10	7.5	0.662

[a] Column percentage. NNT = numbers needed to treat, RCT = randomized controlled trial, OASIS = obstetric anal sphincter injury, epi = episiotomy.

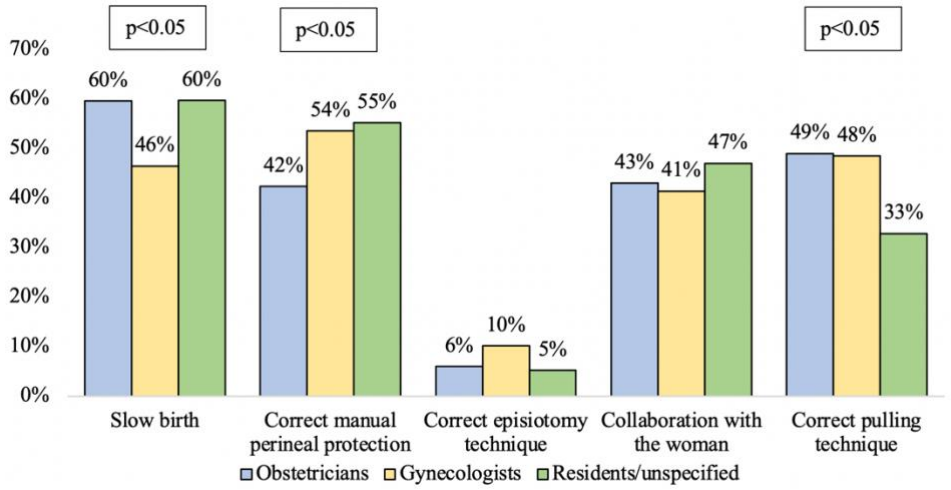


Figure III:5. Proportion of doctors in Sweden ranking measures as very important or important to prevent OASIS at vacuum extraction in nulliparous women.

5.4 PAPER IV

Paper IV included 58 nulliparous women with VE and a lateral episiotomy examined by 3D endovaginal ultrasound 6-12 months after delivery. Twelve (20.7%, 95% CI 10.9%-32.9%) of 58 women had a levator ani deficiency (LAD) visible on 3D endovaginal ultrasound (Figure IV:1, Table IV:2). The majority had an intact levator ani muscle (LAM) as the example shown in Figure IV:1.

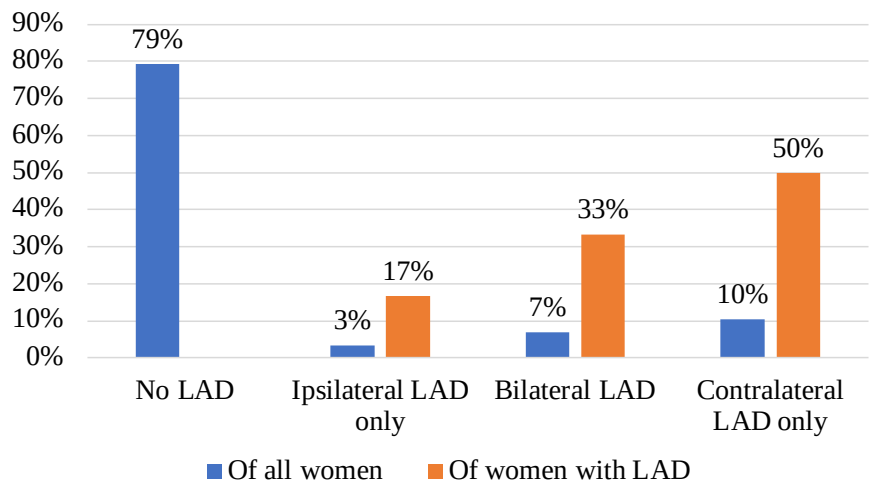


Figure IV:1. Proportion of women without LAD and ipsi-, bi-, and contralateral LAD.

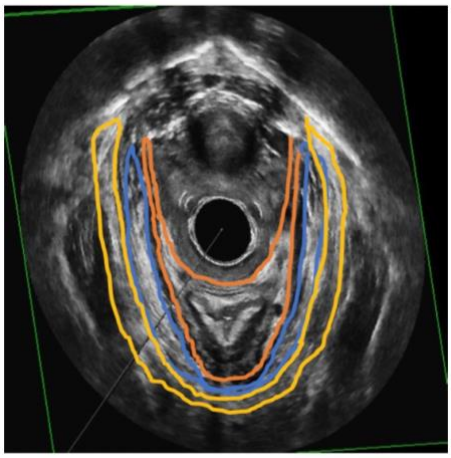


Figure IV:1. Normal finding on 3D endovaginal ultrasound
Endovaginal ultrasound image six to twelve months after first delivery by vacuum extraction using a transducer equipped with 8838 9Hz/12 MHz and high-resolution 3D capability (BK Medical Flex focus, Peabody, MA, USA). Inner portion (orange): Puboperineal and puboanal muscle (PA), Middle portion (blue): Ileococcygeal (Pubovisceral = pubococcygeal) muscle (PV), Outer portion (yellow): Puborectal muscle (PR).

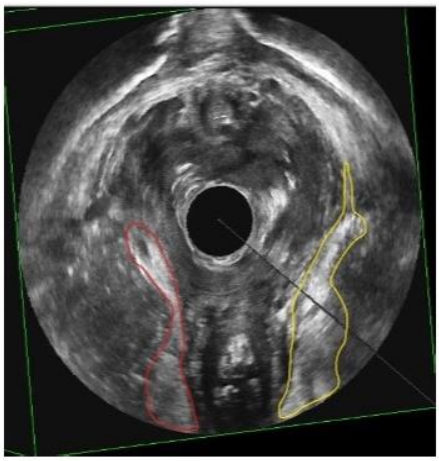


Figure IV:2. Bilateral levator ani deficiency (LAD) on 3D endovaginal ultrasound
Endovaginal ultrasound image six to twelve months after first delivery by vacuum extraction using a transducer equipped with 8838 9Hz/12 MHz and high-resolution 3D capability (BK Medical Flex focus, Peabody, MA, USA). Total defect on the woman's right side (red) with LAD score 9 and a partial defect on her left side (yellow) with LAD score 7.

Table IV:2. Characteristics in women without and with levator ani muscle deficiency (LAD).

		No LAD N=46 (79.3%)		LAD N=12 (20.7%)		p-value
Maternal characteristics		n	%	n	%	
Age (years)	<35	36	78.3	7	58.3	0.27
	≥35	10	21.7	5	41.7	
Height (cm)	<160	6	13.0	1	8.3	1.00
	≥160	40	87.0	11	91.7	
BMI	<25	32	69.9	8	66.7	1.00
	≥25	14	30.4	4	33.3	
Country of birth	Europe/USA	40	87.0	11	91.7	0.14
	Africa	0	0	1	8.3	
	Asia	2	4.3	0	0	
	Other	4	8.7	0	0	
Female genital mutilation	No	46	100	11	91.7	0.21
	Yes	0	0	1	8.3	
Delivery characteristics						
Epidural	No	5	10.9	0	0	0.57
	Yes	41	89.1	12	100	
Prolonged second stage (hours)	<3	17	37.0	3	25.0	0.52
	≥3	29	63.0	9	75.0	
Fetal head station	Outlet	6	13.0	1	8.3	1.00
	Mid-cavity	40	87.0	11	91.7	
Fetal head position	OA	39	84.8	11	91.7	1.00
	OP/Other	7	15.2	1	8.3	
Number of pulls	<4	28	60.9	10	83.3	0.19
	≥4	18	39.1	2	16.7	
Cup detachment	No	45	97.8	12	100	1.00
	Yes	1	2.2	0	0	
Doctors' clinical profile	Obstetrician	24	52.2	6	50.0	0.94
	Gynecologist	5	10.8	1	8.3	
	Resident	17	37.0	5	41.7	
Episiotomy characteristics						
Episiotomy side	Left	36	78.3	11	91.7	0.43
	Right	10	21.7	1	8.3	
Episiotomy length (mm)	<18	9	19.6	0	0	0.12
	≥18	36	78.2	10	83.3	
	Missing	1	2.2	2	16.7	
Episiotomy incision (mm)	<10	20	43.5	3	25	0.40
	≥10	25	54.3	7	58.3	
	Missing	1	2.2	2	16.7	
Episiotomy angle (°)	15-60	36	78.2	8	66.6	1.00
	<15 or >60	9	19.6	2	16.7	
	Missing	1	2.2	2	16.7	
Standardized lateral episiotomy*	No	27	58.7	5	41.6	0.73
	Yes	18	39.1	5	41.7	
	Missing	1	2.2	2	16.7	
Neonatal characteristics						
Head circumference (cm)	<35	12	26.1	3	25.0	1.00
	≥35	34	73.9	9	75.0	
Birthweight (g)	<3000	4	8.7	0	0	0.38
	3000-3999	36	78.3	9	75.0	
	≥4000	6	13.0	3	25.0	

LAD=levator ani deficiency, OA=occiput anterior, OP=occiput posterior.
No women with Kristeller maneuver (fundal pressure).
*Fulfilling all criteria: Length ≥18 mm, incision point ≥10 mm, and angle 15-60°.

