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Obstetric anal sphincter injuries

Risk factors, episiotomy characteristics, and pelvic floor dysfunction

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A dissertation for the degree of
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TABLE OF CONTENTS

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Tromsø, xxx

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ABSTRACT

Background

Obstetric anal sphincter injuries (OASIS) are well known and serious complications of vaginal delivery. The overall rate varies in different reports (0.6-10.2%). Complications after such an injury are very distressing. Despite sufficient primary repair, cohort studies show that 30-50% of all women suffering such injury experience anal incontinence. To prevent OASIS it is important to accumulate knowledge with regard to risk factors, in particular those modifiable to obstetric interventions.

The incidence of OASIS in Norway increased from below 1.0% in the 1960s to 4.3% in 2004. As a consequence a national strategy to reduce the number of OASIS was initiated by the Directorate for Health and Social affairs/ National Advisory Committee for Obstetrics. As a part of this strategy an interventional programme primarily focused on perineal support during the final part of second stage of labour was conducted. First the programme was introduced at one hospital, and then subsequently at four other hospitals. After the interventional programme the OASIS rate fell from 4-5% to 1-2%.

The role of episiotomy has been subject for debate. Whereas there is evidence that midline episiotomy is associated with increased risk of OASIS, consensus is lacking regarding the role of mediolateral episiotomy. While recent studies have indicated that mediolateral episiotomy is protective against OASIS both during operative vaginal deliveries and for primiparous women, other studies have shown that mediolateral episiotomy is a risk factor for OASIS.

As mentioned, OASIS might cause anal incontinence (AI), but is also associated with urinary incontinence (UI) and sexual problems. Episiotomy is identified both as a risk factor and protective factor for OASIS as well as an independent risk factor for postpartum AI and sexual problems. However, lately episiotomy with true mediolateral or lateral characteristics has recently been shown to have possible protective properties in relation to OASIS. However, little is known about the relationship between such episiotomy characteristics and pelvic floor dysfunction.

Main Objectives

Study I: To evaluate and compare the risk profile of sustaining OASIS after the OASIS rate was reduced from 4.6% to 2.0% following an interventional programme. Further, to investigate associated risks in five risk groups (low to high).

Study II: To investigate the association between the geometrical properties of episiotomies and OASIS.

Study III: To investigate AI, UI, and sexual problems in two groups of primiparous women with episiotomy, comparing women with and without OASIS, and assess associations between episiotomy characteristics and the dysfunctions: AI, UI, and sexual problems.

Method

Study I: Four Norwegian obstetric departments and 40 154 vaginal deliveries in 2003-2009 were included in this multicentre interventional cohort study with before and after

comparison. Pre- and postintervention analyses were conducted and the associations of OASIS with possible risk factors were estimated using odds ratios obtained by logistic regression.

Study II: This was a case-control study based at The University Hospital of North Norway, Tromsø and Nordland Hospital, Bodø, Norway, comparing two groups of women. Seventy-four women with episiotomy were included. Cases (n = 37) had sustained OASIS at birth, while controls (n = 37) had not. The groups were matched for instrumental delivery. The episiotomy scar was photographed, and relevant measures taken. Data were analysed using conditional logistic regression analysis.

Study III: The sample was the same as in study II. AI, UI and sexual problem symptoms were obtained from St. Mark's scoring-tool and self-administered questionnaires. Conditional logistic regression models and Pearson´s correlation coefficient were used to estimate the differences between women with and without OASIS, and the associations between episiotomy characteristics and symptoms, respectively.

Results

Study I: The risk of sustaining OASIS decreased by 59% (OR 0.41; 95% CI 0.36-0.46) after the intervention. The key risks factors remained the same, comprised 1st vaginal delivery (OR 3.84; 95% CI 2.90-5.07), birth weight ≥ 4500g (OR 4.42; 95% CI 2.68-7.27) or forceps delivery (OR 3.54; 95% CI 1.99-6.29). However, the highest reduction in OASIS, (65%), was observed in group 0 (low-risk) (OR 0.35; 95% CI 0.24-0.51).

Study II: The risk of sustaining OASIS decreased by 70% (odds ratio [OR] 0.30; 95% CI 0.14–0.66) for each 5.5-mm increase in episiotomy depth, decreased by 56% (OR 0.44; 95% CI 0.23–0.86) for each 4.5 mm increase in the distance from the midline to the incision point of the episiotomy, and decreased by 75% (OR 0.25; 95% CI 0.10–0.61) for each 5.5 mm increase in episiotomy length. Lastly, there was a ''U-shaped'' association between angle of episiotomy and OASIS (OR 2.09; 95% CI 1.02–4.28) with an increased risk (OR 9.00; 95% CI 1.1–71.0) of OASIS when the angle was either smaller than 15°or >60°.

Study III: The mean time from birth to assessment was 34.5 and 25.9 months for women with and without OASIS, respectively. Women with OASIS reported more AI: 15 (41%) vs. 3 (8%), p= 0.05, more sexual problems (score points 10.0 vs. 12.6, p= 0.04, low score =more symptoms), and had different episiotomy characteristics: length (13 mm vs.17 mm, p=0.01); depth: (11 mm vs.16 mm, p=0.01); incision point from midline (6 mm vs. 9 mm, p=0.04); correct angles 23 (62%) vs. 31 (84%), p=0.04 compared to women without OASIS. Episiotomy length was associated with sexual problems in women without OASIS (r= 0.41, p=0.03). No other associations between episiotomy characteristics and dysfunctions were found.

Conclusion

After the interventional programme the most significant decrease in OASIS was observed in low-risk births. The main risk factors for OASIS remained unchanged being 1st vaginal delivery, high birth weight ≥ 4500g, and forceps assisted delivery.

We found that scarred episiotomies with depth > 16 mm, length > 17 mm, incision point > 9 mm lateral of midpoint and angle range 30–60° are significantly associated with less risk of OASIS. However, shrinkage of tissue must be considered.

Lastly, women with OASIS had more AI and sexual problems. There was no association between episiotomy characteristics and dysfunctions except between episiotomy length and sexual problems in women without OASIS.

The final conclusion of this work strongly suggests that an interventional programme significantly reduces the risk of OASIS and in particular in low-risk births. Episiotomy with lateral incision point, sufficient length and correct angle appear to protect against OASIS. Finally, a sphincter tear is associated with both AI and sexual dysfunction and should be avoided by using correct episiotomy, if indicated.

LIST OF ORIGINAL PAPERS

I. Stedenfeldt M, Øian P, Gissler M, Blix E, Pirhonen J. **Risk factors for obstetric anal sphincter injury after a successful multicentre interventional programme.** BJOG 2013;e-pub ahead of print

II. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. **Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study.** BJOG 2012;119:724-30.

III. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. **Episiotomy characteristics and anal incontinence, urinary incontinence and sexual problems in primiparous women.** Submitted

ABBREVIATIONS

OASIS	Obstetric anal sphincter injuries
AI	Anal incontinence
UI	Urinary incontinence
EAS	External anal sphincter
IAS	Internal anal sphincter
RCT	Randomised controlled trial
RCOG	Royal College of Obstetricians and Gynaecologists
MBRN	Medical Birth Registry of Norway
G	Grams
mm	Millimetres
OR	Odds ratio
CI	Confidence interval
OS	Observational studies

"We have come a long way - we have only just begun"
Harold Drutz

INTRODUCTION

Historical perspective

Pregnancy and birth have been, and in many places still is, hazardous and life threatening for both the mother and the baby. Thanks to the development of modern obstetrics, western women deliver their babies very safely. Modern obstetrics has evolved in relation to instrumental delivery, delivery techniques, hygiene routines, antisepsis and antibiotics, systematic regulated education, and caesarean section. In interplay with industrialization, economic growth and increasingly better living condition, and the women's rights movement the risk of maternal mortality and morbidity has decreased dramatically.[1] The Maternal mortality rate is today about 7 in 100 000 in Western Europe, compared to 1 in 200 in the 19thcentury. However, the benefits of modern obstetrics have unfortunately not reached women in developing countries where the mortality rate is 1-2 in 200 (Sub-Saharan Africa) even today.[2]

Although modern obstetrics has made childbirth remarkably safe and far from a life-threatening event in the western world, there are still certain challenges. The nature of vaginal birth and the anatomy of the pelvic floor in humans inevitably expose the perineal tissue to potential injury. Investigations of the relationship between the maternal pelvic inlet and the size of the neonatal head in a range of primate species show that the cranium in humans is actually larger than the anterioposterior dimension of the pelvic inlet (Figure 1). The almost identical correspondence between the foetal head and the maternal pelvic dimensions requires that all dimensions are lined up at all points, and the cardinal movements (a series of rotations) occur successfully during the birth process.[3]

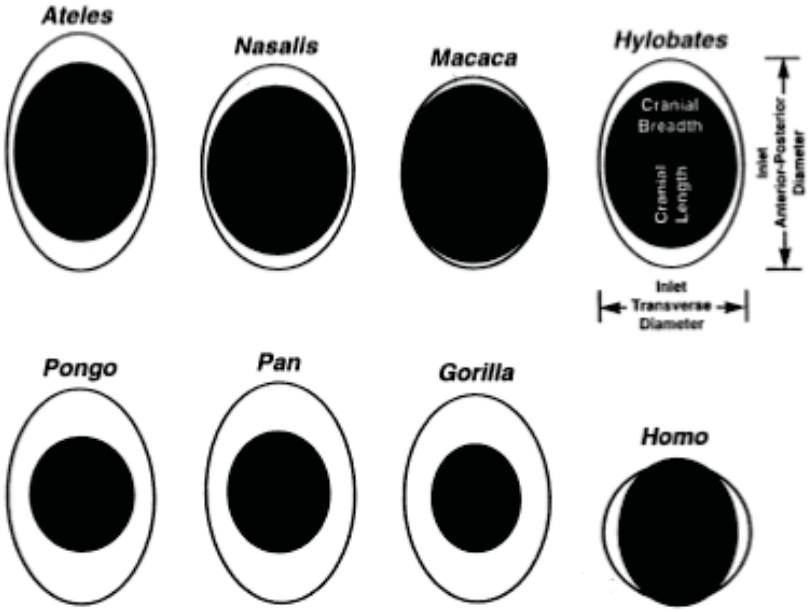


Figure 1.The relationship between the size of the maternal pelvic inlet and the size of the neonatal head in a range of primates series. In the monkeys and the gobbon (Ateles, Nasalis, Mocaca and Hylobates) the dimensions of the neonatal cranium are only slightly smaller than the dimensions of the mother´s pelvis. In great apes (Pongo, Pan and Gorilla), the pelvic inlet is relatively spacious, whereas in humans the neonatal cranium is longer than the anterior- posterior dimension of the pelvic inlet (Rosenberg & Trevathan, BJOG 2002;109:1199).[3] Printed with permission from publisher.

Thus, perineal care has been a natural focus through history. Early evidence of such care was described by the physician Soranus of Ephesus (98-138 A.D). Cloths drenched with warm oils and warm hands were suggested as effective remedies to preserve the tissue. Medical scripts from the 11th century gave the first written description of severe perineal trauma which, it explained, might happen if precaution is neglected.[4] During the eighteenth century men entered the field of midwifery and more technical and instrumental solutions to delivery were gradually developing. Incision to increase the outlet and to prevent tears, known as episiotomy, and forceps gradually gained acceptance as a regular intervention in assisting delivery[4;5] (Figure 2).

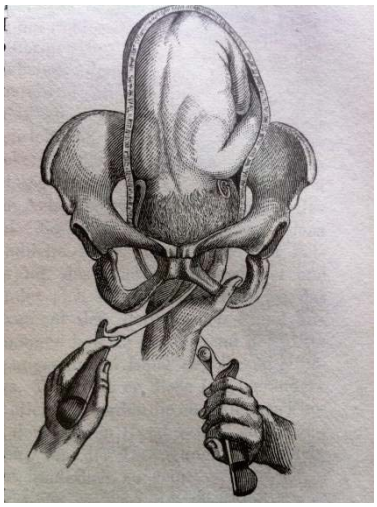


Figure 2. ”Die Einfuhrung des rechten Loffels” Scanzoni 1855: 818.[5]

Literature from the early 1900 emphasises the importance of avoiding perinal tears. Flew 1940 [6] wrote the following about perineal tears:

"What are the possible disadvantages of a torn perineum? The greatest is a complete tear through the sphincter and the mucous membrane of the rectum, so that patient is left with a recto-vaginal cloaca, incontinent of flatus and faeces. This is a disaster…. There can be no argument against the statement that a perineal tear involving the rectum must be avoided at all costs."

Episiotomy became gradually routine in obstetric care from 1940 to 1980 and some would say that the perineum had become a surgical site. More often than not women were obliged to adopt a supine position and anaesthetised, the perineum was then shaved, swabbed and draped to prepare for the surgery that inevitable followed.[4]

However, starting in the late1980`s, the medicalisation of childbirth was questioned, suggesting that unnecessary medical intervention in normal childbirth was given far too often.[7;8] Consequently, a movement for change came in the 1980 and 1990, aimed at re-emerging the original midwife. Key features were a focus on women's autonomy, challenging the view that childbirth is an illness and supporting non-medicalised perinatal care.[9] Broadly this was labelled the social model. This movement created a degree of disagreement between a dominant surgical tradition and the social model of perineal care.[4] A growing number of reviews and studies were conducted investigating delivery methods and obstetric intervention, questioning the surgical tradition and medical gain versus the cost. Two areas of investigations and focus became path breaking for obstetric care. Evidence on episiotomy showed that routine episiotomy caused more severe trauma than a more restrictive policy.[10] This changed the episiotomy practice from routine to restrictive. Further, questions regarding the protective benefit of perineal support during second stage of delivery generated a few report proclaiming that "hands off" gave better perineal outcome than "hands on".[11;12] As a result, manual protection of the perineum was not specifically recommended in neither policies dictated by the World Health Organisation and the Cochrane Pregnancy and Childbirth database. [13] In the beginning of year 2000 major shift in obstetric care was reported form Sweden. Alternative birth positions predominated, the woman was encouraged to choose way of delivery and perineal protection was not practised to the same extent as before.[13] One can presume that that the obstetric care in Norway was influenced by this movement as well.

