Obstetric anal sphincter injuries: Incidence, risk factors, consequences and prevention

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PhD thesis 2013
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ACKNOWLEDGEMENTS

The present PhD work was carried out at the Department of Obstetrics, Oslo University Hospital, Ullevål and at The Faculty of Medicine, University of Oslo, during 2008-2013. The University of Oslo provided salary as a clinical lecturer and research fellow from 2009, providing the opportunity for these PhD studies. I am grateful for support from both the University of Oslo and the Women and Children's Clinic at Oslo University Hospital, directly or indirectly through my main supervisor Annetine Staff, covering the running costs for the studies.

I wish to express a huge gratitude to my wonderful main supervisor, Professor Annetine Staff. Your enthusiasm, knowledge and stamina combined with your warm heart and empathy in every situation must make you the best supervisor in the world. Thank you for the endless encouragement and the power to always find a solution to all challenges around research.

I am also grateful to my co-supervisor, Professor Leiv Sandvik for the support in epidemiology and statistics. I also want to thank you for the interesting and creative discussions around research, epidemiology, interventions and even politics.

Special thanks to Professor Finn Egil Skjeldestad, who introduced me to epidemiology, statistics and not at least how to perform analyses in SPSS, and guiding me to become a self-reliant researcher.

I am grateful to the members in the Research Group of Obstetrics and Gynaecology for the support and feedback when preparing talks, papers and thesis, and especially to the coordinator Tone Haug helping with numerous practical issues during the years.

Many thanks to Sari Räisänen for sharing the burning interest for women’s health issues in research and for proof reading the thesis.

Thank you Wenche Rotvold, Anne Elisabeth Bjerkreim and Kathrine Fodstad for participating in the mission of conveying the message of improved delivering techniques to the world.

Without enthusiastic clinicians, a clinical research would not be possible to conduct. I am grateful to the midwives at the Fetal Medicine Unit for helping me to
collect questionnaires from the women attending to the ultrasound examination. Midwives at the three delivery units and doctors in Oslo University Hospital, Ullevål changed there working methods and we achieved results we can be proud of, thank you for that. I also want to thank all the colleagues, both midwives and doctors, at Østfold Hospital trust, we started the perineum-project as the pilot hospital in Norway, and together showed the world that as health care workers we can provide improved quality if we want to.

Many people have influenced the formulation of this thesis during the years, and I would like to thank everyone who has taken part in this work, and not least the women who have participated in the studies.

Sakari and Siri, thank you for your support, patience and understanding during these years, and for tolerating my absence.
LIST OF PAPERS


IV. Laine K, Skjeldestad FE, Sandvik L, Staff AC. Incidence of obstetric anal sphincter injuries after training to protect the perineum: cohort study. BMJ Open 2012;2(5).
ABBREVIATIONS

AI  Anal incontinence
aOR  Adjusted odds ratio
BMI  Body mass index
CI  Confidence interval
IAS  Internal anal sphincter muscle
EAS  External anal sphincter muscle
MBR  Medical birth register
NS  Non-significant
OASR  Obstetric anal sphincter rupture
OASIS  Obstetric anal sphincter injuries
OR  Odds ratio
UI  Urinary incontinence
SUMMARY

Anal incontinence is defined as involuntary loss of flatus, solid or liquid fecal material, including soiling (staining of underwear), an embarrassing complaint that can cause social and hygienic problems, isolation, reduced self-esteem and reduced quality of life. Severe and frequent anal incontinence can even reduce the ability to non-domestic work due to the need of having immediate access to use the toilet. Obstetric anal sphincter injury is assumed to be the most important risk factor for female anal incontinence. Obstetric anal sphincter injury is a severe maternal complication during a vaginal delivery and occurs even in otherwise uncomplicated deliveries. In addition to anal incontinence, obstetric anal sphincter injuries (OASIS) may cause pain, discomfort and sexual dysfunction. Reported incidences of OASIS vary from 1 to 6% in different countries and between delivery units.