The LAM injuries were described using LAD score (Table IV:3). Only one woman had a severe LAM injury with LAD score 16 (Figure IV:2, Table 3). Six women had a moderate injury, and five women had a mild injury (Table IV:3). Nine (75%) of 12 women had a LAD on the right side, seven (58.3%) had a LAD on the left side, including those with a bilateral LAD. In total, four (25%) women had a bilateral LAD (Table IV:3). Six (50.0%, 95% CI 21.1%-78.9%) of 12 women had a LAD on the same side as the episiotomy, including four women with bilateral LAD (p=1.00 compared to the stipulated proportion of 50%). The prevalence of LAD on the same or opposite side from the episiotomy was not related to the trigonometric properties of the episiotomy (not in tables).

Table IV:3. Description of the levator ani muscle deficiency (LAD).

Case number	**Episiotomy side**		**Shobeiri LAD score**									**LAD side**
			Inner portion (Puboanal)		Middle portion (Puboviscerel)		Outer portion (Puborectal)		Total score	Total score	Total score	
	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Total	
1		1	3	3	3	3	3	1	9	7	16	Bilat
2		1	3		3		3		9	0	9	Contra
3		1	3		3		3		9	0	9	Contra
4		1	3	3	1	1			4	4	8	Bilat
5		1	3		3		2		8	0	8	Contra
6		**1**		**3**		**3**		**1**	**0**	**7**	**7**	**Ipsi**
7		**1**		**3**		**3**		**1**	**0**	**7**	**7**	**Ipsi**
8	1			3		3			0	6	6	Contra
9		1	3	3					3	3	6	Bilat
10		1	3	3					3	3	6	Bilat
11		1	3		3				6	0	6	Contra
12		1	1						1	0	1	Contra
Number of cases	1	11	9	7	6	5	4	3	9	7	12	

Bold letters: Ipsilateral LAD. Bilat = bilateral, Contra = contralateral, Ipsi = ipsilateral. Shobeiri LAD score (per side): 0 p = no muscle loss, 1 p = muscle loss <50% thickness, 2 p = muscle loss >50% thickness, 3 p = total muscle loss

6 DISCUSSION

6.1 METHODOLOGICAL CONSIDERATIONS

Paper I and II are register-based studies, **paper III** is a survey, and **paper IV** is a clinical cohort study. Although **paper I-IV** used different methods, there are some common methodological pitfalls and considerations to be mentioned.

6.1.1 Internal validity – systematic error

Internal validity describes to what extent a study reflects what it purportedly observes, i.e., how sound the research is and how confident one can be that the cause-effect relationship cannot be explained by other factors. Systematic errors are non-random and occur because of inaccurate selection of the study population (selection bias), inaccurate classification of the studied variables (information bias), or when other interacting variables that may influence the results are disregarded (confounding). To some extent such, and other sources of, bias are present in all observational data and cannot be compensated for by a large sample size.

6.1.1.1 Selection bias

Selection bias occurs when the relation between exposure and outcome differs between the study population (sample) and the source population, i.e., the population from which we extract the study population. Even with carefully chosen criteria, the sample may not be completely representative of the intended study population. Characteristics between treated/exposed and untreated/unexposed patients may be different. This may lead to both under- and overestimation of effects.

In **paper I and II**, we included women in SMBR with certain selection criteria. The SMBR is updated on a yearly basis and evaluated as described in Methods (198). Registration in SMBR is mandatory, compared with quality registers in which patients can decline to participate. Since nulliparity was a selection criterion, the parity variable is important. Information about parity in SMBR is based on self-reports forwarded from antenatal care records. Parity can also be extracted from Statistics Sweden (SCB) in which the first childbirth in Sweden is registered as the first-born child. To evaluate the parity variable in SMBR, data has been compared between SMBR and SCB (198). From 1982 to 1998 registration forms of parity in SMBR were not optimal, leading to false registration of nulliparity (198). Between 1982 and 1998 there was a discrepancy of 8.7%, meaning that 8.7% of nulliparous women were in reality multiparous (198).

Including all births in the nation decreased selection bias based on maternal characteristics which could occur if we had included women from a certain region for example. In **paper I,** we included women with a live, singleton baby in cephalic presentation, except those with pre-labor cesarean section. Data gave no possibility to discriminate between elective or emergency pre-labor cesarean section. This leads to a possible selection bias towards low-risk women only. Since the selection criteria applied to both the exposure group (women ≥40

years) and the reference group (women 25-29 years) it is less likely to influence the internal validity of **paper I**.

In **paper II,** we excluded women delivered with forceps or sequential methods (trial of VE, then forceps). Forceps were hardly used (0.5%). Sequential methods amounted to 1% of all vacuum attempts in our cohort. Albeit few, this selection could lead to a bias towards easier extractions, since those converted to forceps are usually more difficult, and thereby lead to an underestimation of effects. We prioritized a more homogenous population delivered with VE to avoid confounding. We also excluded births with unknown/other fetal presentation, which also may cause a selection bias if those with unknown/other fetal presentation represent fetuses with complex or asynclitic cephalic presentations.

Also, in **paper III** selection bias may be present. Members of the SFOG could hold other opinions than non-members but most of all, respondents likely hold other opinions than non-responders, as discussed below. The questionnaire in Swedish was sent to members with a registered email address and was to be answered using a digital screen. This may lead to a selection bias towards younger, technically savvier, and more integrated respondents. On the other hand, older doctors may be more dutiful in responding. How this influenced internal validity is unclear.

In **paper IV**, the cohort consisted of women delivered with VE and a lateral episiotomy, nested within an RCT. All trial hospitals received education in pelvic floor anatomy, lateral episiotomy technique, and suturing prior to trial start. The hospitals participating in the nested ultrasound study were selected based on the hospital's wish and capability of learning pelvic floor assessment using 3D ultrasound. This could lead to a selection bias towards less pelvic floor injuries at delivery due to a higher general competence, and thereby an underestimation of effects.

6.1.1.2 Information bias

Information bias occurs when information about the participants is systematically inaccurate or misclassified. When the misclassification is equally distributed in the exposed and unexposed it is called *non-differential misclassification* and may dilute the cause-effect relationship and entail a type 2-error (missing the cause-effect relationship). When there is a difference in misclassification between the exposed and unexposed it is called *differential misclassification.* This can entail both under- and overestimation of results and may cause either a type 2- or type 1-error (a cause-effect relationship that does not exist) (210).

As described above, in SMBR the registration of parity is misclassified in 8.7% (198). Consequently, women in **paper I** and **paper II** might be erroneously classified as nulliparous, especially women with previous childbirths outside Sweden. This could be a *non-differential misclassification bias* in **paper I**, since women of Swedish and non-Swedish origin were equally distributed between women ≥40 years and women 25-29 years. Women born outside Sweden and women born in Sweden have almost the same degree of misclassification (8.7% vs. 8.9%) (198). Yet, it is likely that there are more misclassified

multiparous women ≥40 years simply due to age. This would be a *differential misclassification bias* and cause overestimation of vaginal delivery in women ≥40 years, as multiparous women have a higher success rate in trial of labor. In **paper II**, including nulliparous VE births from 2000 to 2011, this misclassification bias is less likely, given that VE is uncommon in multiparous women and the registration of parity improved after 1998 (198).

Systematically missing data on maternal weight is a known source of information bias in SMBR. Women with a high BMI may underestimate or withhold their weight (211). Missing data on BMI could be a *non-differential misclassification bias*, since it was evenly distributed between the comparison groups in **paper I** and **paper II**. The evaluation of SMBR in 2003 confirmed that lack of data on variables surely affects the estimates of prevalence, while there is usually little impact on risk estimates if the missing information is random (198).

Measurement error is another type of information bias. It may be caused by inadequate equipment, incorrect measurements, or incorrect definition of a condition leading to incorrect results and conclusions. This type of information bias could be present in **paper III,** where the drawings of an episiotomy on a digital screen were converted from picture coordinates to millimeters and degrees. It is unexplored if an electronic modification of a depicted episiotomy can reliably measure episiotomy technique. Previous studies of episiotomy techniques have used physical pictures to draw on and from which trigonometric data have been calculated (111, 114, 212).