An injured perineum has been viewed as a negative aspect and somewhat accepted as part of vaginal birth.[14] However, an increasing rate of severe perineal injuries, obstetric anal sphincter injuries (OASIS) as well as a growing awareness of the potential sequelae of perineal injury have focussed attention on finding methods to prevent such injury.[15,16]

Perineal body in females

The perineal body which first was named in 1889[17], is a complex mass into which many fibromuscular structures insert.[18] It occupies the area between the posterior wall of the vagina and the anorectal junction.[17] Its three-dimensional form has been compared to a pine cone, with each "petal" representing an interlocking structure such as an insertion site of muscles or fascia.[18] Due to the multiple junctures structure of the perineal body it possesses great clinical importance (Table 1) with anatomical components important for both urinary and faecal continence. This serves as a fundamental anchor for the vagina and anorectum, as well as a terminal insertion site for part of the external urethral sphincter (Figure 3 and 4). During intercourse the perineal body is stimulated because of its attachments to the various levator ani muscles, which narrows the urogenital hiatus.[18]

Table 1. Clinical importance of the perineal body

Anchors the anorectum
Anchors the vagina
Prevents expansion of the urogenital hiatus
Provides a physical barrier between the vagina and rectum
Maintain the orgasmic platform
Maintain urinary continence
Pudendal nerve innervation
Maintain faecal continence

From Woodman and Graney, Clincal Anatomy 2002;15:321-334.[18] Printed with permission from publisher.

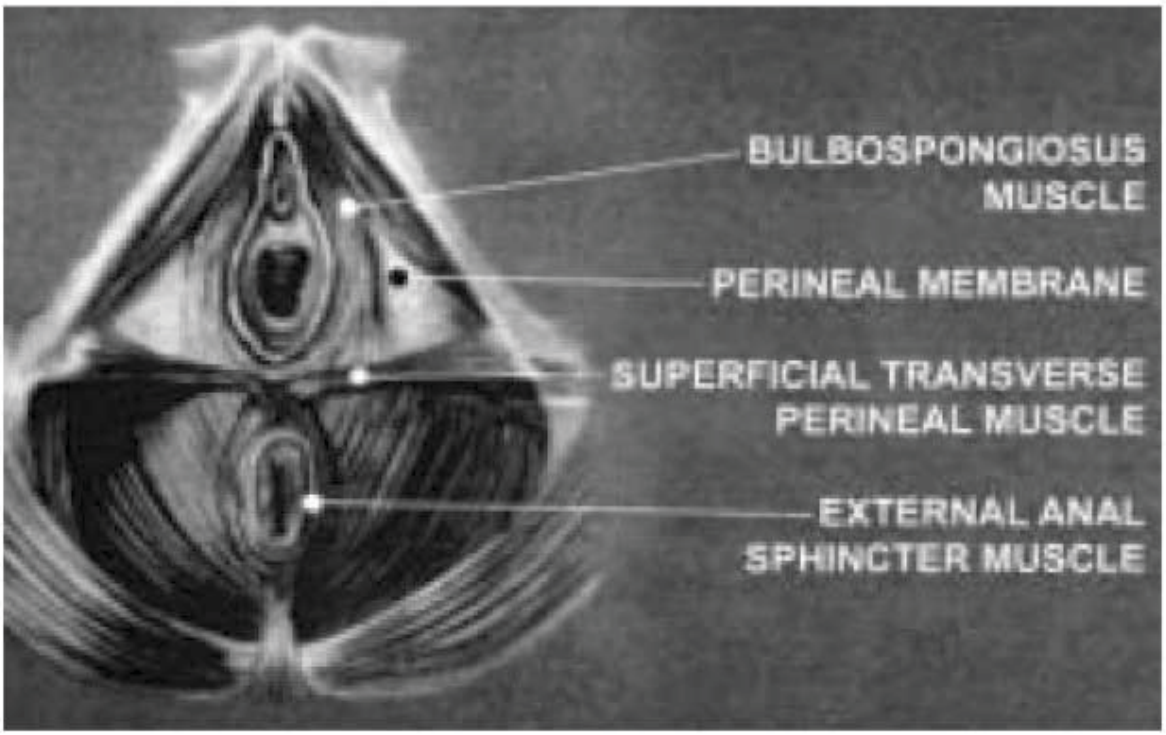


Figure 4. Schematic diagram of the perineum showing the superficial transverse perineal muscle, external sphincter and perineal body. Hudson et al Aust N Z J Obstet Gynaecol 2002: 42:193.[14] Printed with permission from publisher.

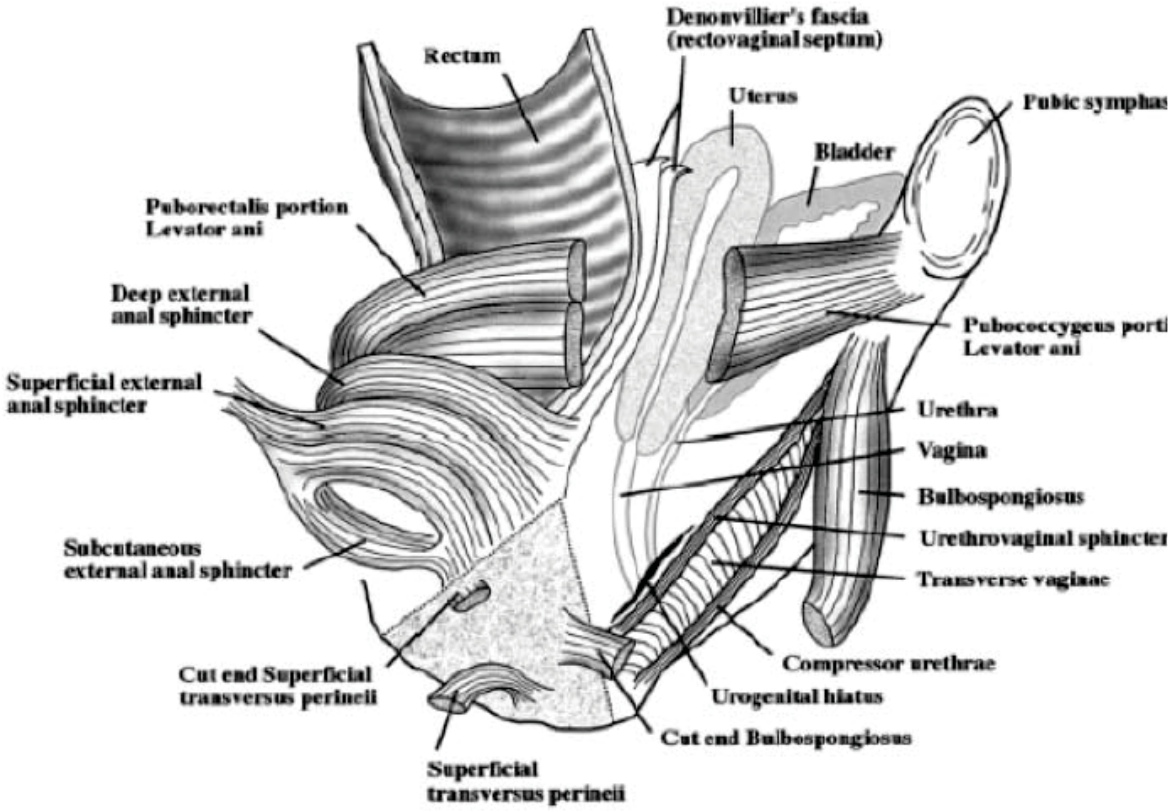


Figure 3. Female perineal body (shaded triangle). Woodman and Graney, Clinical Anatomy 2002; 15:321-334.[18] Printed with permission from publisher.

Obstetric anal sphincter injuries

The first physical evidence of severe perineal trauma caused by childbirth is from the mummy of an Egyptian woman 2050 AD, approximately 22 years of age. Her pelvis was abnormally shaped, there was a rupture of vagina into the bladder, and the lower bowel was found protruding from the anus.[19]

In OASIS the anal canal is involved. This anatomical structure is approximately 2-5 cm[20] long and is surrounded by the striated external anal sphincter (EAS) and the smooth internal anal sphincter muscle (IAS). Obstetric injuries are graded by the degree of perinal tissue and sphincter complex involved[21] (Figure 5). OASIS is the one and foremost reason for anal incontinence (AI) amongst women. AI is experienced in 30-50% of all women sustaining OASIS, even after primary repair.[22-24]

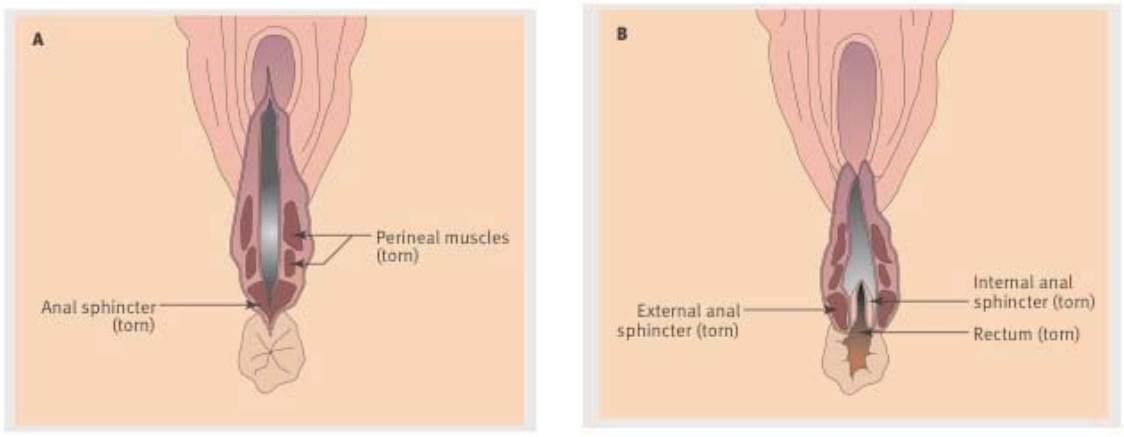


Figure 5. (A) Third degree tear affecting the anal sphincter. (B) Fourth degree extending to the anal mucosa. Abbott et al. BMJ 2010; 341:c 3414. Printed with permission from publisher.

Classification

Classification of perineal injuries described by Sultan[25], adopted by the International Consultation on Urological Disease and the Royal College of Obstetricians and Gynaecologists (RCOG), divides the injuries into four groups:

First degree	Injury to the perineal skin only
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter
Third degree	Injury to perineum involving the anal sphincter complex: 3a: Less than 50% of external anal sphincter complex torn. 3b: More than 50% of EAS thickness torn 3c: Both EAS and IAS torn
Fourth degree	Injury to perineum involving the anal canal sphincter complex (EAS and IAS) and anal epithelium

Incidence

The incidence of OASIS for all vaginal births ranges from 0.6-10.2%.[15;26;27] It is difficult to estimate the true incidence of OASIS. Due to a variety of ways of examination, and different tools used to identify injury[28], there are potential errors in reported results. Cohort studies from the USA report incidences ranging from 2.8-23.0%[29;30] in primiparous women whereas the incidence in European studies is reported to be between 0.4-25.0%.[24;26;31;32] However, one meta-analysis and a recent prospective cohort study report a true incidence of OASIS of 27.0-28.0% in primiparous women and 8.5% in multiparous when using 3D/4D ultrasonography.[33;34] There is little and poor quality evidence from developing countries. In a study investigating the incidence of OASIS in 24 developing countries, located in Africa, Asia and Latin America, it was fond extremely high variations in reported prevalence.[35] Of a total of 372 facilities, 142 (38.1%) did not report any cases of OASIS, whereas some facilities reported incidence over 60%. In other words both under and over diagnosis of OASIS may be common in developing countries,[35] thus the magnitude of this problem remains largely unknown. Reports from Arabic countries have not been found.

There are good and reliable reports from the Scandinavian countries. This because of the public health system and the compulsory registration of obstetric data from the birth units to the medical birth registers. In 2004 the incidence was 4.1% in Norway, 5.2% in Sweden and 3.6% in Denmark whereas in Finland the rate was only 0.6%.[36]

A steady increase of OASIS In Norway since 1967 to 2004 is documented[15,] and numbers from 2008 showed great variations between delivery units ranging from 1.8 to 4.7% .[37] A similar trend has been observed in all the Nordic countries.[36] Recently, an overall reduction in OASIS rate was observed in Norway in 2012, but there were still notable variations between units.[38]

Injuries not detected, occult injuries, and misdiagnoses represent a challenge when reporting "true" rates.[39] Andrews et al.[40] found that the incidence of OASIS increased from 11.0 to 24.5% when 254 women having their first vaginal delivery were first examined at delivery by the accoucheur and then re-examined right after by an experienced research fellow. At Norwegian delivery units the common procedure is to re-examine the women if there is a suspension of OASIS, it is however not common to re-evaluate all women after vaginal delivery.

Risk factors

What factors influence the incidence of OASIS? Numerous studies have been conducted and many factors have been identified. These factors can be divided into: location of delivery unit, obstetric, maternal and foetal factors. They can further be grouped into modifiable and not modifiable factors. When working on preventing OASIS, knowledge of modifiable factors is of particular importance. However, a main challenge with identifying associated risk factors is the high level of multicollinarity, or strong correlation, between many of the factors. Table 2 presents an overview of common identified risk factors. As an attempt to clarify a rather complex picture, the risk factors are classified as "location/birth unit", "obstetric factors: delivery method/medical intervention/others (length of second stage of delivery, previous C-section, delivery hour)", "maternal factors" and "foetal factors". They are further categorised as "modifiable/not modifiable" and what type of studies the results are from. Finally, according to the results each risk factor is marked-off as either: "protective" (a reduction of OASIS from baseline/between groups), "no-association" (no change of OASIS from baseline/between groups) or "risk" (an increase of OASIS from baseline/between groups).