The main aims of this thesis were to assess the prevalence of and risk factors for anal incontinence during and after pregnancy, and the incidence and risk factors for obstetric anal sphincter injuries. The changing incidences of OASIS during the last decades and different OASIS incidences between countries were studied. Risk factors for obstetric anal sphincter injuries in two time periods were explored, before and after reduction of incidence of OASIS to evaluate the effect of improved delivery techniques on OASIS incidence and risk factors.

In this thesis, St. Mark’s incontinence score was used to evaluate anal incontinence. St. Mark’s score range from 0 (no anal incontinence) to 24 (complete anal incontinence). No agreement for minimum score as definition of anal incontinence, or score limits for defining severity anal incontinence exists. A St. Mark’s score 3 may include either weekly flatus or fecal incontinence, or a combination of three different symptoms each occurring rarely. In this thesis, a St. Mark’s score of 3 or more was defined as anal incontinence.

Papers 1 (2 846 pregnant women) and 2 (591 women with OASIS) in this PhD thesis assessed anal incontinence. Women with a previous obstetric anal sphincter injury had a significantly higher prevalence of anal incontinence (24-38%), defined by St. Mark’s score 3 or above, than parous women with one previous vaginal delivery (7.8%) without OASIS. The risk of the more severe forms of anal
incontinence (St. Mark’s score >5) was also higher among women with an injured anal sphincter. Risk for anal incontinence was significantly higher among women with a persistent defect in the sphincter muscle detected one year postpartum by endoanal ultrasound than among women without such a defect. Anal incontinence was reported also by women without previous deliveries, 7.8% of the nulliparous women reported episodes of anal incontinence. Factors related to self-reported anal incontinence among the nulliparous women were low educational level and co-morbidity.

In paper 3 the alterations in OASIS incidences in the four Nordic countries were studied (574 175 deliveries), based on the national birth registries. In Norway, the incidence of OASIS was reduced by 48% (from 4.2% to 2.3%) from 2004 to 2010. Denmark was the Nordic country with the highest OASIS incidence in 2010 (4.2%), with a 16.7% increase from 2004 to 2010 (from 3.6% to 4.2%). In Finland the OASIS incidence increased by 43% (from 0.7% to 1.0%) during the same years. In Sweden, a 24% reduction in the incidence of OASIS was observed from 2004 to 2009 (from 4.2% to 3.2%), but the OASIS incidence increased again slightly to 3.6% in 2010. The main maternal and fetal characteristics and obstetrical care are similar in these four Nordic countries. Most obstetrical interventions are also similarly used in these four countries. The use of episiotomy was however different; in Denmark and Sweden the episiotomy frequency is only 5-6%, while in Finland and Norway the reported episiotomy use is fourfold (20-24%), and the OASIS incidence was markedly lower in Finland and Denmark (1-2%). The role of episiotomy is difficult to assess, but a correctly and selectively used episiotomy may partly explain the lower incidence of OASIS in Finland and Norway compared to Denmark and Sweden. It is unlikely that the marked reduction in OASIS rate in Norway since 2004 is by chance or the result of an extensive and novel underreporting. More likely explanation for the rapid and consistent OASIS reduction in Norway is the re-introduction of manual perineal protection during second stage of delivery, as recommended in the national plan in Norway.

All the presented Norwegian delivery units had reduced the OASIS incidence from 2004 to 2010. OASIS incidence was threefold in the units with the highest
OASIS incidence compared to units with the lowest incidence. In Denmark, the
OASIS incidence varied from 2.9% to 5.6% between delivery units during the study
years, in Finland from 0.1% to 2.1% and in Sweden from 2.0% to 5.7%.

In paper 4, two time periods were compared (2003-05 and 2008-10), before
and after reduced OASIS rate in a large university hospital. Data was obtained from
the hospital obstetrical database and hospital discharge register, and in total 31 709
vaginal deliveries were studied. OASIS incidence was reduced with 50% from first
to second time period. The OASIS incidence was reduced with 50% in all studied
subgroups of women, in spontaneous and instrumental deliveries, in all parity
groups, as well as in all subgroups of infant birth weight. The reduced OASIS
incidence occurred simultaneously with a training program in manual perineal
protection for the staff in the delivery unit. Between these study periods, instrumental
deliveries become more frequent but other population characteristics remained
mainly unchanged. Episiotomy use during spontaneous deliveries was reduced, but
increased during instrumental deliveries.