In **paper III**, a tailored questionnaire was used. It had not been validated, but was adapted from a previous publication (159). This may also lead to some *measurement errors*. For a questionnaire to be validated, validity and reliability must first be tested (213).

In **paper IV,** unfavorable examination conditions during 3D ultrasound, like air in the vagina or equipment flaws, could cause *measurement errors*. The trigonometric properties of the episiotomy scar were measured manually with a ruler and protractor which could entail a *measurement error*. Considering the small sample size, even one technically difficult ultrasound assessment or an incorrect measured scar could have impact on the internal validity. In addition, we used endovaginal technique which is routine in many pelvic floor centers in Sweden but may not be suited for detection of smaller scars.

6.1.1.3 Intra- and interobserver reliability

Intra-observer reliability can be explained as the stability of an individual's observation of the same phenomenon at two or more occasions within a specific timeframe. Interobserver reliability can be explained as the stability of two or more individuals observing the same phenomenon. In **paper IV**, the images were examined by one well experienced observer at one time point, thus *intra- and interobserver reliability* could not be assessed. One observer may have promoted coherence in the assessments considering the small sample size, while two or more observers could have increased validity in a larger sample if they would not differ systematically in their assessment. Discrepancies between observers can usually be

solved by consensus, while discrepancies between operators cannot. The ultrasound examinations were performed by three different physicians in three different hospitals. Two physicians were trained on 3D ultrasound assessment by the third physician until consistent technique was used which could improve coherence. However, reproducing ultrasound assessments in LAM injury has proven difficult (84).

6.1.1.4 Response bias

Response bias refers to a tendency for participants, especially in surveys, to respond inaccurately or falsely to a question, deliberately or not. This may be the case in **paper III**. Unexperienced respondents (residents) may not have experience enough to assess the questions accurately, leading to "false" answers in this group, and thereby falsely drawn conclusions.

Response bias may also refer to the characteristics of participants in a survey motivating them to participate. In survey studies of doctors, high performing doctors are more prone to participate in surveys which affect the generalizability (214). In **paper III,** it is likely that more doctors who favor episiotomy participated in the survey, which could have impact on both the internal and external validity as discussed below. The self-reported use of episiotomy in nulliparous VE in our study was 43%, which exceeds the national average of 33% (16). It could be a true proportion, or a result of respondents' wish to be "good participants", although the anonymity of participants makes it less likely.

In **paper III**, the respondents were asked if they were willing to contribute to the EVA trial. Again, it is possible that respondents could be tempted to please the investigators or that more doctors who were positive towards the ongoing RCT participated in the survey. This would be a response bias leading to an overinterpretation of the results. On the other hand, the RCT is conducted in eight hospitals covering 40% of all births in Sweden, while doctors reporting that they already participate in the RCT constituted 25% of respondents in the survey.

6.1.1.5 Non-response bias

A low response rate can be a problem if it leads to a non-response bias. Response rates below 60% is said to correlate to a high likelihood of non-response bias (215). Non-response bias, also known as participation bias, takes place when the opinion of those who do not respond differs from those who respond. If the reason for not responding is not related to the questions per se, no non-response bias is present. Non-response bias leads to a lower external validity and consequently low generalizability. It is possible to control for non-response bias if background information is available on non-respondents. In **paper III**, that was not possible. There was no information on how many non-respondents received the survey. Even with the information, we could not know if they differed in characteristics or opinions compared with the respondents due to the anonymous character of survey. Therefore, the results of **paper III** should be interpreted with some caution.

6.1.1.6 Confounding

Confounding is one of the key biases in epidemiological research. Confounding is a blurring of effects and is defined by factors being associated with both the exposure and the outcome. Multivariate analyses can be performed to control for confounders, given that the confounders are known, measurable, and measured. Residual confounding is the possible imbalance that remains due to unmeasured confounders.

In **paper I** and **paper II** a limitation is the inability to adjust for confounding factors not available in the register, such as attitudes, policies, and treatment traditions. We aimed to compensate by adjusting for year of delivery and hospital of delivery. Another limitation of SMBR is that the timing and reason for operative intervention including episiotomy is not specified, making it difficult to analyze the reason for intervention in both **paper I** and **paper II.** Specifically in **paper II,** the maternal and delivery characteristics contributing to OASIS correspond to characteristics leading to episiotomy. Hence, causal inference versus confounding is difficult to detangle, even when using IPW as a balancing statistical method.

In **paper I** and **paper II** we have unmeasured protective factors that may reduce the risk of OASIS, such as improved manual perineal support over the years or across hospitals. This may be seen as a confounder if an improved manual perineal support both reduces the use of episiotomy and decreases the prevalence of OASIS. It can also be seen as an effect modifier. This is a factor that has impact on the outcome without changing the exposure. In **paper II**, it is more likely that manual perineal support is an effect modifier, given that episiotomy at VE in Sweden has only slightly increased, while the prevalence of OASIS has decreased.

6.1.2 External validity and generalizability

External validity is the generalizability of results, reflecting the degree to which study results are applicable for other cohorts in another settings. Since **paper I** and **paper II** are based on national data the external validity is high in Sweden. In **paper I,** we used a reference group aged 25-29 years, as the median age of having the first child was 27.2 years during our study period. Median age at first birth has increased and was 29.9 years in 2020 (16). The prevalence of women ≥40 years giving birth for the first time has increased slightly (2.1% in 2011 to 2.7% in 2020) (176). Thus, the results of first-time labor in women ≥40 years would likely still possess external validity, even though the difference between women ≥40 years and the reference group would decrease with time.

The noticeable differences in prevalence of OASIS at VE within and between countries may limit external validity of **paper II**. According to a recently published Swedish study, the respondents in **paper III** correlate well to the distribution of clinical profile, age, and number of VE in the past 12 months in Swedish labor wards (52). Accordingly, the external validity and generalizability of **paper III** may be acceptable for Sweden provided that the response rate of 25% does not exclusively mirror non-response bias. The low prevalence of forceps limits the generalizability to countries where forceps is preferred to VE.

6.1.3 Random error

Random error reflects the variability of the data. The effect of random errors can be reduced by a large sample size which in turn leads to increasing precision. A confidence interval (CI) of 95% is an established way of presenting random error. A CI of 95% indicates that if the same analysis would be repeated in a hundred samples from the same source, the same result would occur in 95 samples. A narrow CI represents high precision and low impact of random errors, while a wide CI may represent low precision and is more common in small sample sizes or with rare outcomes. The random error can also be presented as the p-value. The p-value is used for statistical hypothesis testing. The p-value indicates the risk of erroneously rejecting the null hypothesis and claiming a relation between exposure and outcome. The precision in **paper I** and **paper II** can be regarded as high due to large sample size and narrow CIs. In **paper III** and **paper IV,** the CIs are wide and the sample sizes small, which mirrors low precision and a lower internal and external validity.

6.2 THE RESULTS IN A CLINICAL CONTEXT

6.2.1 Paper I

In **paper I**, the risk for intrapartum cesarean section was more than tripled in women ≥40 years compared with women 25-29 years after spontaneous onset and doubled after induced labor. Similar findings were presented in a Norwegian population-based study by Herstad et al (185). The elevated risk of intrapartum cesarean section has been associated with an increased need for oxytocin augmentation and longer second stage of labor (216-218). This has been interpreted as being due to a decrease in uterine muscle function with age, although the theory of impaired muscle contractility with age has not been confirmed by in vitro studies (217, 219). We could not confirm that diagnoses of labor dystocia were more frequent in women ≥40 years compared with women 25-29 years undergoing intrapartum cesarean section.

The rate of operative vaginal delivery was increased in nulliparous women ≥40 years compared with women 25-29 years in both onsets of labor, even though the difference was less prominent than for cesarean section. Fetal distress diagnoses were more common in women ≥40 years than in women 25-29 years undergoing operative vaginal delivery. This is plausible with duration-dependent fetal intolerance due to decreased placental function in older women (220). Or possibly, doctors may intervene at an earlier stage due to perceived risks or more "precious babies" in older women. However, the indication for, or timing of, operative delivery is not clearly defined in SMBR, making it hard to analyze reasons for intervention.

The risk of OASIS was not increased in women ≥40 years compared with women 25-29 years, neither in operative or spontaneous delivery, nor after spontaneous onset or induction. The OASIS rates in Sweden are high compared with other European countries and may be

related to the low rate of episiotomy as discussed below (8). The effect of episiotomy on OASIS rates in operative vaginal delivery was studied in **paper II** and will be studied in an ongoing multicenter RCT.

The risk of a 5-minutes Apgar score <7 was not significantly increased in women ≥40 years compared with women 25-29 years, when adjusted for mode of delivery, as supported by others (171, 172). We used the Apgar score as a simple marker for adverse fetal outcome, but a complete assessment of neonatal outcomes was beyond the scope of this study.