Table 2. An overview of identified factors associated with OASIS, categorised as modifiable/not modifiable, protective/no association/risk.

Risk factors of OASIS	Not modifiable	Modifiable	Type of studies	Risk category/comment		
				Protective	No association	Risk
Location/birth unit[15;32;37;41;42]		X	Cohort	The risk of OASIS is associated with the birth unit		
Obstetric factors- perineum protection						
Delivery posture/position[43-46]		X	Cohort/RCT		X	Position: squatting on chair
"Hands off"[12;47;48]		X	RCT	X	X	X
"Hands on"[47]		X	RCT		X	
Modified Ritgen's maneuver[49]		X	RCT		X	
Perineal massage[48]		X	RCT		X	
Warm compresses[48;50]				X	X	
Deficient perineal protection/visualisation[13]		X	Cohort			X
Intervention ("hands on", perineal protection/visualisation, birth team teaching/focus)[41;51-54]		X	Cohort/ intervention/ case-control	X		
Obstetric factors- medical interventions						
Induction[15;31]		X	Cohort			X
Augmentation[43]		X	Cohort			X
Epidural[55]		X		X		
Episiotomy (undefined)[29;44;56-58]		X	Case-control			X
Medial[15;43;59]		X	Cohort			X
Mediolateral[26;55;59]		X	Cohort	X	X	X
Lateral[60]		X	Cohort	With 1st vaginal delivery		With the 2nd or more vaginal delivery
Ventouse extraction[11;15;29;31;32;43;56-60]		X	Cohort/case-control		X	X
Forceps delivery[11;15;24;29;31;56-61]		X	Cohort/case-control			X
Obstetric factor-others						
Long duration of second stage[31;32;44;60]		X	Cohort			X
Previous caesarean section[58]	X					X
Delivery hour (night vs. day) [43;62]				Different hours/seasons are associated		
Maternal factors						
1st. vaginal delivery[13;15;24;29;31;43;55;56;58]	X		Cohort/case-control			X
Advanced age[15;32;43;56;57]	X		Cohort/case-control			X
Gestational age>40 weeks[15;26;59]	X		Cohort			X
Previous OASIS[63]	X					X
Ethnicity [56;59;63]	X		Cohort/case-control			Asian, African, Hispanic, Native American
Foetal factors						
Higher birth weight [11;13;15;24;29;31;32;43;55-57;59-61]	(X)		Cohort/case-control			X
Large head circumference[15]	X		Cohort			X
Abnormal presentation[24;31;55;57-60]	X		Cohort/case-control			X

Not modifiable: Maternal and foetal risk factors

Table 2 shows that the foremost foetal risk factors are: high birth weight, large head circumference and abnormal presentation. Of these, birth weight contributes the highest risk of sustaining OASIS. The main maternal risk factors are nulliparity and advanced maternal age. Foetal and maternal factors are rarely modifiable and also in some instances difficult to accurately identify at the time of birth.

Modifiable: Obstetric risk factors

Obstetric factors are modifiable because they are composed of individual characteristics (both maternal and accoucheurs), procedures, technique, choices, tradition and equipment.

Delivery methods

Recently, studies have shown that delivery methods are especially important factors in the work of reducing OASIS. Significant reductions of OASIS have been observed after changing delivery methods. These studies are cohorts, interventional, case-control, and RCT studies. In fact, the few RCTs conducted investigating cause-effects upon OASIS are categorized as "delivery method". In general, it seems that attendance to, and visualisation of, the perineum is important to keep the OASIS rate low.

The greatest reduction of incidence of OASIS is found in a large intervention study. The study compared the incidence of OASIS three years before vs. three years after the intervention. In total 40 152 vaginal births were investigated, and the results showed a significant decrease in women sustaining OASIS from 4-5% to 1-2%.[51]

In a case-control study, the delivery method used by the attending midwife was explored.[54] In total 1072 primiparous were included and women with and without OASIS were compared. The only method related to a decrease in OASIS was "easing of the perineum", a technique that was abandon in the 90´s in the belief that the hands should be kept off the perineum.[54]

When comparing two birth units, Malmö, Sweden vs. Turku, Finland with OASIS rates of 2.7% vs. 0.4% respectively, Pirhonen et al. found no population differences for known risk factors. [41] The two units practice different delivery techniques. In Malmö, the baby's head

was allowed to pass freely through the vaginal introitus without much "hands on" support, while in Turku the tradition has been to control the speed of the crowning and simultaneously steadily support the perineum.[41] Further analysis of the results suggested that the low OASIS rate in Finland spared the low-risk normal deliveries (foetal weight < 4000g, normal presentation, no operative delivery) from sustaining OASIS.[41]

On the other hand, a recent Cochrane report[64] reviewed published and unpublished randomised and quasirandomised controlled trials reported conflicting results. The aim of the review was to evaluate any described perineal techniques during the second stage and their effect upon perineal trauma. Two of the primary outcome measures were third- and fourth-degree trauma. Eight trials and 11 651 randomised women were included and meta-analyses were performed for the following perineal techniques: "hands off" vs. "hands on"; warm compress vs. "hands off" or no warm compresses; massage versus hand off/care as usuall.[64] The review concluded that the technique: warm compress, was the only single factor proven to be favourable against OASIS.[12;47;48;50;64]

Medical interventions/others (length of second stage of delivery, previous C-section, delivery hour)

The key obstetric risk factors classified as medical interventions are forceps delivery, ventouse assisted delivery, undefined or medial episiotomy and prolonged duration of second stage. Quite consistently, the literature shows that forceps imposes the highest risk. Mediolateral episiotomy is often associated with OASIS, in some studies the procedure is identified as a protective factor, while in others a risk factor (Table 2).

Primary repair of OASIS

The RCOG guidelines recommend that OASIS are repaired within a few hours after delivery in an operating theatre by an appropriately trained clinician.[21] There are two surgical techniques described: either "end to end" or "overlap".[65] It is not proven that one technique is better than the other.[21] It is, however, important for the outcome that the IAS and EAS are repaired separately when IAS is disrupted, and that the full anatomical length is obtained.[65;66]

Episiotomy

Classification

Episiotomy was one of the surgical procedures entering the field of obstetric care during the 1800 century. The procedure was first described in 1746 by Sir Felding Ould.[30] The purpose was to either enhance the vaginal opening to ease and/or facilitate the release of the foetal head, to give space to the newly invented forceps instrument or to prevent perineal tears.[6] Originally, the suggested techniques were to do multiple nicks around the vaginal opening or to cut bilateral perpendicular to the vaginal opening.[30] In 1799 Michaelis suggested to do only one midline incision, which was strongly supported by several obstetricians in the late 1800.[6] Mediolateral episiotomy was first advocated in by DeLee in 1915.[67] He thought that the mediolateral technique would conserve the pelvic integrity in addition to release tension and hasten terminations of second stage of labour. Thus, this technique would be beneficial for the child as well be more advantageous to the mother.[6;67]

Today we find seven types of episiotomy incisions described in the literature (Figure 6). Still, only three types are commonly used: midline, mediolateral, and lateral episiotomy.[68;69] Midline episiotomy is the tradition in USA, whereas mediolateral episiotomy is the most common in Europe. The lateral episiotomy is used in Finland and scatteredly throughout Scandinavia.

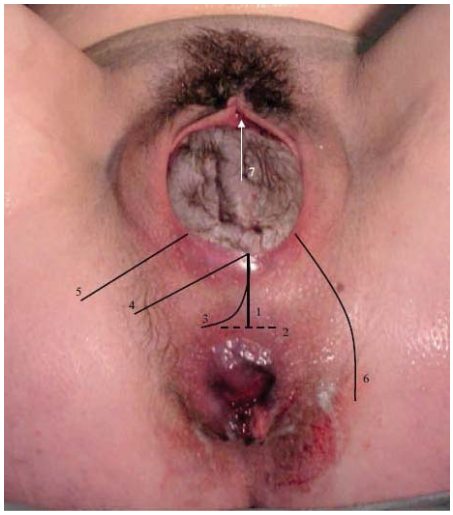


Figure 6. Types of episiotomy. 1:median/midline episiotomy, 2:modified median episiotomy, 3: 'J'-shaped episiotomy, 4:mediolateral episiotomy, 5: lateral episiotomy, 6:radical lateral (Schuchardt incision), 7: anterior episiotomy (white arrow). There are currently no international standards as to whether episiotomy ought to be incised on the right or the left side (median episiotomy excluded). This picture serves for a comparison of the locations of different types of episiotomy.
Kalis et al. BJOG 2012:119:522. Printed with permission from publisher.

Although specific episiotomy techniques are described, there are also individual interpretations of episiotomy.[70-73] Tincello et al.[73] demonstrated that mediolateral episiotomy was practiced differently between midwives and doctors and Kalis et al.[70] found an obvious lack of consensus when 122 different hospitals were questioned about how they defined mediolateral episiotomy: 19% of the hospitals had no definition; 17% offered a definition that was not precise and 61% of the hospitals used a total of 16 different definitions. Another challenge, is that episiotomy technique is usually poorly defined in the in research literature.[68]

The role of episiotomy

The role of episiotomy has been subject for debate for a long time. In 1940 Flew[6] stated:

"*The indications for episiotomy must now be considered. Broadly speaking, in any case which the perineum seriously delays the birth of the presenting part, or in which there is the need for intravaginal manipulation or forceps delivery in all primigravida and some multiparas, an episiotomy should be performed.*"

Although a call for consideration of indication for episiotomy, no structured or definitive evidence was produced. The opinion of frequent use of episiotomy gained acceptance, leading to an increase in many developed countries. In USA the usage of episiotomy in vaginal deliveries increased from less than 5% in 1915 to 64% in 1979.[30] In Great Britain the rate rose from 21% in 1958 to as much as 90% in some hospitals in 1978. On the other hand, the rate was at this point at only 8% in the Netherlands, where over 40% of the women delivered their babies at home.[30]

The theory of episiotomy being a protective procedure against third (and fourth) degree lacerations was increasingly questioned in the beginning of the 1980s. One of the first reviews was done by Thacker et al. in 1982.[30] By going through 33 studies from 1919-1980, the authors found that episiotomy was beneficial in the sense of decreasing incidences of lacerations, but questioned the routine use due to risk of pain and infections.[30]

Consequently, in the 1980s and 1990s, several randomised controlled trials (RCT) and larger cohort studies sought to establish evidence to either support or refute the use of episiotomy.[74] Systematic reviews and more recent reports have later concluded that a policy with restricted use of episiotomy is clearly beneficial resulting in less perineal trauma, compared to routine use of episiotomy.[10;74-76]

Since a policy of restricted use of episiotomy has been encouraged there has been a steady decrease in the episiotomy rate in the USA, Europe and Scandinavia. National data from the USA revealed a consistent decline in episiotomy use from 64-35% between 1979 and 1997 and further down to 24% in 2004.[77;78] The Scandinavian birth registers (Medical Birth Registry of Norway, Finnish Medical Birth Register, Swedish Medical Birth Register) have shown that the episiotomy rate has decreased from 23-19% between 1999 (the register did not register episiotomies until 1998) and 2013 in Norway[79], from 80-22% between 1997 and 2011 in Finland[80], and from 12% to 6% between 2000 and 2011 in Sweden.[81]

However, there are wide variations of the use of episiotomy both between birth units and birth attendants.[82] In the USA rates vary from 13- 85%.[74] This is supported by data from Finland were the rate varied from 38-86% in nulliparous and 8-30% in multiparous women.[80]

Another part of the discussion has been how midline and mediolateral episiotomy each impacts the risk of OASIS and pelvic floor function. Evidence shows that midline episiotomy is associated with increased risk of OASIS[74;83;84], while results for mediolateral episiotomy have not been as clear cut.[84] In one prospective study of 241 women at a university hospital in England, mediolateral episiotomy was a strong risk factor for perineal trauma.[26] However, in two other large cohort studies from Norway and Finland and a retrospective cross-sectional study from England, mediolateral episiotomy appeared to protect against OASIS in first vaginal deliveries, but not in the second or higher order of vaginal deliveries.[15;60;85]

The role of episiotomy in instrumental delivery has been specifically assessed in quite a few studies. The same pattern is found. While midline episiotomy has consistently been associated with an increased risk of OASIS in instrumental delivery[84;86-88], the evidence for mediolateral episotomy have been far more inconclusive. Some studies report that mediolateral episiotomy is a risk factor for OASIS[86], others a neutral factor[89], and some conclude that mediolateral episiotomy is protective against OASIS.[61;90;91]

However, evidence indicated that there are individual interpretations of how episiotomies are performed. This has recently raised the important question: is mediolateral episiotomy actually mediolateral? A few studies have specifically looked at episiotomy characteristics and how they might be associated with the risk of OASIS. Andrews et al.[71] measured

episiotomy characteristics such as angle, length and depth immediately after repair as illustrated in Figure 6, and demonstrated that episiotomies angled more acutely were associated with increased risk of sustaining OASIS. This result was supported by a case-control study. The authors measured episiotomy characteristics three months following delivery and found that a larger episiotomy angle was associated with a lower risk of third degree tear.[72]

This discrepancy between definition and technique highlights the important question as to whether previous conclusions have been inaccurate, based on literature which is flawed by a lack of precise and explicit descriptions of the types of incision made.[68]

Pelvic floor dysfunction

Pelvic floor dysfunction is a broad term that encompasses one or more of the following symptoms: pelvic pain, urinary and/or anal incontinence and sexual dysfunction.[92] UI, AI and sexual dysfunctions are problems that can occur after childbirth. When present, they often cause significant biological, psychological and social distress for the women.[93-96]

Vaginal birth can include several obstetric interventions that also are associated with increased occurrence of AI, UI and sexual dysfunction. Forceps, ventouse delivery, and episiotomy have all been associated with these problems.[93] However, the picture is rather complex. OASIS, which is associated with all three obstetric interventions: forceps, ventouse delivery and episiotomy, are also the strongest associated factor with pelvic floor dysfunction. Because of the overlapping nature of these different factors it is difficult to determine the causal relationship between each and postpartum AI, U I and sexual dysfunctions.[93,97] In an attempt to give a succinct overview of the literature, AI, UI and sexual problems will each be discussed separately in relation to OASIS, episiotomy and instrumental delivery.