The PhD study documented that anal incontinence is reported among both
nulliparous and parous women. The study showed that the risk of AI increases with
increasing number of vaginal deliveries, and is most frequent among women with a
history of OASIS during delivery. The study also confirmed large variations in
OASIS rate between Nordic countries, delivery units and time periods. This PhD
study suggests that the observed differences in OASIS over time between countries
and delivery units in this study are mainly associated with different routines and
delivery techniques during second stage of delivery.

The PhD student proposes that improved delivery techniques significantly
reduce the occurrence of OASIS and thereby may have a marked positive effect in
both short and long term women’s health, as it will probably reduce the prevalence
of health deteriorating anal incontinence.
1 INTRODUCTION

“When compared to the hands the sphincter ani is far superior. If you place into your cupped hands a mixture of fluid, solid and gas and then, through an opening at the bottom try to let only the gas escape you will fail. Yet the sphincter ani can do it. The sphincter apparently can differentiate between solid, fluid, and gas. It apparently can tell whether the owner is alone or with someone, whether standing up or sitting down, whether its owner has his pants on or off. No other muscle in the body is such a protector of the dignity. A muscle like that is worth protecting.” Walter C. Bornemeier, a former president of the American Medical Association (1).

1.1 Female anal incontinence

Fecal incontinence has been called the “unvoiced symptom” due to the embarrassment it can cause to women suffering from it (2). Anal incontinence is a distressing and disabling complaint that can cause social and hygienic problems, isolation, reduced self-esteem and reduced quality of life. Anal incontinence can have a negative effect both in physical and psychological health, and may affect the daily life by limiting occupational, leisure and social activities and can also have a negative effect on sexual function (3-5). Severe and frequent anal incontinence may cause disability to maintain non-domestic working activities due to the need of having immediate access to use a toilet. Due to these complaints and life style limitations, anal incontinence also affects the quality of life (3,6,7).

1.1.1 Definition of anal incontinence

The term anal incontinence includes both fecal and flatal incontinence. Anal incontinence can be subdivided into several components: involuntary leakage of gas, solid, loose or liquid stools, passive leakage of stool (soiling or staining), and urgency incontinence. The terms anal incontinence and fecal incontinence are used some inconsequently, sometimes even as synonyms in medical texts (8). The International Urogynecological Association (IUGA) and International Continence Society (ICS) have introduced the following definitions: Fecal incontinence is an involuntary loss of solid or liquid feces. Passive fecal incontinence includes soiling
without warning, or difficulty of wiping clean after defecation. Fecal urgency is a sudden need to defecate that is difficult to defer whereas fecal urgency incontinence is the involuntary loss of feces related to urgency (9). These definitions do not include any description of the frequency of the symptoms or the impact on lifestyle.

1.1.2 Methods for diagnosing anal incontinence
Diagnosing anal incontinence is based on self-reporting by the patient, her subjective evaluation of anal incontinence symptoms. No objective method for measuring anal incontinence exists. Information of anal incontinence can be collected by questionnaires filled out by the patient, or a health care worker may use such a form during an interview in a clinical follow-up/consultation or by telephone. To assess and describe the prevalence and severity of anal incontinence symptoms, several scoring systems are developed, such as Wexner, St. Mark’s and Pescatori (10,11). The scoring systems measure the type of anal incontinence (flatus, solid or liquid fecal incontinence and urgency) and the frequency of these symptoms. Some questionnaires also include questions of how anal incontinence effects social or everyday life, as do St. Mark’s incontinence score (10,12). These scoring methods can be used in longitudinal studies to assess effect of aging, treatment or intervention on individuals or to compare patients or patient groups with different risk factors for anal incontinence.
Table 1. St. Mark’s incontinence scoring:
Never = no episodes in the past four weeks;
Rarely = 1 episode in the past four weeks;
Sometimes = >1 episode in the past four weeks but <1 per week;
Weekly = 1 or more episodes a week but <1 per day;
Daily = 1 or more episodes a day.
One score from each row: minimum score = 0 perfect continence; maximum score 24 = totally incontinent.