This study was undertaken to describe delivery outcomes after trial of labor in women ≥40 years compared with younger women, not designed to compare induction of labor to expectant management. Induction of labor does not increase intrapartum cesarean section rates when compared with expectant management in RCTs (18-20, 188). Despite likely differences in management of older and younger mothers-to-be, the total rate of vaginal deliveries without adverse outcomes for women ≥40 years (OASIS and low Apgar score) was encouraging. The clinical implication of our results could be a more detailed and well-founded discussion when counselling first-time mothers ≥40 years on induction of labor and mode of delivery, weighing outcome of labor against the likelihood of subsequent births.

6.2.2 Paper II

In **paper II** we assessed the effect of lateral or mediolateral episiotomy on OASIS in VE in nulliparous women in Sweden by using propensity score methods. Sweden is a clinically interesting setting with a high rate of OASIS and a low rate of episiotomy. The calculated average treatment effect (ATE) suggests that OASIS rates could decrease significantly if all nulliparous women with VE received a lateral or mediolateral episiotomy. In a meta-analysis by Lund et al in 2016 of 15 earlier register studies, the average NNT 18.3 was required to avoid one OASIS (12). Lund et al also found that an episiotomy rate exceeding 75% may be more protective (12). The calculated NNT 27 was in **paper II**, which is within the range seen in other studies (Table 2 in background) (47, 105, 122-128). The somewhat higher NNT in our population could mirror a low use and/or lack of episiotomy technique.

During the study period 2000-2011, the overall OASIS rate in nulliparous women with VE was 14.2%. Since then, the OASIS rate in this group has decreased in Sweden and is now 11.1%, possibly owing to improved perineal support or slightly increasing episiotomy rates (16). Register data can as of yet not measure the impact of perineal support, since this is not entered in any register. Differences in the rate of OASIS within and in between countries may not exclusively depend on episiotomy rates (8, 16). Treatment traditions, population differences, over- or underdiagnosis, reporting bias, poor prevention, or inadequate manual perineal support may all contribute. Several measures may be needed to achieve a lower OASIS rate in Sweden.

A limitation of **paper II** is that there is no way to assess episiotomy technique. Previous research has found that episiotomy incision point, length, and angle may all be of importance

to prevent tearing toward the anus (100-102). Thus, we cannot assess if differences in NNT are due to episiotomy technique.

In conclusion, the results from our study add to the growing body of evidence from several observational studies that a lateral or mediolateral episiotomy can prevent OASIS at VE in nulliparous women (Table 2) (11, 12). Some authors claim that an RCT is no longer needed, nor feasible (11). Given the treatment effect in our study, an RCT would require 2700 nulliparous women with VE allocating 1350 women to each treatment arm, which would be a massive challenge in most settings. However, if trial conditions are good, like Sweden, where the OASIS rate is high, the episiotomy rate is low, and the technique can be improved, a greater treatment effect may be seen. Until the results of an RCT can guide practice, we suggest a liberal use of a correct lateral or mediolateral episiotomy at VE in nulliparous women.

6.2.3 Paper III

After the results from **paper II** together with a slow inclusion rate in the EVA trial, we wanted to explore the knowledge about episiotomy technique and attitudes toward the intervention among doctors working in obstetric practice in Sweden. In **paper III**, we hypothesized that the high rate of OASIS at VE may be related to a poor technique, doubtful attitude, or lack of training. In accordance with our hypothesis, we found that the credence in episiotomy was low, along with a substandard self-reported technique. The results suggest a negative circle of incorrect teaching, learning, and performance, which in turn may lead to the prejudice that episiotomy does not work.

Doctors reported a low individual episiotomy rate, plausibly reflecting a restrictive attitude toward episiotomy. Since junior doctors largely adopt practices from senior colleagues, learning how and when to use episiotomy in a restrictive setting could be problematic if an incorrect technique is customary (160, 221). About 10 episiotomies under skillful supervision is required to optimize the technique (111).

In 2021, European guidelines on peripartum care regarding episiotomy was published (134). The guideline emphasizes the importance of regular training for correct episiotomy technique as well as audits on episiotomy performance to ensure a high quality and protective effect of the intervention (134). Considering these recommendations, we hope that the implication of our results could be increased acceptance and regular training in correct episiotomy technique. Once the technique is right, the attitudes may change with improved results.

6.2.4 Paper IV

In **paper IV** we aimed to explore if a lateral episiotomy could cause an iatrogenic LAM injury, which was not confirmed in our study. The homogenous group of primiparous women delivered with VE and standardized lateral episiotomy is unique to our study. Our study explored the risk of cutting the LAM, while previous research has focused on risk factors for any LAM injury (136). Previous studies have neither found an association between LAM

injury and episiotomy, nor presented data on whether the LAM injury was ipsi-, contra- or bilateral (222).

One reason for a low observed prevalence of levator ani deficiency on the side of the episiotomy could be small episiotomies, since LAM injury was not seen in women with episiotomy scars shorter than 18 mm. Other reasons could be adequate repair, poor examination, wrong equipment or failing assessment of the 3D ultrasound images. The use of endovaginal ultrasound technique is both a possible strength and limitation in **paper IV**. The ultrasound probe is placed close to the anatomical landmarks of the LAM, enabling vivid images and a high resolution of the inner portion of the LAM, including the pubovaginal, puboperineal, and puboanal muscles, where a lateral episiotomy could cause injury (206).

However, some researchers mean that the endovaginal technique may distort the anatomy (223). If the levator hiatus is distended, air may enter the vagina at probe insertion and blur the ultrasound image and blight correct diagnosis. Moreover, the endovaginal technique may hamper comparison with other studies, since most studies assessing LAM injury use translabial/transperineal ultrasound or MRI and these techniques generate a different scoring system (63, 224). However, in Sweden endovaginal or endoanal 3D ultrasound technique is common practice to assess the pelvic floor components and LAM. In any case, it is challenging to assess LAM injuries as no technique has been truly validated and to reproduce the results from earlier assessments have proven difficult (84).

Altogether, our results should be interpreted with caution. The sample size was small and confidence intervals were wide and based on an assumption of at least 50% injury if the episiotomy would be placed in the LAM. Still, it can be made likely that the lateral episiotomy performed in the study do not cause or increase LAM injury. In addition, the indications for episiotomy coincide with risk factors for LAM, as is the case with OASIS (73). There is no published RCT balancing potential confounders, although there might be possible to assess the causal association between episiotomy and LAM injury in the secondary analyses of the EVA trial (205). The clinical implication suggested from **paper IV** is that doctors may continue to perform lateral episiotomy without causing persistent LAM injury.

7 CONCLUSIONS

The conclusions of the studies included in the thesis are

I. Trial of labor resulted in vaginal delivery in the vast majority of first-time mothers 40 years or older. However, only two thirds of them experienced spontaneous vaginal delivery. Intrapartum cesarean section and VE were more common compared with younger women (25-29 years), in both spontaneous onset of labor and induction. OASIS or 5-minutes Apgar score <7 was not increased by age after any mode of onset. Episiotomy was similar in women ≥40 years compared with younger women.

II. Lateral or mediolateral episiotomy has the potential to reduce prevalence of OASIS in nulliparous women delivered with VE. The calculated average treatment effect was significant, and numbers needed to treat 27.

III. Doctors working in Sweden reported low use of episiotomy in VE and depicted lateral type episiotomies. The variation in depicted episiotomies resulted in that most pictures did not fulfill trigonometric properties of a protective episiotomy. Episiotomy was ranked of low importance in order to prevent OASIS in VE. Most doctors were willing to contribute to an RCT of episiotomy or not in VE, or were already contributing.

IV. In primiparous women delivered with VE and lateral episiotomy, one in five women had a LAM injury visible on 3D endovaginal ultrasound one year after delivery. There were few injuries on the side of the episiotomy alone. LAM injury was not seen in women with episiotomy scars shorter than 18 mm. There was no excessive risk of cutting the LAM while performing lateral episiotomy.

8 POINTS OF PERSPECTIVE

8.1 EVIDENCE FOR THE USE OF EPISIOTOMY

8.1.1 Observational studies on episiotomy in operative vaginal delivery

This thesis joins the substantial number of observational studies that support the use of routine lateral or mediolateral episiotomy in VE in nulliparous women (Table 2 in the background). Episiotomy will not eradicate OASIS but is an established risk modifying factor, and therefore should not be withheld women while waiting for an accurately sized and powered RCT (11, 225). Some experts even say that there is no need of more evidence (225).

Nonetheless, an important limitation of all register studies is the risk of selection bias and inability to adjust for unavailable factors that influence the treatment effect. For episiotomy, this may be exemplified by ill-defined procedures, policies, operator skills, and tissue properties. Consequently, an adequately sized RCT to compare routine lateral episiotomy with no episiotomy in VE in nulliparous women has been called for by several authors in the field (1, 12, 130, 226). A multicenter RCT is therefore now ongoing in Sweden (205).