Incontinence and sexual dysfunction

Anal incontinence (AI)

There are several methods of classifying the symptoms and causes of AI, and there is a lack of consensus among the specialists and the researchers.[98] However, AI is often described as involuntary leakage of stool and/or gas.[99] Factors to be taken into account when classifying

AI include whether the incontinence is solid or liquid stools, or to flatus alone; whether it is passive or accompanied by urgency, what the frequency of leakage is and how it affects lifestyle and quality of life.[100] Cohort and cross-sectional studies show a widely varying estimates of prevalence, ranging from 1-20% of adults, depending on the definition and scoring systems used.[95;98;101]

The mechanisms for continence and incontinence are complex and to date not fully understood. However, some important factors have been identified as significant in causing AI, including sphincter injuries (often after vaginal delivery), injury to the pudendal nerve and constipation, diarrhoea, mental state and abnormal gastrointestional function.[95;101]

The negative consequences of AI are numerous, and include psychological morbidity, poor self-image, impaired social function, and sexual avoidance or aversion.[102-104]

Urinary incontinence (UI)

UI is defined as either: stress, urge or mixed incontinence. Stress incontinence is leakage of urine after strains such as laughing/coughing, sneezing or lifting. Urge incontinence is the sudden urge to urinate and inability to reach bathroom in time and mixed incontinence is when there are a mix of both stress and urge incontinence.[105] While the prevalence of UI is reported to be between 35-50% for women in general[106], 46% experience UI during pregnancy and 38% reports UI postpartum.[107]

Risk factors particularly strongly associated with stress UI include advanced age, pregnancy, spontaneous and operative vaginal delivery, postpartum incontinence, hysterectomy, parity[95;108-113] and UI during pregnancy.[107] Also, one large cohort study from Norway shows that women who deliver by caesarean section have a higher risk of UI compared to nulliparous women.[112] UI has been associated with strongly adverse effect on quality of life.[114]

Sexual dysfunction (SD)

Although estimates of prevalence of SD vary widely according to the definitions measures used, prevalence between 15-61% in women are common.[115] Female sexual dysfunction is defined as a disorder of sexual desire, arousal, orgasm or sexual pain that results in personal distress. It is well recognised that its aetiology involves an interplay between physical and

psychological factors. Feelings for the partner and the relationship with partner during intercourse has been identified as the strongest predictor for sexual health.[116] Normal changes in sexual function related to age, pregnancy, parturition, breastfeeding and menopause can also influence function for shorter or longer period of time.[115]

OASIS and anal incontinence, urinary incontinence and sexual dysfunction

Although AI postpartum is found to be related to the presence of incontinence in pregnancy[117], women with clinically recognized OASIS are more likely to report postpartum AI than women without injury.[22;118-121] Long-term outcome following OASIS shows that between 30 and 50% experience AI after 10-15 years.[103;104;122] On the other hand, in a prospective study in 241 women Andrew et al. recently reported no AI four years after injury in 59 women.[113]

OASIS is inconsistently associated with UI. Borello-France et al. compared 407 primiparous women with clinically recognized OASIS during delivery with 309 without recognized OASIS and 124 delivered by caesarean and found no difference in the prevalence of UI between groups.[118] De Leeuw et al.[120] found no association between OASIS and UI in a retrospective cohort study, whereas significantly more women suffered from UI ten weeks after delivery in a matched case case-control study which included 100 women with OASIS and 104 controls.[123] Further analysis revealed that OASIS and length of second stage of labour were independent risk factors for UI.[123]

Sexual complaints are common after OASIS.[104;121] In a 10-year follow up study Fornell et al. discovered that vaginal lubrication deteriorates significantly after OASIS. Further, vaginal dryness was associated with perineal body measurement of 10 mm or less [122] Perineal pain were significantly more present in 324 women with OASIS than in 309 women without injury four to eight years after delivery.[124] On the other hand, Leeman et al.[125] prospectively investigated postpartum perineal pain in women with major trauma (2nd degree injury and more) compared to women with minor injury and found no excessive pain in the major trauma group after three months.

Episiotomy and anal incontinence, urinary incontinence and sexual dysfunction

The association between episiotomy and AI has been evaluated in several reports. Signorello et al.[126] compared 209 primiparous women who gave birth at term with episiotomy with 206 without episiotomy in a retrospective cohort study. The episiotomy technique used was midline. Compared to women with a spontaneous laceration, women with episiotomy had a three-fold probability of anal incontinence at both three and six months postpartum.[126] Sartore et al.[127] concluded that mediolateral episiotomy did not protect against AI, and a systematic review based on 31 cohort studies found evidence on episiotomy being associated with AI.[97] In a cohort study of 449 women with at least one vaginal delivery no association between episiotomy and AI was found, nor between episiotomy and UI.[128] These results were supported by a large prospective cohort study exploring UI and AI during pregnancy and postpartum.[117] On the other hand studies investigating correct mediolateral technique have not found any association with AI.[72;129]

In a prospective follow-up study of 243 women Chang et al.[76] compared complaints of UI in women who delivered with or without episiotomy. UI was significantly more prevalent in the episiotomy group compared to the no-episiotomy group three months postpartum. However, few studies have been able to identify meaningful differences in urinary incontinence between groups with vs. without episiotomy or between groups with routine vs. restricted episiotomy.[74;130;131] On the other hand, episiotomy has neither been found to protect against UI in any way.[74;127;132]

Going through literature there seems to be a number of studies showing an association between episiotomy and perineal pain and/or dyspareunia. However, time of investigation and investigation measures as well as definitions varies. A prospective study by Klein et al. reported more perineal pain in women with episiotomy three months after birth.[133] Chang et al.[76] found similar results with a similar study design. However, several prospective studies have not reported significant differences in sexual function comparing women with vs. without episiotomy[74;133;134], whereas Sartore and co-authors reported more dyspareunia in women with episiotomy compared to women with no episiotmy.[127] This was supported in a follow-up study 12-18 moths postpartum where episiotomy was identified as an independent risk factor for dyspareunia and vaginal dryness.[135]

Instrumental delivery and anal incontinence, urinary incontinence and sexual dysfunction

Is there any evidence that instrumental delivery causes AI? There are conflicting reports. In a systematic review both forceps and ventouse assisted delivery are recognised as risk factors for AI.[97] Symptoms of altered feacal continence were evaluated in a RCT comparing ventouse with forceps.[136] Thirty-three percent experienced altered continence in the ventouse group vs. 59% in the forceps group. Mazouni et al.[137] investigated the frequency of new AI symptoms in 159 women after their first instrumental delivery using forceps and found that 24.5% reported so. None of these women had OASIS, but mediolateral episiotomy was performed in 97.5% of the women. Forceps was not identified as a risk factor for AI, but was associated with UI in a study of 632 women where four percent experienced faecal incontinence and 35% urinary dysfunction four months postpartum.[130] However, in a prospective cohort study involving 435 women who sustained OASIS approximately 30% reported AI, UI or sexual symptoms three months postpartum, forceps increased the risk of developing both AI and UI.[121]

MacArthur et al.[138] interviewed 906 women for new symptoms of AI ten months after delivery. The authors reported ventouse and forceps as the only independent risk factors for new AI. On the other hand, Handa et al. found that women with at least one forceps delivery were more likely to report both AI and UI even five to ten years after delivery, but forceps was only significantly associated with overactive bladder. Ventouse delivery did not increase the odds for any pelvic floor disorders (UI, AI, overactive bladder and prolapse symptoms).[128]

In a large survey of 1613 primiparous in Germany the purpose was to evaluate the influence of mode of delivery on sexual function.[139] The response from 655 primiparous revealed that women who had undergone operative delivery had a higher prevalence of severe pain at first sexual intercourse than women with spontaneous vaginal delivery without perineal injury.[139] Women with instrumental delivery were 2.5 times more likely to report dyspareunia at six months postpartum in a retrospective cohort study. The operative delivery group was compared with spontaneous vaginal delivery, and the results were adjusted for maternal age, breastfeeding status, history of dyspareunia before childbirth, duration of second stage of labour, infant birth weight and degree of perineal trauma.[140]

Neither of the two above studies differentiated between forceps and ventouse assisted delivery. In a review of postpartum female sexual function Abdool et al. found that assisted delivery, either by forceps or ventouse is associated with increased perineal pain and sexual health morbidity. However, the majority of women will resume intercourse six months postpartum.[141]

BASIC ASSUMPTIONS AND AIMS OF THE PRESENT STUDY

Background

In the 1960, the incidence of OASIS in Norway was under 1.0%. In 2004 it was 4.2%.[15] After the Norwegian Board of Health Supervision reviewed 26 delivery units throughout the country the Board stated that the incidence of OASIS was too high. As a result an explicit call for attention was announced to reduce the rate of OASIS.[16]

On the other hand, several reports from all Scandinavian countries showed that Finland consistently had a very low OASIS rate, compared to Norway, Sweden and Denmark. Observations recognized that the delivery practice in Norway differed from methods in Finland. The practice of a specific "hands on" delivery method in Finland has been, and still is, practiced since the 1970s. This particular practice ceased in Norway through the 1980s and 1990s.

The Finnish delivery method

The traditional Finnish method for protecting the perineum is a specific technique and described as follows: when the baby`s head is right at the ridge of the fourchette, and not sliding back between contractions, the midwives or the obstetrician should place the right and on the perineum positioned so that the thumb and the index finger is pointed in opposite direction. The third, fourth and fifth finger are flexed at the metacarpal-phalangeal joint so that fingers can reach and support far back towards the anal opening. The left hand is placed on the baby´s head and gently counterforce the explosion f the head. One should carefully palpate for the baby´s chin through the perineum. Once the chin is detected, the mother is asked to do a fast upper-costal breathing without pushing ("panting"). In this state the baby´s head is slowly and carefully helped forward and out. It is important to constantly observe the progress.

The baby´s head should fit the hand as a fitted bowl. The hand supporting the perineum should not pull the skin towards the midline. There should be a tight support, without any gap. Figure 7 illustrates the methods.

Figure 7. The classic Finnish method. Laine et al. Obstet Gynecol 2008:111:1053. Printed with permission from publisher.

The high incidence of OASIS in Norway caused the Directorate of Health and Social Affairs together with The National Advisory Committee for Obstetrics to initiate a national strategy and an interventional study to reduce the number of OASIS.[16]

Based on the traditional Finnish delivery method the focus of the interventional programme was to: a) establish good communication between the accoucheur and the delivering woman, b) give adequate perineal support, c) have a delivery position which allowed visualisation of the perineum during the last minutes of delivery, and d) use mediolateral/lateral episiotomy only upon indication. In addition, the programme included training for staff in the basics of repair of anal sphincter tears and a presentation of the ongoing project.[51;52]

The intervention was first conducted at one delivery unit [52], and was then advanced to four additional units, one from each of the four health regions in Norway. Of the four hospitals, two were university hospitals and two were county hospitals.[51]

The clinical intervention consisted of active training of the birth team, which included both midwives and physicians. Initially, two to four sessions with the same programme at each

hospital were arranged to ensure training and tutorials for all staff. In addition, a trained midwife (Tiina Pirhonen) then supervised the birth team for 7-13 weeks. All vaginal births three years before and three years after the intervention (2003-2009), in total 40 152 deliveries, were included and evaluated.

The outcome assessment compared the incidence of OASIS before vs. after the intervention. The results showed a significant decrease in OASIS from 4-5% to 1-2%.[51]

This thesis explores factors associated with OASIS. The first part investigates whether obstetric risk factors are altered or the same after this significant reduction in OASIS incidence in these four Norwegian hospitals. We investigate which are the key risk factors before and after the intervention and assess if there are differences. Also, will such a decrease in the OASIS rate affect all vaginal births equally or will high-risk births be differently affected than low-risk births?

In the second part of the thesis, we seek further information about the role of episiotomy in relation to OASIS and pelvic floor dysfunction.

AIMS

The aims of the present study were to:

Paper I

- Investigate whether the risk profile for obstetric anal sphincter injuries changed after a multicentre interventional programme that reduced the incidence of obstetric anal sphincter injury significantly
- Investigate whether there were fewer obstetric anal sphincter injuries among low-risk births compared to births with one, two, three or four risk factors in a setting where the incidence of obstetric anal sphincter injuries was significantly reduced

Paper II

- Assess whether episiotomy characteristics were associated with the risk of sustaining obstetric anal sphincter injuries

Paper III

- Assess whether there was a difference in anal incontinence, urinary incontinence and sexual problems in primiparous women with episiotomy and obstetric anal sphincter injuries compared to primiparous women with episiotomy without obstetric anal sphincter injuries
- Assess whether episiotomy characteristics were associated with anal incontinence, urinary incontinence and sexual problems

SUMMARY OF PAPERS

Paper I

"Risk factors for obstetric anal sphincter injury after a successful multicentre interventional programme"

Materials and methods

This was an intervention study with before and after comparison. Data from four delivery units involved in the interventional programme were collected from January 2003 until June 2009. The data were collected three years prior to the intervention. Following the intervention, the collection time was 3 years and 6 months in Tromsø, 3 years in Lillehammer, 2 years and 9 months in Ålesund and 2 years and 3 months in Stavanger. Two of the hospitals are university hospitals (University Hospital of North Norway, Tromsø and Stavanger University Hospital Stavanger) and two regional hospitals (Møre and Romsdal Hospital Trust, Ålesund and Innlandet Hospital Trust, Lillehammer).