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Rarely</th>
<th>Sometimes</th>
<th>Weekly</th>
<th>Daily</th>
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<td>1</td>
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<td>3</td>
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<tr>
<td>Incontinence for liquid stool</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Incontinence for gas</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Alteration of lifestyle</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Need to wear pad or plug</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taking constipation medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of ability to defer defecation for 15 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

1.1.3 Classification and severity of anal incontinence

Although the scoring systems provide a possibility to classify severity of anal incontinence in scores, there is no consensus or agreement for incontinence score cut-off; defining the lowest score that identifies anal incontinence or which scores classify the severity of anal incontinence.

As long as such a consensus of defining anal incontinence and quantitating anal incontinence symptoms is lacking, it is challenging to compare studies on anal incontinence. Some authors report frequency of anal, fecal or flatal incontinence separately, such as weekly or daily incontinence, without combining the scores to a sum of the different complaints. Other studies report only fecal incontinence, even if also flatal incontinence can be disabling and embarrassing. Many studies have relatively low number of participants and the heterogeneity of the studies makes it difficult to perform valid meta-analyses.

1.1.4 Prevalence of female anal incontinence

The prevalence of anal incontinence varies depending on the chosen population, reflecting for example variations in age, parity or time from delivery, selected or
unselected inclusion of participants. Inclusion of patients before or after delivery, a population based inclusion or invitations from a special clinic may also impact the findings resulting in different prevalences. Also, the definition of anal incontinence used in the study (including only fecal or both fecal and flatal incontinence) and scoring system used for anal incontinence will affect the reported prevalence, as will the chosen method for obtaining the relevant subjective patient information (including the use of different questionnaires). Different study designs also have different features: prospective studies often have a lower number of participating women but provide exact information about them, while surveys can provide information from large number of participants, but the information is less exact and detailed, and risk of errors is larger. Studies designed to study urinary incontinence can be underpowered to explore anal incontinence, which is a less frequent complaint than urinary incontinence in women (13).

**Anal incontinence among pregnant nulliparous women**

Previous studies on anal incontinence among pregnant nulliparous women are heterogeneous, and thus, the reported prevalence of components of anal incontinence differs largely: In available studies, prevalence of

- Fecal incontinence varied from 1% to 6.0% (13-16)
- Flatal incidence from 0.7% to 42.3% (14,15,17)
- Anal incontinence from 6.8% to 8.0% (18,19)

The authors in these studies have used different frequencies of incontinence complaints; some excluded women with previous neurological, gastrointestinal, anorectal, urinary tract ailments or surgery (13,15,16,18), some did not (14,17,19). Number of nulliparous participants in these studies varied from 134 to 3991. Only one of these studies analyzed risk factors for anal incontinence before delivery (18), showing that maternal age over 35 years and excessive weight gain were independent risk factors for anal incontinence during pregnancy. The remaining studies explored the risk factors for fecal, flatal or anal incontinence only after the participants had delivered.
Postpartum anal incontinence

Postpartum (2-6 months after delivery) prevalence of anal incontinence varies from 7.3% to 29% in previous studies (18,20). Fecal incontinence is reported from 2% to 13.6% (14,20,21), and flatus incontinence is reported by 25-26% of the women (25-26%)(14,20,21). This large variation can again be explained by the methodological differences of the studies and inclusion criteria of the women (prospective or retrospective inclusion; before or after delivery).

Although the current published anal incontinence studies in many ways are heterogeneous, they are consistent with the conclusion that the risk of anal incontinence is markedly increased after obstetric anal sphincter injuries (OASIS) compared to women with a delivery without OASIS. The postpartum prevalence of fecal incontinence is doubled among women with obstetric anal sphincter injury (7.8-17%) compared to women without anal sphincter injury 2.9-8% (20-22). Similarly, flatal incontinence is also more common among women with anal sphincter injury (23-45%) than in women without such injury (18-20%) (21-23).

Some of the longitudinal postpartum studies reveal that the increased prevalence of fecal, flatal or anal incontinence short time (6 weeks-5 months) after delivery can be reduced in a follow-up longer time interval after delivery (13,15,22). This could indicate that pelvic floor injuries to some extent can heal during the first year after delivery. However, Nazir et al. described an opposite development; increasing fecal incontinence from 7% to 17% was shown in repeated surveys at 5 and 18 months postpartum (24).