That said, RCTs are not without pitfalls (227). Even though selection bias can be avoided by randomization and intention-to-treat analysis, this is of no value if adherence to allocated treatment is low, like in the studies by Murphy et al and Sagi-Dain et al (130, 158, 228). RCTs may enroll selected or unselected participants, wherein internal validity, or external validity and generalizability, may suffer.

8.1.2 RCTs on episiotomy in operative vaginal delivery

8.1.2.1 Previous studies

One pilot RCT was carried out 2008 in the United Kingdom, regarding routine versus restrictive use of episiotomy in operative vaginal delivery in nulliparous women (158). A total of 200 women were allocated to either standard routine use, or the new restrictive use of episiotomy. In the restrictive use group, episiotomy was recommended only if tearing "became apparent". The rate of OASIS did not differ significantly between groups although there was a trend towards a protective effect of episiotomy (8.1% OASIS in the routine group and 10.9% in the restrictive group) (158). The study was underpowered to demonstrate this modest difference. The high use of episiotomy in the restrictive group hampered the comparison between two groups. The possibility to intervene with episiotomy in the restrictive group if tearing became "apparent" introduced a risk of bias. In addition, the type of episiotomy was not specified, which may have led to inclusion of inefficient and unprotective episiotomies. Furthermore, the external validity may be limited in a Swedish setting since the trial included a high rate of forceps deliveries (64%). Altogether, the British trial showed that a larger trial is feasible and results to inform practice could be achieved with correct sample size and funding (158).

Another attempt to perform an RCT addressing episiotomy and perineal tears was carried out in Israel on mixed modes of vaginal delivery in nulliparous women (130). The study was not primarily designed to evaluate episiotomy in VE, but episiotomy in any vaginal delivery and with any tear as an outcome. Women were allocated to standard care, which was restrictive use of episiotomy, or no episiotomy. The sub-analyses of VE and OASIS did not show a difference between the two groups, but the rate of episiotomy was similar in both groups (228). The multi-center setting was switched to a single-center RCT as hospitals did not want to change their episiotomy standards and therefore refused to participate (229). This illustrates the difficulties for clinicians to adhere to the allocated intervention, especially if it deviates from their usual practice.

8.2 IMPLEMENTATION OF EVIDENCE IN CLINICAL PRACTICE

Changing the way healthcare is provided has proven difficult, despite when there is strong scientific evidence (230). Observational studies regarding the effect of episiotomy in VE have not universally convinced clinical practice. Will the results from an RCT change practice?

The reluctance to change may depend on organizational, contextual, and/or personal factors (230). The results of the Term Breech Trial almost instantly changed management of breech birth (231). This could be related to the marked effect of personal perceived value of the intervention and motivation to change (230). Choosing planned cesarean section seemed highly motivated to avoid the clinical situation where your management could make the difference between “life and death”, even if this was at the expense of maternal surgical risks (231).

Several well conducted RCTs and meta-analyses have shown improved neonatal survival after induction of labor in term and post-term pregnancies, and refuted association with adverse maternal outcomes (17, 189). In contrast to the effect of the Term Breech Trial, this evidence has still not convinced all regions in Sweden to implement induction of labor at 41 weeks. The organizational capacity, including workforce and facility resources, is likely the main obstacle. An ambiguous perceived value of the intervention among clinical staff could also be a hurdle. In daily practice, labor induction compared to spontaneous onset is related to an increase of medical interventions, thus the preconception about induction is confirmed by reality. The fact that expectant management does not always result in spontaneous onset, but also postponed induction or pre-labor cesarean section, is not evident in the delivery room.

The situation for choosing episiotomy or not is similar to choosing induction or expectant management. If you refrain from episiotomy, it will ideally result in an intact perineum, but it may also result in an equally sized spontaneous tear, or much worse: OASIS. Knowledge, training, education, teamwork, and leadership may all facilitate the implementation of interventions to prevent OASIS (90, 93). Irrespective of the components of a care bundle, a joint vision where all members of the team aim for the same outcome, a decrease in severe perineal tears, is crucial for success and ultimately improved obstetric care.

9 SUPPLEMENTARY MATERIAL

9.1 PAPER I

Appendix I:1. ICD-10, ICD-9 and procedure codes used to identify cases with chosen diagnoses or surgical procedures.

Diagnosis/condition	ICD-10	ICD-9	Procedure
Preeclampsia	O119, O140, O141, O141A, O141B, O141X, O142, O149, O150, O151, O152, O159	642E, 642F, 642G, 642H	
Gestational hypertension	O139	642D, 642	
Chronic hypertension	O100, O110, O111, O112, O113, O114, O119, I109, I110, I120, I130, I140, I150	642C, 642H	
Gestational diabetes	O244, O244A, O244B, O244X	648W	
Pre-gestational diabetes	O24, O240, O241, O242, O243, E109, E119, E129, E139, E149	648A, 250	
Pre-labor rupture of membranes	O756B, O756A, O756X, O756	658A, 658C, 658AD	
Obstetric anal sphincter injury (3rd and 4th degree perineal injury)	O702, O7020, O702A, O702B, O702X, O702C, O702E, O702D, O702H, O703, O7030, O703A, O703B, O703Z	664C, 664D	MBC33
Episiotomy			TMA00
Fetal distress	O680, O682, O683, O688, O689	656D	
Labor dystocia	O620, O621, O622, O628, O629	661A-E, 661X	

Appendix I:2. Risk factors for intrapartum cesarean section after spontaneous onset and induction of labor.

		Spontaneous onset		Induction of labor	
		Cesarean Section n (%)	Crude OR (95% CI)	Cesarean section n (%)	Crude OR (95% CI)
Age group	≥40 years	890 (15.4)	3.15 (2.93-3.39)	744 (37.2)	2.33 (2.12-2.57)
	25-29 years	12 888 (5.4)	1.0 (ref)	5611 (20.2)	1.0 (ref)
BMI	≥30	1566 (11.1)	2.24 (2.12-2.37)	1086 (30.1)	1.73 (1.60-1.87)
	<30	10 362 (5.3)	1.0 (ref)	4496 (19.9)	1.0 (ref)
Single/no cohab	Yes	677 (7.0)	1.27 (1.17-1.37)	376 (24.4)	1.21 (1.07-1.37)
	No	12 322 (5.6)	1.0 (ref)	5604 (21)	1.0 (ref)
Country of birth	Non-Nordic	2085 (6.8)	1.24 (1.18-1.30)	1022 (24.4)	1.22 (1.13-1.32)
	Nordic	11 554 (5.6)	1.0 (ref)	5296 (21.0)	1.0 (ref)
Year of delivery	≥1997	10 475 (6.0)	1.22 (1.17-1.27)	5354 (22.5)	1.42 (1.32-1.53)
	<1997	3303 (4.9)	1.0 (ref)	1001 (16.9)	1.0 (ref)
Assisted reprod	Yes	284 (8.7)	1.60 (1.41-1.81)	226 (29.3)	1.55 (1.32-1.81)
	No	13 494 (5.6)	1.0 (ref)	6129 (21.1)	1.0 (ref)
HT/Preeclampsia	Yes	553 (9.2)	1.71 (1.56-1.87)	1348 (20.5)	0.93 (0.87-1.00)
	No	13 225 (5.6)	1.0 (ref)	5007 (21.6)	1.0 (ref)
Diabetes	Yes	232 (12.2)	2.33 (2.03-2.68)	276 (31.0)	1.68 (1.46-1.94)
	No	13 546 (5.6)	1.0 (ref)	6079 (21.1)	1.0 (ref)
PROM	Yes	1514 (10.0)	1.94 (1.83-2.05)	970 (17.6)	0.75 (0.69-0.80)
	No	12 264 (5.4)	1.0 (ref)	5385 (22.2)	1.0 (ref)
Epidural	Yes	8647(8.6)	2.48 (2.40-2.57)	3738 (21.0)	1.03 (0.98-1.09)
	No	5131(3.6)	1.0 (ref)	2617 (21.7)	1.0 (ref)
Gestational week	37-38	1448 (3.8)	1.0 (ref)	870 (16.7)	1.0 (ref)
	39-40	6388 (4.6)	1.24 (1.17-1.32)	1748 (17.8)	1.08 (0.99-1.18)
	41	4114 (7.9)	2.19 (2.06-2.33)	1165 (23.8)	1.56 (1.41-1.72)
	≥42	1828(12.6)	3.67 (3.41-3.94)	2572 (26.2)	1.78 (1.63-1.94)
Birthweight (g)	<2999	1377 (5.2)	1.34 (1.26-1.43)	826 (18.5)	1.17 (1.06-1.28)
	3000-3499	3559 (4.0)	1.0 (ref)	1403 (16.3)	1.0 (ref)
	3500-3999	4806 (5.4)	1.38 (1.32-1.44)	1979 (20.0)	1.29 (1.19-1.39)
	4000-4499	3024 (9.8)	2.63 (2.50-2.77)	1476 (28.4)	2.04 (1.88-2.22)
	≥4500	977 (18.3)	5.45 (5.05-5.89)	660 (42.9)	3.86 (3.45-4.34)
Head circ (cm)	≥38	762 (10.7)	2.09 (1.93-2.25)	558 (27.9)	1.47 (1.33-1.63)
	<38	12 296 (5.4)	1.0 (ref)	5532 (20.8)	1.0 (ref)

Row percentages are presented; for example, 890 (15.4%) of women ≥40 years had a cesarean section after spontaneous onset. Cohab: cohabitation, reprod: reproduction, HT: hypertensive disease, PROM: pre-labor rupture of membranes, circ: circumference.