Population

In total 47 428 deliveries were enrolled, of whom 40 154 had vaginal births. 1349 women sustained OASIS during this time period. Data from the group with OASIS were gathered directly from the four delivery units to ensure the highest level of validity and to minimize bias involved with recording data. To minimize the bias of recording administrative data, all obstetric data were manually checked at the time of database enrolment.[51]

Anonymous obstetric data for the delivered women without OASIS, 46 394 births, were supplied by the Medical Birth Registry of Norway (MBRN). This registry is based on compulsory notification from all delivery units in Norway, and has been shown to have high validity for the purpose of investigating OASIS.[15] Deliveries <22 weeks (n=90) and neonates with birth weight <500g (n=225) were excluded, and the 46 079 births from MBRN were then merged with the file of 1349 births.

The classification of OASIS

The classification of OASIS in all the obstetric departments was as follows: 3a less than 50% of the external anal sphincter torn; 3b, more than 50% of the external sphincter torn; 3c, the internal sphincter torn, with or without more than 50% external sphincter torn; and 4, injury of the anal sphincter complex and anorectal epithelium.[25;51] This classification differ from

Sultans [25] classification where a 3c injury always includes tearing of both IAS and EAS. The OASIS diagnosis was made by the midwife or physician responsible for the delivery and then confirmed by a specialist in obstetrics and gynaecology.[51] The surgical notes were read to confirm the classification of the OASIS and birth records were assessed by the authors for obstetric factors at the end of the intervention period.

Outcome and independent variables

Third and fourth degree OASIS were pooled as one dependent variable. Clinically relevant obstetric factors were chosen as independent obstetric and background variables and comprised the following: maternal age in years (<20, 20-29, 30-39, >40); induction of labour (yes or no); induction of labour by oxytocin/amniotomy (yes or no); other induction (yes or no), episiotomy (yes or no); foetal presentation (head normal, head abnormal, breech); epidural (yes or no); birth weight in grams (<2500, 2500-2999, 3000-3499, 3500-3999, 4000-4499, ≥4500); head circumference in centimetres (≤33, 34, 35, ≥36); vaginal birth order, based on the number of previous vaginal deliveries (0, 1, 2, ≥3); length of pregnancy in weeks (<37, 37-38, 39-40, ≥41); method of delivery (normal vaginal, ventouse, forceps, breech). In addition, we analysed the association between OASIS and Apgar score after 5 minutes (0-6 and 7-10). The missing values for birth weight (n=45), head circumference (n=691), pregnancy length (n=1680), induction amniotomy (n=258) and oxytocin (n=260) were replaced by mean values, and missing equals "no induction", respectively.

To assess low to high-risk deliveries we computed five risk groups, risk group (0-4), based on the following obstetric factors: birth weight, vaginal delivery, method of delivery, and foetal presentation. The independent variables included were selected based on previous research.[4;13;20] We defined low-risk birth as risk group 0, which comprised deliveries characterised as follow: birth weight <4000g, occiput anterior presentation, spontaneous vaginal delivery, 2nd and 3rd vaginal delivery. Risk groups 1-4 were defined as: birth weight ≥4000g, abnormal foetal presentation, instrumental delivery (ventouse/forceps), 1st vaginal delivery with one of these factors present in group 1, two in group 2, three in group 3, and all four in group 4, respectively.

Data analyses

Statistical difference between groups before and after intervention was evaluated using the independent t- test, the test of relative proportions, the Chi Squared test and logistic regression analysis, where appropriate. The logistic regression models included age, parity and birth weight as confounders to assess differences in caesarean section rates before and after the intervention. Furthermore, to examine changes before and after the intervention in obstetric and background variables, logistic regressions were performed adjusting for age and parity. For OASIS, forceps/ventouse and episiotomy were included in the model. The odds ratio (OR) of sustaining OASIS before vs. after intervention based on obstetric and background variables were calculated. Finally, OR for OASIS for each background characteristic and for low-/high-risk grouping before and after the intervention were examined both between groups and within each group. We tested correlation by using Pearson's R-test for continuous variables, point biserial correlation for continuous-dichotomous variables, Kendall tau rank correlation coefficient for categorical variables and polychoric correlations between categorical-continuous variables. A significance level of 0.05 was set throughout. Data were analysed using SPSS version 18 (SPSS Inc, IL, USA).

Results

Overall changes in population characteristics before vs. after the intervention were small. The mean birth weight (3562g vs. 3517g, $p<0.01$) and head circumference (35.3 cm vs. 35.1 cm, $p<0.01$) decreased in the post-intervention period. Also the percentage of vaginal births (83% vs. 79%, $p<0.01$) decreased, but the proportion of children with low Apgar score <7 after 5 min (1.2% vs. 1.5%, $p<0.02$) increased significantly from the pre- to post-intervention period.

After the intervention period there was a relative risk reduction of 59% (OR 0.41; 95% CI 0.36-0.46.).

Across the periods there was an increase in induction of labour (15.0% vs. 17.0%; OR 1.15, 95% CI 1.10-1.22), use of episiotomy (14.4% vs. 24.3%; OR 1.92, 95% CI 1.82-2.02), and a decrease of abnormal foetal presentation (6.1% vs. 5.3%; OR 0.84, 95% CI 0.78-0.92).
The adjusted regression analyses showed that all except four obstetric variables had a significantly lower association with sustaining OASIS after the intervention. Maternal age of

40 years or more (OR 0.20; 95% CI 0.08-0.52); head circumference of 36 cm (OR 0.24; 95% CI 0.16-0.38); forceps delivery (OR 0.23; 95% CI 0.12-0.45) and second vaginal birth (OR 0.30; 95% CI 0.23-0.39) were obstetric variables where the associated risk of sustaining OASIS decreased significantly below the overall reduction in risk of sustaining OASIS.

Compared to within group reference the key risk factors associated with OASIS were forceps delivery (OR 6.80; 95% CI 4.88-9.45), birth weight of 4500g or more (OR 4.88; 95% CI 3.70-6.45), breech (OR 3.57; 95% CI 1.23-10.30), 1st vaginal birth (OR 2.70; 95% CI 2.30-3.16), and ventouse (OR 2.60; 95% CI 2.22-3.05). After the intervention there were in total less factors associated with the risk of sustaining OASIS than before the intervention.

The low-risk group, with none of the risk factors present, sustained 65% less OASIS after the intervention (OR 0.35; 95% CI 0.24-0.51). In groups with 1-3 risk factors the reductions were 57% (OR 0.43; 95% CI 0.35-0.52), 61% (OR 0.39; 95% CI 0.31-0.48), and 58% (OR 0.42; 95% CI 0.30-0.60), respectively. No change was observed in women with all four risk factors, risk group 4.

Paper II

"Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study"

Materials and methods

The study was carried out at the University Hospital of North Norway and Nordland Hospital, Norway. We performed a matched case-control study using the electronic patient journal system Partus® (CSAM Health AS), which identified eligible participants. Obstetric information for all births was obtained by a search from 2004-2011.

Population

Women with their first vagianal delivery and episiotomy were initially included in the study. This group was further subdivided using Sultan's classification for OASIS[25].
Cases were women with clinically identified third or fourth degree tears at birth, graded as 3a, 3b, 3c or 4, whereas controls were women having no obstetric anal sphincter injuries. Cases and controls were matched for ventouse/forceps due to a strong association between

OASIS and instrumental delivery.[15;26;27] A power calculation using results from Andrews et al.[26] was undertaken for episiotomy angle, with an anticipated difference of 11° between groups, with a standard deviation of 13°, giving a significance level of 5%, and power of 90%. The sample size required 37 women in each group.

Fifty-three women with OASIS and 75 matched controlled women were contacted and asked to participate by letter and phone-call. Five women were excluded due to language and/or pregnancy and 49 (16 OASIS cases and 33 matched controls) women declined to participate. Seventy-four eligible women were willing to participate. The included women signed written informed consent and were called in to a physical examination.

Episiotomy characteristics

This study attempted to measure the lines and angle given between the fixed points of the posterior fourchette, the episiotomy and the most anterior point of the anal epithelium, named distances *a*, *b*, *c*, *d*, *e* and angle *α* (Figure 8).

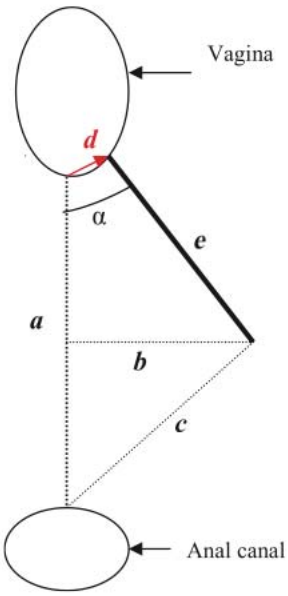


Figure 8. Adapted from Andrews et al. which illustrates the measurements taken. a = line drawn from the posterior fourchette to the outer edge of the anal epithelium; b = episiotomy depth, a line from the caudal end of the episiotomy to the anterior outer edge of the anal epithelium; d= line from the posterior fourchette to the point of episiotomy incision and e = episiotomy length. Stedenfeldt et al. BJOG 2012:119:724.Printed with permission from publisher.

During the physical examination, the vaginal introitus/perineum was investigated for the episiotomy scar, and a picture was taken. All women were in a semilithotomy position with legs resting in knee holders. A Nikon Coolpix S8000 camera was used. The camera was fixed at a tripod. The procedure instructed the camera lens to be levelled horisontally, with a 40 cm distance from the introitus. The aim of focus was the vaginal opening, and included in the

photograph was the anal and vaginal opening in addition to the episiotomy scar. For measure reference a surgical ruler (CODMAN) was included in the photograph, positioned vertical to the episiotomy.

The episiotomy scar was marked with a surgical pen (CODMAN) before the photographs were taken. To annotate the photographs and draw all lines between the fixed points as in Figure 8 an Adobe Photoshop version CS5 Exclusive was used. The photographs were taken by the first author (MS) and four photographs were taken of each woman. Two experienced obstetricians (PØ, JP) blinded for cases and controls did the selection of the photographs, one for each case and control. All the relevant lines and angles for further measures were drawn twice into two identically sets of photographs. The drafter measured the double set of lines on separate occasions.

This study was approved by the Regional Ethics Committee North Norway (163/2008)

Data analyses

Agreement between the two readings was evaluated using Bland-Altman plot, intraclass correlation coefficient (ICC) and coefficient of variation (CV). ICC greater than 0.90 indicates very good agreement, CV below 15% is recognised as sufficient.[143-145] Data were analysed using SPSS version 18 (SPSS Inc, IL, USA).

A conditional logistic regression model was used to assess differences between cases and controls and to calculate odds ratio (OR) for OASIS. The OR was estimated for standard deviation increase in continuous variable. Pair-wise combinations of episiotomy characteristics were simultaneously included in the regression models in order to identify associations adjusted for other episiotomy characteristics. A significance level of 0.05 was set throughout. Associations were adjusted for birth weight.

To look at associations between OASIS and angle ranges, and very narrow/very wide angles we transformed the continuous variable “angle” into categories (0-15°, 16-30°,31-45°, 46-60°, >60°) and a dichotomous variable with intervals:15 - 60° and <15°; >60°. Both crude and adjusted OR were estimated. In addition, to capture a possible U-shaped association between the continuous variable angle and OASIS a linear and quadratic term was tested.

For sensitivity analysis extreme values of birth weight were identified and excluded. All statistical analyses were then executed again without the outliers.

Results

Women sustaining OASIS gave birth to children with significantly higher mean birth weight compared to women with no such injuries (3764g versus 3377g, $p = 0.009$). Mean head circumference was also significantly higher in the case group compared to the controls (36.9 cm versus 35.9 cm, p = 0.036).

Interobserver reliability was based on replicated drawings and measures of all pictures. ICC was 0.88, (95% CI 0.80-0.92), and CV 15.4% for distance *a*, ICC was 0.99; (95% CI 0.99-0.99) and CV 6.7 for distance *b*, ICC was 0.98; (95% CI 0.94-0.98) and CV 9.7 for distance *c*, ICC was 0.92; (95% CI 0.78-0.90) and CV 29.9 for distance *d*, ICC was 0.98; (95% CI 0.96-0.99) and CV 8.5 for *e* and ICC was 0.99; (95% CI 0.99-0.99) and CV 7.9 for episiotomy angle. For all measures, a Bland-Altman plot was created combining ICC, CV. Distances *b*, *c*, *d*, *e* and angle proved a high level of agreement whereas distance *a* showed only a moderate level of agreement.

Mean distance *b* was smaller in cases (11mm) than in controls (16mm). This was also the case for mean distance *d* (6mm vs. 9mm*)* as well as mean episiotomy length *e* (13mm vs. 17mm). The mean angle did not differ between the two groups. However, a significant u-shaped association between angle and OASIS was captured (OR 2.09; 95% CI 1.02-4.28) and when the angle was transformed to a dichotomous variable such as angle smaller than 15° or greater than 60° versus angle range 15-60°, there was a significant difference between the groups.

The odds ratio estimates show that there was a 70% reduced risk (OR 0.30; 95% CI 0.14-0.66) of sustaining OASIS for each 5.5 mm increase in depth of the episiotomy. In addition, by increasing the distance from the posterior fourchette to the incision point of the episiotomy by 4.5 mm the risk for an obstetric anal injury decrease by 56% (OR 0.44; 95 % CI 0.23-0.86). Also, there was a 75% reduced risk (OR 0.25; 95% CI 0.10-0.61) of obstetric anal injuries for each 5.5 mm increase in the length of the episiotomy, and there was an increased risk of sustaining such injury when the angle is either smaller than 15°or larger than 60°(OR 9.0;

95% CI 1.1- 71.0). The results remained the same after adjusting for birth weight. Neither excluding two extreme values of birth weight (5254g and 1922g) altered the findings.