Follow-up studies 5-18 years after delivery reveal that women with OASIS still have higher prevalence of anal incontinence than controls without OASIS (4,25-27).

Anal incontinence in general female population

A population based study on women over 30 years of age reported 19% anal incontinence and 3% fecal incontinence among Norwegian women above 30 years of age (28). Another population based study including all adult age groups of women from 20 years of age revealed a gradually increasing fecal incontinence prevalence
from 7.3% among women aged 20-29 to 22% among women aged 50-59 years, and no further increment of anal incontinence in the oldest age groups (29).

Prevalence of anal incontinence has also been studied in different outpatient clinics: the prevalence among women attending to a urogynecological clinic was 16-29% (30,31), 7% in an antenatal clinic (30), 5.6% in a general outpatient clinic and 4.4% in the general population from the same area in Switzerland. Women living in nursing homes have the highest prevalence of anal incontinence 50-60%- the oldest women with frequent additional co-morbidity (32,33).

1.1.5 Risk factors for anal incontinence
Risk factors for anal incontinence can be categorized as factors related to

- Pregnancy and delivery
- Aging
- Co-morbidity
- Tissue type or predisposing factors

Pregnancy and delivery
A large number of studies have confirmed that obstetric anal sphincter injury (OASIS) is a major risk factor for anal incontinence among younger women of reproductive age (14,20-22). Increasing parity increases the prevalence of anal incontinence to some extent (28,34,35). This effect of vaginal deliveries is measurable after two or three deliveries. Caesarean delivery does not seem to protect from anal incontinence, when compared to uncomplicated vaginal delivery, probably because a normal vaginal delivery increases the risk of anal incontinence only slightly (20). Instrumental delivery (14), especially delivery with forceps (17,20,21,35-38) is an independent risk factor for anal incontinence. Other obstetrical factors, such as prolonged first stage of labor (17), prolonged second stage of labor (14,20) and infant birth weight (14) have been risk factors for anal incontinence symptoms in some studies, but not in others (16,18,34). Signorello et al. concluded that a midline episiotomy was an independent risk factor for anal incontinence, even without anal sphincter injury (39). Similarly, in a study of Eason et al. only midline
episiotomy and anal sphincter injury remained risk factors for anal incontinence, after adjustment for other maternal, fetal and obstetrical factors (21).

The role of pudendal nerve damage during vaginal delivery is controversial, some studies show association between denervation injury and anal incontinence (40,41) but measuring pathological pudendal nerve terminal motor latency did not predict anal incontinence (24,38,42).

**Aging and body mass index**
Older women have higher risk for anal incontinence, both in studies exploring effects of pregnancy and delivery (14,18,34), and in studies assessing general female population (6,28,29,43).

Aging process might be an independent risk factor for anal incontinence, however, the estrogen deficiency after menopause can partly explain the increasing risk of anal incontinence related to aging (34,44,45). Additionally, co-morbidity also increases with advanced age, and might impact in anal incontinence prevalence.

Higher body mass index (BMI) has been related to risk of anal incontinence complaints in some studies (6,15,20,28), but BMI was not related to anal incontinence symptoms in other studies (16,21).

**Co-morbidity**
Medical conditions that increase the risk of anal or fecal incontinence can be classified as medical, surgical, neurological and gynecological conditions (6,19,28,29,33,46):

- Diabetes, scleroderma
- Irritable bowel syndrome, inflammatory bowel disease
- Lower abdominal, colorectal and urological surgery
- Multiple sclerosis, neuropathies, spinal cord injury
- Gynecological surgery
Tissue type, collagen weakness or predisposing genetics

Tissue type has probably only a minor or no effect on risk of anal incontinence (34,47). In a study exploring collagen weakness and anal incontinence among nulliparous women before and after delivery, higher joint mobility was associated with flatal incontinence, but not with fecal incontinence. Complaints of incontinence after first delivery were not associated to any other measured physical markers of collagen weakness such as striae, hernia, hemorrhoids, varicose veins, family history of incontinence or pelvic organ prolapse (16). A study on identical twins revealed that nulliparous women had significantly lower prevalence of anal incontinence as compared to their parous twin sisters (34). However, women with urinary incontinence more frequently report anal incontinence also (17,34). This finding, also called double incontinence, could be a sign of incontinence predisposing tissue type, but can also be a sign of similar causative risk factors for anal and urinary incontinence, such as parity, obstetrical complications/events and aging.