9.2 PAPER II

Table SII:1. Diagnosis (ICD-10) and procedure codes used to identify cases with chosen diagnoses or surgical procedures.

Diagnosis/condition	ICD-10	Procedure
Obstetric anal sphincter injury (3rd and 4th degree perineal injury)	O702, O7020, O702A, O702B, O702X, O702C, O702E, O702D, O702H, O703, O7030, O703A, O703B, O703Z	MBC33
Episiotomy		TMA00
Diabetes, all types	O244, O244A, O244B, O244X O24, O240, O241, O242, O243, E109, E119, E129, E139, E149	
Preeclampsia, hypertension	O119, O140, O141, O141A, O141B, O141X, O142, O149, O150, O151, O152, O159 O139 O100, O110, O111, O112, O113, O114, O119, I109, I110, I120, I130, I140, I150	
Crohn's disease or Ulcerative colitis	K500, K501, K508, K509, K510, K512, K513, K514, K515, K518 K519, K523, K528, K529	
Female genital mutilation	O347A, O348C, Z917	TLF00
Labor dystocia	O620, O621, O622, O624, O628, O629, O631, O639, O750 O640, O643, O645, O648, O649, O668, O669 O662, O366	
Intrapartum fetal distress	O680, O682, O683, O688, O689	
Fetal head station at vacuum extraction		MAE00 (outlet) MAE03 (midcavity)
Shoulder dystocia	O660	

Table SII:2. Balance summary after IPW (outcome OASIS).

	Standardized differences		Variance ratio	
	Raw	**Synthetic**	**Raw**	**Synthetic**
Maternal age				
≤19 years	0.0029842	-0.0061797	1.020556	0.9581729
20-24 years	0.0318873	-0.002896	1.060572	0.9945969
30-34 years	-0.0242612	0.0054214	0.9824617	1.003884
35-39 years	-0.0336169	0.0051533	0.92103	1.012433
≥40 years	-0.001771	0.0049668	0.9878019	1.034538
Continent of birth				
Latin America	-0.0488072	-0.0022625	0.6093348	0.9785646
Asia	-0.0245443	-0.0069596	0.9297831	0.9796582
Africa	0.047202	-0.0061009	1.406831	0.9558979
Unspecified	0.0088431	-0.0054006	1.104553	0.939885
Maternal height				
<160 Cm	0.0311859	0.0014612	1.071285	1.003253
Unspecified	-0.0294577	-0.0032112	0.8960833	0.9882739
Maternal BMI				
<18.5	0.0212487	-0.0038388	1.140399	0.9760527
25.0-29.9	0.0005943	-0.0055519	1.000911	0.9917113
30.0-34.9	-0.0084146	0.002048	0.966705	1.008204
≥35	-0.0058856	-0.0042767	0.9598826	0.9703439
Unspecified	-0.0051565	-0.0037166	0.9879873	0.991302
Cohabitation				
No	-0.0217003	-0.0096174	0.9233046	0.9649829
Unspecified	-0.056465	0.0002807	0.7862981	1.001158
Diabetes, all types				
Yes	0.0152513	-0.0024199	1.133	0.9800723
Preeclampsia/hypertension				
Yes	-0.0105967	-0.0053985	0.9593306	0.9790474
Female genital mutilation				
Yes	0.0420657	-0.007389	2.970472	0.8354332
Gestational age				
34-36 weeks	-0.0149822	-0.0001109	0.9108638	0.9993135
≥41 weeks	0.0682878	-0.0082392	1.034503	0.9956031
Neonatal sex				
Girl	-0.0525679	0.0056066	0.9867102	1.001271
Epidural				
Yes	-0.0794211	0.0014497	1.043056	0.9991957
Labour dystocia				
Yes	0.0168479	0.0071206	0.9910281	0.9961599
Intrapartum fetal distress				
Yes	-0.0317011	-0.003481	0.9906601	0.9989811
Fetal head station				
Mid-cavity	0.1103801	0.0128002	1.06803	1.008035
Unspecified	-0.0315306	0.0052284	0.9493663	1.008506
Fetal head position				
Occiput Posterior	0.1940446	0.0023427	1.764157	1.007179
Fetal head circumference				
≥38 cm	0.0246787	0.000574	1.088734	1.002002
Unspecified	0.1364234	-0.0047384	1.989298	0.9756324
Birthweight				
≤2999 g	-0.0636036	-0.0036063	0.8550498	0.9913512
3000-3499 g	-0.0704341	0.0043164	0.9474556	1.003155
4000-4499 g	0.0879785	-0.0011633	1.174067	0.9978171
≥4500 g	0.0456869	-0.0026113	1.281268	0.9857381
Apgar at 1 minute				
<4	0.0744735	0.0041705	1.467015	1.022184
Shoulder dystocia				
Yes	0.0415609	-0.0003998	1.55915	0.9957532

Table SII:3. Balance summary after IPW (outcome OASIS) continued.

	Standardized differences		Variance ratio	
	Total	**Synthetic**	**Total**	**Synthetic**
Year of delivery				
2001	0.1319164	-0.0029753	1.563145	0.9895433
2002	0.0948779	0.0051591	1.346828	1.016739
2003	0.0953172	0.0084747	1.324147	1.025701
2004	0.0611236	0.0057707	1.196505	1.017407
2005	-0.0015235	-0.0119608	0.9954864	0.9642175
2006	-0.0439497	-0.009231	0.8777513	0.9731783
2007	-0.0735207	-0.0004961	0.805635	0.9985898
2008	-0.0938463	0.0045596	0.7576302	1.012872
2009	-0.0739701	0.0029719	0.8061703	1.008358
2010	-0.0863321	0.0072425	0.7788756	1.020086
2011	-0.1239022	-0.0059298	0.6852716	0.9830763
Hospital of delivery				
Akademiska	-0.0870801	-0.0001599	0.6523426	0.9992618
Falun	-0.1535125	-0.0023738	0.2756306	0.984286
Gällivare	0.0517686	0.0003002	2.404379	1.005284
Gävle	-0.0953953	-0.0025702	0.4617696	0.9816022
Hallands Halmstad	0.0663475	-0.0001184	1.736399	0.9989819
Hallands Varberg	0.0550516	0.0023865	1.625376	1.021599
Helsingborgs	-0.1773715	-0.0488674	0.2158518	0.7067552
Huddinge	-0.2321128	0.0030442	0.3203764	1.012073
Hudiksvalls	0.0082226	0.0007305	1.103327	1.008834
Höglandssjukhuset	0.0631116	-0.0019529	1.778802	0.9814471
Karlskoga	0.150934	0.0011264	5.143074	1.011826
Karlskrona	-0.0368086	-0.0079915	0.7389415	0.9374299
Karlstad	0.0626125	-0.0054786	1.441978	0.9669532
Karolinska	0.0659556	0.0143555	1.26811	1.05259
Kristianstad	0.0287448	0.0016328	1.263473	1.013533
Ljungby	0.0677242	-0.0026868	4.399118	0.9452947
Lycksele	-0.0386122	0.0000998	0.5657836	1.00136
Länssjukhuset	0.0158053	-0.0057249	1.131084	0.9550497
Mora	0.0063363	0.0003499	1.08702	1.00466
Motala	-0.0487671	0.0024893	0.3057508	1.049997
Mälarsjukhuset	-0.0275808	0.0011635	0.7971848	1.009323
Norrlands	0.1143191	-0.0009074	2.302478	0.9932441
NU-Sjukvården	0.2108972	0.005733	3.493766	1.035662
Nyköping	0.0179842	0.0014022	1.179259	1.013047
Ryhov	0.0102979	-0.0091558	1.07445	0.9360662
Sahlgrenska Universitetssjukhuset	0.1796902	-0.0009023	1.734738	0.9970976
Skellefteå	0.0111436	-0.0027216	1.127806	0.9703856
Skövde	0.012291	-0.0036094	1.092133	0.9740307
Sollefteå	0.0501024	0.0005794	2.452774	1.010594
Sunderbyn	0.0193057	-0.001155	1.162828	0.990826
Sundsvall	0.1032498	0.0001029	2.023756	1.000726
Södersjukhuset	-0.1772431	0.0078093	0.5302525	1.025075
Södertälje	-0.0654586	-0.004631	0.614491	0.9679325
Södra Älvsborg	0.2102806	-0.0058111	4.508889	0.9607294
Universitet Linköping	-0.1199629	-0.0002343	0.4617428	0.9986653
Universitet Lund	0.0266101	-0.001577	1.175466	0.9902883
Universitet Malmö	-0.1108271	-0.040886	0.4065864	0.7296784
Universitet Örebro	0.1212588	-0.0013105	1.965223	0.9923933
Visby Lasarett	0.0100937	0.0008104	1.131764	1.010086
Vrinnevi	-0.0418326	-0.0030856	0.7513998	0.9797435
Värnamo	0.0878495	0.0013768	2.651564	1.016057
Västervik	0.0444058	-0.0021855	1.67651	0.9735627
Västerås	0.0256609	0.0100969	1.16612	1.061413
Växjö	0.0986462	-0.0003067	2.065349	0.9976862
Ystad	0.0250206	0.0027938	1.247241	1.025013
Örnsköldsvik	0.0378405	0.0009245	1.74269	1.014096
Östersund	0.037523	-0.0005874	1.430343	0.9942529