In a separate set of multivariable models we included pair-wise combinations of the significant continuous variables *b*, *d* and *e*. In the model with *d* and *b*, *d* was not significantly associated with OASIS (p=0.41), whereas depth *b* was (p=0.01). In the model with *d* and *e*, *d* was not significant (p=0.19), whereas length, *e*, was (p=0.01) and in the model with depth *b* and length *e* there was a non-significant trend for both measures towards association with OASIS (*b*: p= 0.07; length: p =0.06).

Paper III

"Episiotomy characteristics and anal incontinence, urinary incontinence and sexual problems in primiparous women"

Materials and Methods

Setting, population and episiotomy characteristic

This study is a continuation of study two, and the setting, population and episiotomy characteristics are described in the summary of paper II.

Scoring and interview tools

Appropriate scoring tools registered bowel, urinary, and sexual problems. AI was defined as an involuntary loss of flatus, liquid, or solid. Symptoms were assessed with the St. Mark's scoring system, which is a validated interview tool consisting of seven questions for grading the severity of AI during the final four weeks[146]. The scores range from 0 to 24. In this study, the severity of symptoms was graded according to clinical relevance: 0-3 = "no AI"; 4-8 = "mild/moderate"; ≥9 = "severe". In order to estimate the proportion of AI, scores were also dichotomized so that 0-3 = "no AI" and ≥4 = "AI". The first author (MS) carried out all the interviews and scorings.

UI was defined as a symptomatic involuntary loss of urine and documented by the validated self-administered questionnaire ICIQ-UI SF, which was developed for assessing the type of UI as well as its prevalence, severity, and impact on quality of life[147]. The answers resulted in a sum ranging from 0 to 21. To demonstrate the rate of UI, scores were dichotomized so that

0 = “no UI” and 1 = “UI” as done by Klovning et al. 2009.[148] Furthermore, according to clinical relevance, UI was categorized as 1-8 = “mild” and ≥9 = “moderate/severe”.

Sexual problems were evaluated by questions originally used by The Norwegian Institute of Public Health to assess sexual problems in Norway.[149] Each woman was asked whether she was sexually active, with the response options being “YES” or “NO”. If the answer was “YES”, the degree of sexual problems was measured by the question: “Have you experienced any of the sexual problems listed below during the past 12 months/or since sexual activity was retained after birth”. The following three problems were listed: 1) reduced sexual desire, 2) orgasm problem, 3) experience of genital pain during intercourse. Response categories for each of the items were 0 = “not active due to problems”, 1 = “problem all the time”, 2 = “problem nearly all the time”, 3 = “problem quite often”, 4 = “problem quite rarely”, and 5 = “never problem”. The responses from all three items were then added together to produce an overall score from 0 to 15. Sexual problems were then categorized as 0-3 = “all the time,” 4-6 = “almost all the time,” 7-10 = “quite often,” 11-14 = “quite rarely”, and 15 = “never”. The study was approved by the Regional Ethics Committee of North Norway (163/2008).

Data analyses

Data were analysed using SPSS version 18 (SPSS Inc, IL, USA). A conditional logistic regression model was used to assess differences between women with and without OASIS in the rate of AI, UI, and sexual problems. Pearsons correlation coefficient was estimated to assess the association between episiotomy characteristics and AI, UI and sexual problems in the two groups separately. In a subgroup analysis of the women with OASIS, a two-sample t-test was used to compare mean differences in St. Mark’s score between 3a and 3b versus 3c and 4 injuries. A two-sided 5% significance level was used.

Results

Anal incontinence was significantly more frequent in women with OASIS compared to women without OASIS, 14 (41%) vs. 3 (8%), respectively (p= 0.05). In women with OASIS, 8 (21%) reported mild AI and 6 (14%) reported moderate/severe AI. Two (5%) women without OASIS reported mild AI and 1 (3%), moderate/severe AI. We observed a significant difference in AI symptoms between women with grade 3c and 4 compared to women with grade 3a and 3b within the case group. The mean St. Mark’s score was 3.9 higher for women with 3c

and 4 injuries compared to women with 3a and b injuries (95% CI for mean difference, 0.85-7.01, p= 0.01)

There were no significant difference in the rate of UI between cases and controls. Fifteen (40%) women with OASIS and 17 (46%) women without OASIS reported involuntary leakage once a week or less.

Sexual problems differed significantly between women with and without OASIS (score points 10.0 vs. 12.6, p=0.04) (Table 2). Only 2 (5%) women with OASIS reported no sexual problems compared to twelve (32%) without OASIS. On the other hand, 5 (14%) women with OASIS compared to no (0%) women without OASIS reported no sexual activity or sexual problems all the time.

When investigating correlation coefficient (r) between episiotomy characteristics and AI, UI and sexual problems separately in the case and the control group, none of the coefficients were significant except between episiotomy length and sexual problems (r=0.41, p =0.03) in women without OASIS.

DISCUSSION

Paper I

The intervention: perineal protection method

Hals et al.[51] identified a reduction of over 50% in the incidence of OASIS after the implementation of the interventional programme at the four hospitals. We found that with adjusted logistic regression analyses that this intervention gave a relative risk reduction of 59%. We have not found any previous research has shown a similar grand reduction in a cohort of such size.

Modifiable, non-modifiable, obstetric, maternal and foetal risk factors are often and naturally observed collectively in studies investigating associated risks for sustaining OASIS. However, in terms of strategies to reduce the OASIS rate, it is essential to differentiate risk factors into appropriate categories since they require different intervention and decision making when addressed in clinical practise. If one can consider modifiable factors as a part

of a unit's management and preferred practise (Table 2), this will be the superior place to start looking for possible changes to be made for reducing the OASIS rate.

However, general practise is a wide term. As for example, Minaglia et al.[150] found a reduction in OASIS rate from 11.2% to 7.9% in a retrospective cohort study of 16 667 vaginal deliveries over a nine year period. The observed changes of practice were: decreased episiotomy rate (midline) from 9.0% to 8.0%, decreased ventouse assisted delivery from 5.1% to 2.9%, decreased forceps assisted delivery from 1.7% to 0.0%, and an increase of the caesarean rate from 18.2% to 32.3%. On the other hand, a recent retrospective cohort study identified a reduction of OASIS from 4.4% to 2.2% after an education programme changing the unit's clinical practice. The programme focused on more staff involvement at vaginal births, mediolateral episiotomy instead of medial and steady guidelines of when to use episiotomy resulting in an increase in episiotomy rate from 12.6%-20.1%.[151]

Delivery technique is an intricate part of obstetric practice. Like episiotomy, there are a wide variety of techniques, often based upon local beliefs and tradition. Certain delivery techniques are more passive while others require hands-on practice and even specific communication skills with the mother as well as an appropriate visualisation of perineum during the last phase of second stage of delivery. Pirhonen et al.[41] compared two similar sized birth units, one in Malmö, Sweden with one in Turku, Finland. Obstetric practise differed in several ways between the two units. Turku practised the classic Finnish delivery method whereas in Malmö the technique is to allow the baby´s head to pass through the vaginal introitus naturally or occasionally with a light degree of pressure on the baby´s head by one hand whilst supporting the perineum with another. In Turku the caesarean rate was 16.2% compared to 9.1% in Malmö and the episiotomy rate was 37.2% vs. 24.3%, respectively. The incidence of OASIS in Turku was significantly lower at 0.36% compared to 2.69% in Malmö.

A comparison of five hospitals in Norway in 2005 showed that while there were no differences in variables such as gestational length, birth weight, presentation, previous caesarean section, maternal age, previous sphincter tears, duration of the second stage of labour, and shoulder dystocia, there were significant differences between hospitals in the

incidence of OASIS.[37] The authors suggested that one possibility for this unexplained difference in OASIS rate could be different perineal protection support techniques.[37]

However, a recent Cochrane review examined published and unpublished randomised and quasi-randomised controlled trials to evaluate the effect of perineal technique during the second stage of labour upon perineal trauma. Of 12 identified clinical trials, eight were included in the analysis. The review concluded that no randomised controlled studies have been able to prove that delivery techniques except the modality "warm compress" protects against OASIS.[64]

Due to discrepancies between conclusions from several observational studies and this Cochrane review, it is important to critically evaluate the studies included in the review.

Two of the reviewed trials compared "hands off" vs. "hands on" during the second stage of labour. Mayerhofer et al.[12] defined the "hands on" method as pressure on the infants head by the midwife`s left hand, whereas the right hand was placed against the perineum. The "hands off" method was described as no touching of the perineum, only guiding the mother through the birth, however being prepared to apply light pressure to the infant´s head. How the two methods were thought was not described. There were 2.7% women in the "hands on" group compared to 0.9% in the "hands off" group that sustained OASIS, which was a significant difference. It is not clear, however, how many of the midwives in the study arm "hands off" applied pressure to the infants head, and if so, whether they also touched the perineum. Also, at this hospital they performed both midline and mediolateral episiotomy. The "hands on" group received significantly more episiotomies than the "hands off" group. Not knowing whether these episiotomies were midline or mediolateral, but knowing midline episiotomy is a larger risk factor of sustaining OASIS than mediolateral, it is impossible to say whether the episiotomies confounded the results. In addition, the parity was closer to one in the "hands on" group compared to two in the "hands off" group. It is unclear whether there were more nulliparous women in the "hands on" group vs. in the "hands off" group. Nulliparity is one of the principal risk factors for sustaining OASIS, thus it is not clear whether this is a confounder in the study. Lastly, occult OASIS was not taken into account and the primary aim of the study was assessing perineal trauma.

The second trial in the Cochrane review[64] evaluating "hand on" vs. hands off" was by McCandlish et al.[47] and had perineal pain as the primary outcome. "Hands on" instructions were to put pressure on the infant's head in the belief that flexion will be increased and to support the perineum. Lateral flexion was used to facilitate delivery of shoulders. The "hands off" was described as not touching the head or the perineum and allowing spontaneous delivery of the shoulders. In this study the analyses were by "intention to treat" and full compliance was described, which was lower in the "hands off" group. There was no difference in primary outcome between groups, or in the incidence of OASIS. There were more episiotomies in the "hands on" group than in the "hands off" group.

The Cochrane review[64] included the trial by Jönsson et al.[49] investigated whether modified Ritgen's maneuver decreased the risk of OASIS compared with simple perineal support. The Ritgen's maneuver is a specific technique originally described as: "... *in an interval between pains … two fingers are applied just behind the anus, and forward an upward pressure is made upon the brow through the perineum"*.[152] The accoucheurs reach for the foetal chin between anus and coccyx and pulled anteriorly. The fingers of the other hand are placed on the fetus occiput to control the speed of delivery and keep flexion of the infant's head. To prevent perineal tearing the head is delivered before the next contraction.[152] In Jönssons et al's study the technique is modified by head being delivered during a contraction.[49] This method was compared to the unit's standard care which entailed perineal support with one hand and control of the speed of crowning with the other. The study showed no difference in the rate of OASIS (5.5% vs. 4.4%) between the groups. There is no description of how the teaching of the modified Ritgen's maneuver was conducted except that senior colleagues instructed the midwives that were unfamiliar with the procedure. Nor was the two techniques used controlled at the time of delivery. Since the intervention is a technique that need thorough practise, this raises the question whether the teaching was sufficient enough to assure appropriate implementation of the method in the Ritgen's group. The authors refer to this as the method used in Finland, but it is errorous to compare the method used in this study to the method used in Finland (which is described at page 31). In addition, there was a 20% cross over from the study arm "modified Ritgen's manoeuvre" to "standard care".

The Cochrane review[64] concluded that the only modality protecting against OASIS, proven by RCT, was warm compresses when compared to "hands off". Dahlen et al.[50] randomised 717 women with low-risk birth (breech, ventouse and forceps assisted deliveries were excluded) into a warm compress group or a group without warm compresses. The primary outcome was perineal trauma that required perineal suturing, and the secondary objective was perception of pain at birth and on day one and two after. There was not a significant difference between the two groups for the trial's primary outcome. However, there was a significantly lower incidence of OASIS in the warm compress group. The procedure for use of warm pack was to soak a sterile perineal pad, which was wrung out before being placed on the perineum during contraction. To maintain warmth between contractions the pad was resoaked accordingly. The questions are whether this also meant if there was pressure or exerted extra support to hold the packs in place, or if the communication between the accoucheur and the mother was affected by the intervention. Also, did the focus upon the perineum in general differ in the warm-pack group vs. the "hands off" group? There are confounders in this study that can have contributed to the reduction of OASIS. If warm packs in themselves were to be examined, they should have been placed on the perineum with the same pressure, in the same manner preferably by a mechanical device. In addition, the rate of OASIS was very high in both groups: 4.5% in the warm pack group and 8.0% in the control group even after the intervention. Is a rate of 4.5% a sufficient reduction even though it is statistically different from 8.0%?