Table SII:4. Year of delivery.

	Exposure		Outcome	
	No episiotomy N=43853	Episiotomy N=19801	No OASIS N=54626	OASIS N= 9028
Year	n (row %)	n (row %)	n (row %)	n (row %)
2000	2278 (56.1)	1784 (43.9)	3481 (85.7)	581 (14.3)
2001	2393 (57.5)	1769 (42.5)	3502 (84.1)	660 (15.9)
2002	2938 (61.5)	1842 (38.5)	4089 (85.5)	691 (14.5)
2003	3251 (61.8)	2009 (38.5)	448 (85.2)	780 (14.8)
2004	3442 (64.6)	1883 (35.4)	4542 (85.3)	783 (14.7)
2005	3696 (69.1)	1655 (30.9)	4531 (84.7)	820 (15.3)
2006	4015 (73.1)	1556 (27.9)	4761 (85.5)	810 (14.5)
2007	4260 (73.9)	1501 (26.1)	4989 (86.6)	772 (13.4)
2008	4404 (75.2)	1456 (24.8)	5082 (86.7)	778 (13.3)
2009	4318 (73.8)	1531 (26.2)	5117 (87.5)	732 (12.5)
2010	4443 (74.6)	1512 (25.4)	5129 (86.1)	826 (13.9)
2011	4415 (77.2)	1303 (22.8)	4923 (86.1)	795 (13.9)

Table SII:5. Hospital of delivery.

	Exposure		Outcome	
	No episiotomy N=43853	Episiotomy N=19801	No OASIS N=54626	OASIS N= 9028
Hospital name	**n (row %)**	**n (row %)**	**n (row %)**	**n (row %)**
Akademiska sjukhuset	2020 (77.7)	580 (22.3)	2257(86.8)	343(13.2)
Blekingesjukhuset	3 (100)	0	2(66.7)	1 (33.3)
Bodens lasarett	4 (33.3)	8 (66.7)	12(100)	0
Bollnäs sjukhus	0	2 (100)	2 (100)	0
Borås lasarett	1 (100)	0	0	1(100)
Danderyds sjukhus	5100 (88.0)	698 (12.0)	4860(83.8)	938 (16.2)
Falu lasarett	1194 (89.2)	145 (10.8)	1161(86.7)	178 (13.3)
Gällivare lasarett	100 (47.8)	109 (52.2)	192 (91.9)	17 (8.1)
Gävle sjukhus	955 (83.0)	195 (17.0)	1009 (87.7)	141 (12.3)
Hallands sjukhus Halmstad	462 (56.2)	360 (43.8)	729 (88.7)	93 (11.3)
Hallands sjukhus Varberg	429 (57.8)	313 (42.2)	637 (85.8)	105 (14.2)
Helsingborgs lasarett	1300 (91.3)	124 (8.7)	1280 (89.9)	144 (10.1)
Huddinge sjukhus	2993 (88.0)	408 (12.0)	2904 (85.4)	497 (14.6)
Hudiksvalls sjukhus	283 (66.7)	141 (33.3)	367 (86.6)	57 (13.4)
Hälsinglands sjukhus	53 (54.1)	45 (45.9)	86 (87.8)	12 (12.2)
Höglandssjukhuset	380 (55.5)	305 (44.5)	625 (91.2)	60 (8.8)
Kalix lasarett	4 (23.5)	13 (76.5)	15 (88.2)	2 (11.8)
Karlskoga lasarett	170 (30.0)	397 (70.0)	525 (92.6)	42 (7.4)
Karlskrona sjukhus	721 (75.3)	237 (24.7)	764 (79.7)	194 (20.3)
Karlstads sjukhus	973 (60.3)	641 (39.7)	1430 (88.6)	184 (11.4)
Karolinska sjukhuset	2478 (63.4)	1430 (36.6)	3300 (84.4)	608 (15.6)
Kiruna lasarett	4 (36.4)	7 (63.6)	10 (90.9)	1 (9.1)
Kristianstads sjukhus	561 (63.7)	319 (36.3)	741 (84.2)	139 (15.8)
Kristinehamns sjukhus	0	1 (100)	1 (100)	0
Ljungby lasarett	46 (33.6)	91 (66.4)	122 (89.1)	15 (10.9)
Luleå lasarett	7 (53.8)	6 (46.2)	12 (92.3)	1 (7.7)
Lycksele lasarett	267 (79.5)	69 (20.5)	279 (83.0)	57 (17.0)
Länssjukhuset Kalmar	645 (66.5)	325 (33.5)	849 (87.5)	121 (12.5)
Löwenströmska sjukhuset	2 (66.7)	1 (33.3)	3 (100)	0
Mora lasarett	240 (66.7)	120 (33.3)	301 (83.6)	59 (16.4)
Motala lasarett	140 (88.1)	19 (11.9)	127 (79.9)	32 (20.1)
Mälarsjukhuset	695 (73.8)	247 (26.2)	773 (82.1)	169 (17.9)
Mölndals sjukhus	0	1 (100)	1 (100)	0
Nacka sjukhus	2 (66.7)	1 (33.3)	1 (33.3)	2 (66.7)
Norrlands Universitetssjukhus	521 (49.0)	543 (51.0)	892 (83.8)	172 (16.2)
NU-sjukvården	622 (38.1)	1012 (61.9)	1390 (85.1)	244 (14.9)
Nyköpings lasarett	461 (65.5)	243 (34.5)	579 (82.2)	125 (17.8)
Piteå Älvdals sjukhus	32 (57.1)	24 (42.9)	48 (85.7)	8 (14.3)
Ryhov länssjukhus	813 (67.4)	393 (32.6)	1096 (90.9)	110 (9.1)
Sabbatsbergs sjukhus	2 (100)	0	2 (100)	0
Sahlgrenska universitetssjukhuset	2615 (54.9)	2150 (45.1)	4113 (86.3)	652 (13.7)
Skaraborgs sjukhus	24 (27.6)	63 (72.4)	74 (85.1)	13 (14.9)
Skellefteå lasarett	343 (66.5)	173 (33.5)	455 (88.2)	61 (11.8)
Skövde sjukhus	767 (67.1)	376 (32.9)	971 (85.0)	172 (15.0)
Sollefteå sjukhus	88 (47.6)	97 (52.4)	150 (81.1)	35 (18.9)
Sunderbyns sjukhus	633 (65.7)	330 (34.3)	852 (88.5)	111 (11.5)
Sundsvalls sjukhus	623 (52.1)	573 (47.9)	1017 (85.0)	179 (15.0)
Söderhamns sjukhus	3 (75.0)	1 (25.0)	3 (75.0)	1 (25.0)
Södersjukhuset	3920 (81.5)	888 (18.5)	4091 (85.1)	717 (14.9)
Södertälje sjukhus	983 (78.5)	270 (21.5)	1099 (87.7)	154 (12.3)
Södra Älvsborgs sjukhus	391 (32.3)	819 (67.7)	1084 (89.6)	126 (10.4)
Torsby sjukhus	2 (15.4)	11 (84.6)	11 (84.6)	2 (15.4)
Trelleborgs lasarett	1 (100)	0	0	1 (100)
Uddevalla sjukhus	1 (33.3)	2 (66.7)	3 (100)	0
Universitetssjukhuset Linköping	1475 (83.1)	300 (16.9)	1472 (82.9)	303 (17.1)
Universitetssjukhuset Lund	1003 (65.3)	532 (34.7)	1265 (82.4)	270 (17.6)
Universitetssjukhuset Malmö	1019 (84.6)	185 (15.4)	1012 (84.1)	192 (15.9)
Universitetssjukhuset Örebro	915 (52.5)	827 (47.5)	1523 (87.4)	219 (12.6)
Visby lasarett	266 (66.3)	135 (33.7)	346 (86.3)	55 (13.7)
Vrinnevisjukhuset	1018 (74.9)	342 (25.1)	1185 (87.1)	175 (12.9)
Värnamo sjukhus	217 (45.2)	263 (54.8)	407 (84.8)	73 (15.2)
Västerviks sjukhus	246 (56.8)	187 (43.2)	364 (84.1)	69 (15.9)
Västerås lasarett	1039 (65.6)	546 (34.4)	1402 (88.5)	183 (11.5)
Växjö lasarett	537 (51.6)	503 (48.4)	885 (85.1)	155 (14.9)
Ystads lasarett	484 (63.9)	273 (36.1)	654 (86.4)	103 (13.6)
Ängelholms sjukhus	3 (50.0)	3 (50.0)	6 (100)	0
Örnsköldsviks sjukhus	153 (56.0)	120 (44.0)	243 (89.0)	30 (11.0)
Östersunds sjukhus	390 (60.9)	250 (39.1)	539 (84.2)	101 (15.8)
Missing	11 (55.0)	9 (45.0)	16 (80.0)	4 (20.0)