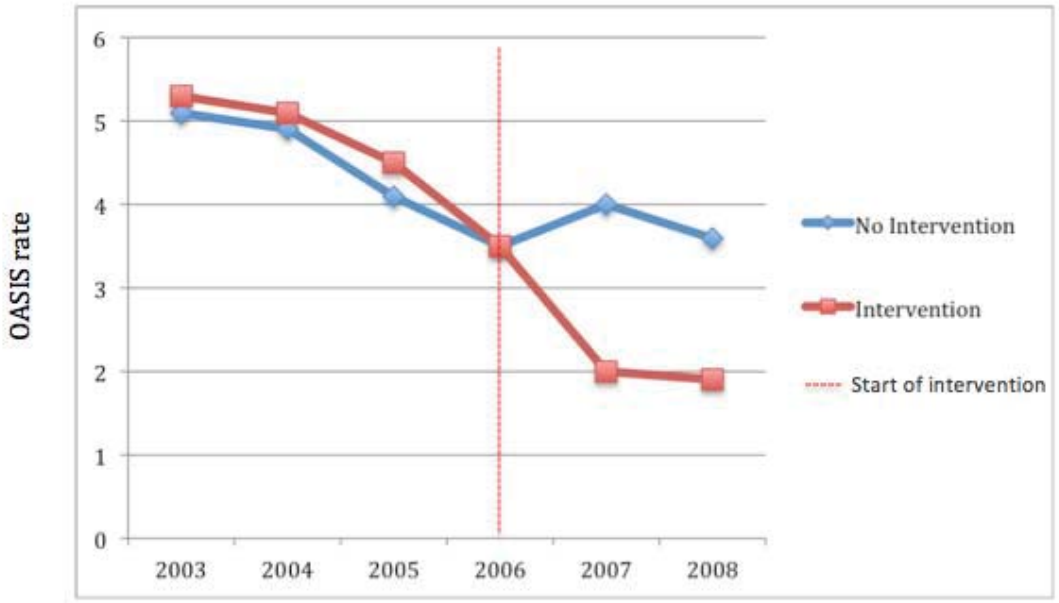
After a general national focus and interventional programme implemented at five Norwegian hospitals there has been a significant and constant reduction in OASIS across the country from 2004 to 2010.[38] A national survey indicates that there has been a widespread introduction of a manual technique for support among accoucheurs at Norwegian maternity departments, and that practice has changed accordingly the last five years.[153] It is suggested that the overall OASIS reduction is caused by the global attention on delivery technique and the positive results from the intervention hospitals.[38]

On the other hand, due to lack of evidence from RCTs, Fretheim et al.[153] questioned the causal relationship between the intervention with the perineal supporting delivery

technique and the significant reduction of OASIS, suggesting that the reduction could be caused by the general strong focus on OASIS causing a number of other changes.

Further, Fretheim et al.[153] are critical of the intervention study which was conducted without a control group, but only with a before and after comparison. The authors call for a prospective study with a control group to evaluate the method. We believe this was impossible in Norway at the time these studies were planned due to the general change in overall practice (Figure 9).

Figure 9. Graph showing the cumulated OASIS rate from 2003-2008 for the four intervention hospitals* vs. four similar hospitals not included in the intervention and the point of the interventional programme.**



* Trondheim University Hospital-St.Olav, Trondheim, Innlandet Hospital Trust, Gjøvik, Sørlandet Hospital Trust Kristiansand and Haukeland University Hospital, Bergen.
** University Hospital of North Norway, Tromsø, Stavanger University Hospital, Stavanger, Innlandet Hospital trust Lillehammer and Ålesund Hospital, Ålesund.

By that time a control group would already have been most likely influenced by the national focus on delivery technique. In addition, such a study design would in our opinion be unethical now. We think many women are spared OASIS by this type of intervention.

What should we conclude when the results from RCTs differs from those of observational studies (OS)? Hannan et al. debate this in a review article.[154] The authors argue that different results often derive from methodological shortcomings. One of the most serious

shortcomings in observational studies is selection bias. There might be large observed or unobserved differences in the study population. In our study we have taken a whole population at four birth units and controlled across the time periods for potential biases. Hannan et al. [154] debates further the importance to question the database, to evaluate if the outcome is meaningful and lastly, whether the OS is actually observing the right type of patients, In our case the database is large enough and has proven validity for the outcome examined. The patients are the right type and the outcome is specific and meaningful. A drawback to RCT´s can be their generalizability. RCTs have often specific inclusion criteria, whereas OS usually apply to a broader population. A good example of that matter in this discussion is the study from Dahlen et al.[50], described previously, where only women without instrumental deliveries were included in the RCT whose aim was to evaluate delivery method and perineal injury.

It is about the level of evidence. The highest level of evidence is multiple RCT`s or a meta-analysis. For the second-highest level of evidence several OS are required. Thus, if one RCT differs from multiple OS there is a need to examine this RCT more closely, and to conduct more RCT´s.[154] In this case there a single RCT (that gives a thorough explanation of the handgrip supporting the perineum during birth and has the appropriate outcome) investigating the modified Ritgen´s technique compared to several cohort studies. Fretheim et al.[153] question the evidence from our OS and others by arguments from the trial by Jönsson et al.[49] which as discussed has many short-comings. At this point, the question is whether it is ethical to conduct a RCT investigating the Finnish method, since we now are in the possession of results from quality OS showing that this method significantly reduces the OASIS rate.

Is RCT always the gold standard for evidence? Black[155] highlights an interesting limitation to RCTs. Some clinical settings are impossible or very difficult to experiment on. Clinical uncertainty will necessarily cause variation in practice. This does not mean that each clinician is uncertain about how to practise. In other words, even though “collective equipoise” exists, “individual equipoise” is absent. Birth delivery method is a skill, influenced by tradition and beliefs. Carrying out RCTs are challenging during delivery due to contamination of methods in different study arms (due to the influence of factors

mentioned above) and problems with standardizing the methods (episiotomy, hand grips, birthing position(s) as well as communication) and blinding patients or staff. In summary, the clinical trials referred to in this discussion had in short problems with bias caused by contamination of compared methods and different use of medial/mediolateral episiotomy[12;47;49], were under-powered to assess OASIS, or were not designed to assess OASIS,[12;47] which influence the validity of these RCTs.[155]

Did the dramatic difference in OASIS rate before vs. after the intervention happened by chance? This is unlikely, as the difference is too large for being a "by chance" change, with or without a control group. There are no other changes that could have influenced the population. The only change in practice during this period was the implementation of the interventional programme (Figure 9), and the likelihood of unknown confounding factors being important is negligibly small.[155] Throughout the history of medicine we have quite a few observed associations that have been passed to a verdict of causation, as for example penicillin for bacterial infections, thyroxin in hypothyroidism, insulin in insulin dependent diabetes and the association between sleeping position and sudden infant death syndrome in babies.[155]

Risk profile – before and after the intervention

The present study shows that with a 59% risk reduction in the OASIS rate the obstetric, maternal and the foetal risk factors are approximately the same as before the intervention. Although there were significant risk reduction associated with all investigated factors, with the greatest reduction observed in forceps deliveries, the foremost risk factors associated with OASIS after the intervention were still forceps delivery, macrosomia, 1st vaginal delivery and ventouse assisted delivery. This is in accordance with numerous previous studies.[15;24;27;41;136;156;157]

The protocol involves midwives managing uncomplicated births alone, whereas physicians are responsible when operative obstetric interventions are needed. Thus, the general risk reduction for all obstetric factors observed in the present study suggests the interventional programme improved practice both among midwives and physicians.

Modifiable risk factors

Looking more closely at the risk factors as to which were modifiable/non-modifiable we observed that while induction with amniotomy/oxytocin and ventouse assisted delivery imposes the same risk both before and after the intervention, the odds of sustaining OASIS with forceps delivery decreased from a 6.8 fold to a 3.5 fold compared to normal vaginal delivery.

The episiotomy rate increased across the intervention period from 14.4% to 24.3%, this due to particular increased use of episiotomy at two hospitals: Stavanger and Ålesund. Multiple logistic regression analyses did not find episiotomy associated with OASIS, either before or after the intervention, although the trend after the intervention was towards a possible protective effect. Several studies have found that the risk of sustaining OASIS is reduced when mediolateral episiotomy is performed during forceps delivery.[90;91;158] Part of this intervention was to use an episiotomy only upon indication. Forceps was reported to be one such indication. Operators were instructed to use a mediolateral episiotomy technique with a lateral incision point and an angle of 40-60°. At the largest birth unit included in this interventional programme the traditional technique employed was the use of an episiotomy resembling a median incision. This unit was also responsible for half of all the forceps deliveries. Episiotomy during forceps delivery at this unit increased from 50% (47/93) before intervention to 85% (65/76) after the intervention. One can speculate that a change in episiotomy technique and rate may have influenced the risk of OASIS during forceps delivery.

However, even though the forceps' associated risk of OASIS was halved after the intervention, the risk of sustaining injuries was still twice as high with forceps as compared to ventouse. Thus, one should consider whether the use of forceps holds enough benefits in comparison to the use of ventouse.

Births with accumulating risk factors

Of the total population, 37.6% of the women where in risk group 0 (low-risk), 45.7% in risk group 1, 13.9% in risk group 2, 2.6% in risk group 3, and 0.2% in risk group 4 (high-risk).

After the intervention, with a reduced OASIS rate from 4.6% to 2.0%, women with low-risk births (birth weight < 4000g, normal presentation, spontaneous delivery, 2nd vaginal delivery) had 65% less risk of sustaining OASIS than before the intervention. The risk groups 1-3 with one, two and three risk factors present, did also significantly reduce their risk of sustaining OASIS equivalent to the general OASIS reduction. In risk group 4 where all risk factors were present, no reduction was observed after as compared to before the intervention.

In other words, when the OASIS rate was between 4-5 % every 70th women with low-risk birth got injured whereas when the OASIS rate was 2%, only one in every 200 women sustained OASIS. In the group with the highest amount of births, risk group 1, the reduction in OASIS were from one in 24 women before the intervention down to one in 56 women afterwards.

Our study is in accordance with Pirhonen et al.[41] They highlighted how low-risk births were spared in a low OASIS rate setting when compared to maternity units with different incidence of OASIS. At the unit with the higher OASIS incidence there was a 13-times higher chance for women with low-risk births to sustain OASIS. These two studies combined do suggest that women especially with low-risk births are unnecessarily injured in a high OASIS rate clinic.

On the other hand, the risk of OASIS increased with number of risk factors present both before and after the intervention. This association was even amplified after the intervention. In a population with a 2.0% rate of sustaining OASIS a woman giving birth with three and four risk factors have currently has 24-fold and 53-fold more chance of sustaining OASIS compared with a woman undergoing a low-risk birth. Only 2.8% of the total population have births with three or four of the evaluated risk factors. Can this information be helpful for the clinicians? After such a reduction of the OASIS rate, is it then possible to identify these high-risk women in advance, for a careful evaluation and a plan of birth?

Previous attempts to develop risk-scoring systems for predicting OASIS have failed.[159;160] However, one study was done in a setting with an OASIS rate of 8.7%[159], whereas the other study was a case-control where subjects were drawn from a hospital with unknown OASIS

rate.[160] Thus, it is likely that the group investigated included a high number of women with low-risk births, which are not as identifiable as women with high-risk births.

Of all the four high-risk factors there is only the number of previous vaginal birth that can be easily determined. Birth weight and presentation might be predicted by clinical and ultrasound examination. However, as of today it is known to be relatively inaccurate, and not very modifiable.[161;162]

Paper II

The debates regarding the true role of episiotomy relative to OASIS have focused on the two main traditions of episiotomy techniques: midline, typically performed in the USA, vs. mediolateral, most commonly used in Europe. The results regarding mediolateral episiotomy have been inconclusive.

No one actually questioned episiotomy characteristics until the beginning of 2000. Tincello et al.[73] clearly demonstrated significant differences in the performance of mediolateral episiotomy between doctors and midwives.

Episiotomy technique also varied in our study supporting the findings of Tincello et al.[73] and a later report.[71] We were able to identify that women with OASIS had significantly different episiotomy scars than women without OASIS. Women with OASIS had episiotomies that were shorter, less deep, oddly angled, meaning either very narrow or very wide angle, and that had incision point closer to the posterior fourchette compared to the women without OASIS.

Our study joins several newer studies specifically looking at the association between episiotomy characteristics and the risk of sustaining OASIS.[71;72;129;163] Common to all studies is the findings that a narrow angle close to the midline is associated with increased risk of sustaining OASIS, and that angles between 40-60 degrees, which is according to textbook descriptions of mediolateral episiotomy, seem to be protective against OASIS. However, we are the first to report clinical results suggesting that point of incision might also affect the risk for OASIS. Previous investigations have measured the episiotomy characteristics from a mediolateral perspective and not considered incision point lateral to the midline even

though Tincello et al.[73] demonstrated that 36% and 31% of the doctors and midwives respectively began the episiotomy lateral to the midline in a hospital setting where the tradition is mediolateral episiotomy.

Interestingly, we found that depth (b), the length of the line from the end of the episiotomy bisecting the midline perpendicularly, was the most predictable for the risk of OASIS, and that a very wide angle did rather increase the risk of OASIS. When looking at figure 8 the depth is (b) a function of episiotomy length (e) and angle (α), length from the posterior fourchette to incision point in relation to the midline (d). In other words, an episiotomy with protective length, incision point and angle characteristic also gives a certain b, which can explain the significance of b in *this* study.

Our results are in accordance with results from larger cohort studies showing that mediolateral and lateral episiotomy might have a protective effect against OASIS.
In addition to technique, there is also a debate about indication, which is highly subjective, and recently, the optimal rate of episiotomy. Although there are wide consensus that liberate use of episiotomy should be avoided in order to spare the sphincter, there is a growing discussion as to whether there is an inverse relationship between episiotomy and OASIS. Twidale et al.[151] showed a significant correlation between a decrease in OASIS rate and an increase in mediolateral episiotomy rate from 12.5% to 20.1%.
In addition, Raisanen et al.[80] found a strong association between liberal use of lateral episiotomy at ventouse in primiparous women and a decreased incidence of OASIS, especially in women with large babies and a long second stage of labour. A 6-fold decreased odds for developing OASIS when a mediolateral episiotomy was performed during operative vaginal delivery was found in a recent large retrospective cohort study[91], supporting other large cohort studies showing episiotomy to be protective, particularly among primiparous women and in instrumental deliveries.[90;91;156;164]

In our study cases and controls were matched for instrumental deliveries (the rate of instrumental deliveries in the total population was 51%). In other words, three of the most significant risk factors were equally present in our two groups: 1st vaginal delivery, instrumental delivery and episiotomy and further, the results were adjusted for birth weight. The observed differences in episiotomy characteristics between the cases and the controls

support that episiotomy might be protective in instrumental deliveries depending on the technique.

Based on recent episiotomy studies one might question the validity of prior research and conclusions regarding mediolateral episiotomy since the episiotomy technique has in many cases been poorly or not controlled. We are starting to get results from clinical audits and cohort studies which are more nuanced regarding the use and effect of episiotomy. As the recent attention to the importance of supervised and "hands-on" training as well as routine audit will be a more common part of the regular hospital practise, we might see an even more unambiguous picture of the role of the different episiotomy techniques.

Paper III

The prevalence of reported AI, UI and complaints of sexual problems in women with OASIS is in concordance with numerous previous studies[19;22;118;120], and so is the rate reported in the women without OASIS.[118] In our study we found significantly more AI (38% vs. 8%) and sexual problems (point score 10.0 vs. 12.6) in the OASIS group whereas urinary incontinence was a frequent but equal complaint in both cases and controls (46% vs. 40%). It is, however, a challenge to compare with other studies since there are variations in the samples and cohorts studied as well as how and when symptoms are measured and scored.[22;66;104;118;120-122;124;130;165;166] Still, these reports quite clearly demonstrate a strong association between OASIS and both short and long term AI and sexual dysfunction.

We found that the more severe sphincter injury, the more AI symptoms the women reported. Other investigators have demonstrated the same.[23] However, recently Sundquist[124] reported no difference in the prevalence of faecal incontinence between women with OASIS less than 50%, compared to women with more severe injury.

Like ours, many investigations have found a general high prevalence of UI, but not an obvious association between OASIS and UI.[113;120;167] So, OASIS per se does not seem to be the main contributing factor in the development of UI, but rather due to a general damage and denervation of the pelvic floor.[113;120]

What is the role of episiotomy in relation to pelvic floor dysfunction? Further, what effect do both episiotomy and instrumental delivery together have on the perineum? If correctly located, episiotomy used only with clear indication can reduce the risk of OASIS, it is important to know if this episiotomy cause pelvic floor dysfunctions. We found no correlation between episiotomy characteristics and AI, UI and sexual problem in the OASIS group. However, there was an association between sexual problems and episiotomy length in the control group. Our study is small, thus its results should be interpreted with caution. A factor we have not considered is episiotomy repair, which might have an impact on perineal pain. We found only one relevant study that has looked at association between episiotomy characteristics and postpartum complications. Fodstad et al.[69] investigated episiotomies in 300 women 0-3 days after delivery, and found no association between perineal pain and episiotomy technique. As discussed earlier, several studies have assessed benefits and complications of episiotomies. However, the majority of previous studies lack an assessment of the technique actually performed. This is a major limitation and might be a reason to conflicting results.

No certain conclusion can be drawn from this small dataset, but this study indicates that the primary factor causing AI and sexual problems is OASIS, not the episiotomy.

The importance of appropriate primary repair must be addressed. Andrews et al.[113] recently reported minimal anal incontinence after primary OASIS where the doctors were trained in performing appropriate repair, highlighting the effect “hands on” training and standardizing technique might have.

These finding are encouraging. Although more studies are needed to demonstrate it convincingly, it is possible that a properly repaired sphincter tear, might not give significantly more dysfunction than what one normally would get after a vaginal delivery. However, this should not detract from a focus on preventing OASIS. OASIS is a physically and psychologically traumatic injury, with the potential to cause both short term and most importantly long term harm. Our study indicated that if a correct episiotomy is used at the right indication, OASIS can be prevented and will not cause sequelae as OASIS.

LIMITATIONS

Study I

This is a retrospective observational study. There are several potential biases which have not been adjusted for such as length of 2nd stage of delivery, BMI and delivery position. In addition, occult OASIS were not investigated and could have affected the pre- and post-rate of OASIS.

Also, data of women without OASIS were retrieved from MBRN. Although the data from the register is validated, there are still potential faults. The consolidation of our dataset with the dataset from MNBR was carefully done, however, the merging could possibly cause errors.

Study II

This is also a retrospective study. The sample is small with only 37 participants in each group. The nature of photography might have caused errors in projecting a 3D scenario to a 2D photography. This might have affected the accuracy of evaluated measurements.

There were also variations in time from birth to assessment between participants that could have affected the episiotomy scar.

This study did not include variables such as length of 2nd stage of delivery and BMI which might be associated with OAIS and could have influenced the result.

Study III

Participants in study III were the same as in study II. The sample is small and data gathered retrospectively. Pelvic floor dysfunction was not the primary aim of the study. Thus power calculation was not performed for these particular outcome measures: AI, UI and sexual problems. Further, the sexual problems score is not a validated questionnaire.

The variation in time since birth to the time of scoring of symptoms varied between participants. We know these symptoms might change with time, thus this might have influenced our results.

Also, the interview for AI was done by one investigator, and further, the investigator was not blinded for which group the women belonged to.

Lastly, information regarding dysfunction before and during pregnancy was not obtained and we did not investigate status of occult OASIS.[80]

CONCLUSION: OUR MOST IMPORTANT FINDINGS

Paper I

The risk of OASIS can be significantly reduced in a population with an OASIS rate between 4.0-5.0%. An interventional programme based on the Finnish delivery method significantly reduced the risk of sustaining OASIS with 59%. The risk reduction of the OASIS incidence at the four delivery units appeared simultaneously with the conduction of the interventional programme.

The risk profile after the interventional programme reducing the rate of OASIS with 59% is similar after intervention compared to before the intervention. The key risk factors after the intervention remained the same as before: forceps delivery, 1st vaginal delivery, ventouse and birth weight 4500g or more.

The greatest risk reduction of sustaining OASIS after the intervention (65%) appeared to be among women with low-risk births (birth weight 4000g or lower, normal presentation, spontaneous vaginal delivery, 2nd and 3rd vaginal delivery).

We also found that the intervention significantly reduced the OASIS rate in births where there were one, two or three risk factors, suggesting that the intervention is efficient in altering practice among both midwives and obstetricians.

However, there was no reduction in risk of sustaining OASIS in the group were all four risk factors were present. This small group might be more resistant to the general change of practice.

Paper II

There were variations in episiotomy technique, such as incision point, episiotomy length, and episiotomy angle among health professionals.

Our findings suggest that episiotomy with incision point close to the midline, short length and depth, and very small and large angles were characteristics associated with increased risk of OASIS.

Paper III

Our results suggested that women with OASIS and episiotomy were more likely to experience AI and sexual problems than women without OASIS and with episiotomy only. However, UI was frequent and equally frequent in both groups (46% and 40%).

Further, episiotomy characteristics were not associated with AI, UI or sexual problems in women with OASIS and episiotomy, but in women with episiotomy only, the length of episiotomy was associated with sexual problems.

SUGGESTIONS FOR FUTURE RESEARCH

The present thesis leaves several unanswered questions that should be addressed in future research. As first stated: "we have come a long way, we have only just begun". I hope that our research will inspire others to continue the journey.

The following are some of the issues emerged from our steps:

- Denmark and Sweden (and many other countries) have still not implemented the Finnish delivery method and have higher OASIS rates than Norway and Finland. Denmark´s OASIS rate is also rising each year. Will an interventional programme at selected hospitals in these countries give a comparable reduction as seen in this study? We suggest a RCT at hospital level in a country that is not yet influenced as Norway is.

- At hospitals with the same low OASIS rate as at the intervention hospitals, do we see the same change in different risk group, as seen in this study? Is it possible to further reduce OASIS rates in risk groups with three or four risk factors? And is it possible to achieve the same level of risk association between OASIS and forceps as between ventouse assisted delivery and OASIS?

- The interventional programme is based on teaching, learning, follow-up and sustainability. How are the long-term effects in sustaining low OASIS rate? Are the birth units capable to make routine training programme and follow-up of staff so that knowledge and skills are maintained and sustains?

- Associations between episiotomy characteristics and OASIS need to be further explored, preferably through a RCT. Is there a difference in risk reducing properties between lateral vs. mediolateral episiotomy?

- What are the appropriate indications for episiotomy? A survey of what accoucheurs perceive as indication for episiotomy could be base for evaluation and a guide for future work for standardization.

- What is the appropriate episiotomy rate to optimally reduce the risk of OASIS, in a delivery setting were the Finnish method is implemented and the staff is trained to do standardized episiotomy upon the same indications?

- A larger cohort study is needed to further establish the association between episiotomy characteristics and pelvic floor dysfunction.

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PAPER I -III

Paper I

Stedenfeldt M, Øian P, Gissler M, Blix E, Pirhonen J.

Risk factors for obstetric anal sphincter injury after a successful multicentre interventional programme.

BJOG 2013;e-pub ahead of print

Paper II

Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P.

Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study.

BJOG 2012;119:724-30.

Paper III

Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P.

Episiotomy characteristics and anal incontinence, urinary incontinence and sexual problems in primiparous women.

Submitted.

APPENDICES

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Deres ref.: Vår ref.: 200805047-7/KST017/400 Dato: 15.01.2009

P REK NORD 163/2008 SFINKTERSKADER (SKADE AV ENDETARMENS LUKKEMUSKEL VED FØDSEL) - EFFEKT AV EN INTERVENSJON - PROSJEKTET GODKJENNES

Vi viser til prosjektleders e-post av 15. januar 2008 vedlagt revidert forespørsel om deltakelse versjon 3 januar 2009.

Etter fullmakt er det fattet slikt

vedtak: *prosjektet godkjennes.*

Det forutsettes at prosjektet er godkjent av andre aktuelle instanser før det settes i gang.
Det forutsettes at prosjektet forelegges komiteen på nytt, dersom det under gjennomføringen skjer komplikasjoner eller endringer i de forutsetninger komiteen har basert sin avgjørelse på. Komiteen ber om å få melding dersom prosjektet ikke blir sluttført.

Komiteens vedtak kan påklages av en part eller annen med rettslig klageinteresse i saken jf. fvl. §28. Klagefristen er tre uker fra det tidspunkt underretning om vedtaket er kommet fram til vedkommende part, jf. fvl. § 29. Klageinstans er Den nasjonale forskningsetiske komité for medisin og helsefag, men en eventuell klage skal rettes til Regional komité for medisinsk og helsefaglig forskningsetikk, Nord Norge. Det følger av fvl. § 18 at en part har rett til å gjøre seg kjent med sakens dokumenter, med mindre annet følger av de unntak loven oppstiller i §§ 18 og 19. For nærmere informasjon om klageadgang og partsinnsynsrett se nettadressen http://www.etikkom.no/REK/klage

Vennlig hilsen

May Britt Rossvoll
Rådgiver/sekretariatsleder

St. Marks inkontinens score

Dette er et validert graderingssystem for anal inkontinens (18). Skjemaet inneholder følgende spørsmål:

	*ALDRI	SJELDEN	AV OG TIL	UKENTLIG	DAGLIG
Lekkasje av gass	0	1	2	3	4
Lekkasje av flytende avføring	0	1	2	3	4
Lekkasje av fast avføring	0	1	2	3	4
Endring av livsstil	0	1	2	3	4

	Nei	Ja
Må bruke bleie/bind eller plugg mot avføringslekkasje	0	2
Bruker forstoppende medisin	0	2
Kan ikke utsette avføring i 15 minutter etter første følelse av trang	0	4

*ALDRI - ingen episoder de siste 4 uker, Sjelden - 1 episode siste fire uker. Av og til - >1 episode siste fire uker men mindre enn 1x/uke. Daglig – En eller flere episoder daglig.

18. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. GUT 1999; 44:77-80

ICIQ-UI Short Form (Norwegian)

Initial nummer

KONFIDENSIELT

DAG MÅNED ÅR

Dagens dato

Mange mennesker lekker urin av og til. Vi forsøker å finne ut hvor mange mennesker som lekker urin og hvor mye dette plager dem. Vi er takknemlige om du vil besvare følgende spørsmål. (Vi vil gjerne vite hvordan du har hatt det, gjennomsnittlig, de siste 4 ukene).

1 Vennligst skriv inn din fødselsdato:

DAG MÅNED ÅR

2 Du er *(kryss av i korrekt firkant)***:** Kvinne ☐ Mann ☐

3 Hvor ofte lekker du urin? *(Kryss av i <u>èn</u> boks)*

aldri ☐	0
omtrent èn gang i uken eller sjeldnere ☐	1
2 – 3 ganger i uken ☐	2
ca. 1 gang per dag ☐	3
flere ganger per dag ☐	4
hele tiden ☐	5

4 Vi vil gjerne vite hvor <u>mye</u> urin du tror du lekker.
Hvor mye urin lekker du <u>vanligvis</u> (enten du bruker beskyttelse eller ikke)?
(Kryss av i en rute)

ikke noe ☐	0
en liten menge ☐	2
en moderat mengde ☐	4
en stor mengde ☐	6

5 Hvor mye påvirker urinlekkasje ditt hverdagsliv?
Vær vennlig, sett en ring rundt et tall mellom 0 (ikke i det hele tatt) og 10 (mye)

0 1 2 3 4 5 6 7 8 9 **10**

ikke i det hele tatt svært mye

ICI-Q: sum 3+4+5 ☐ ☐

6 Når lekker du urin? *(Vennligst kryss av alt som passer for deg)*

aldri, jeg lekker ikke urin ☐
lekker før jeg når toalettet ☐
lekker når jeg hoster eller nyser ☐
lekker når jeg sover ☐
lekker når jeg er fysisk aktiv/trimmer ☐
lekker når jeg er ferdig med å late vannet og har tatt på meg klærne ☐
lekker uten noen opplagt grunn ☐
lekker hele tiden ☐

Mange takk for at du besvarte disse spørsmålene.

Spørsmål om mulige problemer knyttet til seksualitet og til samleie

Har noen av de seksuelle problemene listet opp nedenfor forekommet i ditt seksualliv i løpet av de siste 12 mnd?

Er du seksuelt aktiv? Ja _____ Nei _____

Sett et kryss pr linje	Hele tiden	Nesten hele tiden	Ganske ofte	Ganske sjelden	Aldri
Manglende/liten seksuell lyst ……..	☐	☐	☐	☐	☐
Orgasmeproblemer……..	☐	☐	☐	☐	☐
Smerte (i kjønnsorganet) ved samleie …	☐	☐	☐	☐	☐
Annet (spesifiser): ……..	☐	☐	☐	☐	☐

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