9.3 PAPER III

Questionnaire in English

1. *What role do you normally take at a vacuum extraction delivery?*
   I supervise younger colleagues with vacuum extraction deliveries.
   I perform vacuum extraction deliveries independently without supervision
   I perform vacuum extraction deliveries with supervision from a colleague.
   I do not perform vacuum extraction deliveries.

2. *What role do you normally take at a forceps delivery?*
   I supervise younger colleagues with forceps.
   I use forceps independently without supervision.
   I use forceps with supervision from a colleague.
   I do not use forceps.

3. *How many vacuum extraction deliveries have you performed in the last 12 months?*
   None
   1-5
   6-10
   11-20
   21-30
   >30

4. *How many forceps deliveries have you performed in the last 12 months?*
   None
   1-5
   6-10
   11-20
   21-30
   >30

5. *In your current professional role, when you perform an instrumental delivery on a nulliparous woman – how do you feel? Where 0 is no stress and 100 maximum stress*
   0-10
   11-20
   21-30
   31-40
   41-50
   51-60
   61-70
   71-80
   81-90
   91-100

6. *How old are you?*
   <30 years
   30-39 years
   40-49 years
   50-59 years
   >59 years

7. *What gender do you define as?*
   Female
   Male
   Nonbinary/no gender

8. *How long have you worked within the specialty (including your training)?*
   0-5 years
   6-10 years
   11-15 years
   16-20 years
   >20 years

9. *What is your subspecialty?*
   Obstetrics
   Gynecology
   None of them or both (eg. trainee or working in a smaller hospital)

10. *How would you manage a labour with **low cavity arrest**, a fetal **OA** position and no signs of cephalopelvic disproportion or fetal distress?*

    I would use the ventouse
    Always
    Often
    Rarely
    Never

    I would use forceps
    Always
    Often
    Rarely
    Never

    I would perform a Caesarean Section
    Always
    Often
    Rarely
    Never

11. *How would you manage a labour with **mid cavity arrest**, a fetal **OA** position and no signs of cephalopelvic disproportion or fetal distress?*

    I would use the ventouse
    Always
    Often
    Rarely
    Never

    I would use forceps
    Always
    Often
    Rarely
    Never

I would perform a Caesarean Section
Always
Often
Rarely
Never

12. *How would you manage a labour with **mid cavity arrest**, a fetal **OT or OP** position and no signs of cephalopelvic disproportion or fetal distress?*

    I would use rotational ventouse
    Always
    Often
    Rarely
    Never

    I would perform manual rotation + ventouse/forceps
    Always
    Often
    Rarely
    Never

    I would use rotational forceps
    Always
    Often
    Rarely
    Never

    I would perform a caesarean section
    Always
    Often
    Rarely
    Never

13. *What do you think is hardest to assess when planning an instrumental delivery on a nulliparous woman?*
    Station
    Fetal position
    Risk of caesarean section
    Risk of a large tear
    Risks for the fetus ex scalp trauma, shoulder dystocia

14. *How do you consider an episiotomy affects the risk of a 3rd or 4th degree tear, when delivering a nulliparous woman with vacuum extraction?*
    Increased risk
    No difference in risk
    Decreased risk
    Do not know

15. *How do you consider an episiotomy affects the risk of a 3rd or 4th degree tear, when delivering a nulliparous woman with forceps?*
    Increased risk

No difference in risk
Decreased risk
Do not know

16. *If you use vacuum extraction during delivery, how often do you perform an episiotomy on nulliparous women (%)?*
    0-10
    11-20
    21-30
    31-40
    42-50
    51-60
    61-70
    71-80
    81-90
    91-100

17. *If you use forceps during delivery, how often do you perform an episiotomy on nulliparous women (%)?*
    0-10
    11-20
    21-30
    31-40
    41-50
    51-60
    61-70
    71-80
    81-90
    91-100

18. *How do you believe the risk of acquiring an obstetric anal sphincter injury can be decreased when performing a vacuum extraction delivery on a nulliparous woman?*
    Slow delivery of the second stage of labor (slow birth).
    Correct manual support of the perineum.
    Use of correct episiotomy technique.
    Collaboration with the laboring woman.
    Correct technique and pulling direction of the vacuum extraction.

19. *When do you believe an episiotomy is required in an instrumental delivery?*
    On principle always in vacuum extractions.
    On principle always in forceps deliveries.
    When there is fetal distress/on fetal indication.
    When there is prematurity.
    When there are signs of a large tear ex. Blanching of the skin, started to tear.
    When there are additional risk factors, ex. OP presentation/asynclitic presentation, large fetus, oedematose tissues, small/short mother.
    When the perineum is high, tight and does not give way.
    I do not know.

20. *Picture enclosed in survey*

21. *What do you call the type of episiotomy you have drawn?*

Lateral
Mediolateral
Median (midline)
Do not know/none of these alternatives

22. *Would you consider participating as a doctor in a randomized controlled trial assessing routine use or no/very restrictive use of episiotomy in vacuum extraction deliveries of nulliparous women?*
    Yes
    No
    I or my clinic is already participating

23. *Would you consider participating as a patient (or recommend your partner participating as a patient) in a randomized controlled trial assessing routine use or no/very restrictive use of episiotomy in vacuum extraction deliveries of nulliparous women?*
    Yes
    No
    I/my partner is already participating
    Do not know/do not want to answer

24. *What concerns or objections do you have to an RCT assessing routine use or no/very restrictive use of episiotomy in vacuum extraction deliveries of nulliparous women?*
    Information about the study will increase fears of giving birth.
    Will lead to an increase in episiotomies overall.
    Episiotomies do not help to decrease obstetric anal sphincter injuries.
    An episiotomy is worse than an obstetric anal sphincter injury.
    The woman receives an unnecessary injury (avoidable injury or avoidable episiotomy).
    There are rarely anal sphincter injuries when I perform vacuum extractions.
    I and others can individually assess when an episiotomy is needed.
    Other concerns that are not mentioned here (please describe them at the end of the questionnaire).
    No specific concerns.

25. *What risk/benefit balance do you think is acceptable in terms of episiotomy and the risk of obstetric anal sphincter injury?*
    It is never acceptable to perform an episiotomy as prevention of obstetric anal sphincter injury.
    It is acceptable to perform an episiotomy on 1-5 women to avoid that one woman gets an obstetric anal sphincter injury (NNT 1-5)
    It is acceptable to perform an episiotomy on 5-14 women to avoid that one woman gets an obstetric anal sphincter injury (NNT 5-14)
    It is acceptable to perform an episiotomy on 15-29 women to avoid that one woman gets an obstetric anal sphincter injury (NNT 15-29)
    It is acceptable to perform an episiotomy on 30-49 women to avoid that one woman gets an obstetric anal sphincter injury (NNT 30-49)
    It is acceptable to perform an episiotomy on >49 women to avoid that one woman gets an obstetric anal sphincter injury (NNT >49)

26. *If you have any further answers, comments or opinions, please write them here:*
    (Free text answers)

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