1.1.6 Quality of life and anal incontinence

Anal incontinence has negative effect on quality of life, and more severe anal incontinence increasingly affects the quality of life (3,7,48). However, when anal incontinence and quality of life is assessed simultaneously, a measurable significant association is found only among women with relatively high scores for anal (St. Mark’s >7) or fecal incontinence, women reporting lower scores do not report marked impact on quality of life (3,7,48). One can only speculate reasons for this finding, but it might be explained with the fact that women are able to adapt to a life with anal incontinence, and accept a life with limitations without experiencing reduced quality of life. Secondly, several studies reveal that women neither seek help from the health care services to their incontinence complaints nor mention the episodes of anal incontinence to their doctor, and this can cause under-reporting of the occurrence of anal incontinence. One reason for not seeking help is probably the embarrassment associated with anal and fecal incontinence (2,7,16,17,30,37,38,49-51). Embarrassment may affect the women’s willingness to admit that anal incontinence causes problems. Women with the most severe forms of fecal
incontinence consulted a physician more frequently than women with mild or moderate symptoms (52).

In some studies, women with anal incontinence also reported negative effect on their emotional health (7,53).
1.2 Anatomy

1.2.1 Perineum

The term perineum includes the genital and anal area anterio-posteriorly between the pubic symphysis and coccyx, a diamond shape area consisting of two triangles, the genital (anterior) and the anal (posterior) triangle.

1.2.2 Female pelvic floor

Pelvic floor muscles can be categorized to

- Superficial: Bulbospongiosus (bulbocavernosus), superficial transverse perineal and ischiocavernosus muscle
- Deep: Levator ani, deep transverse perineal muscle

Figure 1

BS: Bulbospongiosus muscle
STP: Superficial transverse perineal muscle
LA: Levator ani muscle
IC: ischiocavernosus muscle
EAS: external anal sphincter
PN: Pudendal nerve
IRN: inferior rectal nerve

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1.2.3 Anal sphincter

The external anal sphincter is a striated muscle and is innervated by a somatic nerve, the pudendal nerve. The external anal sphincter muscle consists of three parts; the subcutaneous, superficial, and deep. This subdivision is difficult to visualize during surgery, and is not even described in all textbooks of anatomy. Internal anal sphincter (IAS) muscle is covered by the external anal sphincter (EAS) and the longitudinal smooth muscle of the rectum lies between them. The internal anal sphincter consists of smooth muscle and is innervated by autonomic nerves.

The IAS contributes the most of the resting pressure in the anal canal (50-60%) and the EAS approximately 30%. Other structures provide the rest of the resting pressure in anal canal. EAS provides the most of the squeezing pressure (54-56).

Figure 2

With permission from: Elsevier B.V. ScienceDirect. (Rewievs in Gynaecological Practice 3. 2003, 188-195)
1.3 Classification and incidence of obstetric anal sphincter injuries (OASIS)

Classification of OASIS

Three main classification systems of perineal tears are most known; Martius, Williams Obstetrics Textbook and Sultan. Martius used three degrees of perineal injury, Williams and Sultan used four degrees, but Sultan presented a classification where the third degree is further subdivided to three more grades (54,57-60).

First degree tears are similarly defined in these three systems. Martius’ second degree tear involves also a partial tear of anal sphincter muscle, and the third degree includes complete anal sphincter tearing. In Williams’ and Sultan’s classification, second degree involves the superficial perineal muscles but not the anal sphincter muscle. Williams’ third degree tears are also called partial tears and include any injury of anal sphincter muscle, while fourth degree tear includes a tearing of rectal mucosa, also called complete tear. Sultan divides the third degree to three subgroups (3A, 3B and 3C), as fourth degree consists of tearing of sphincter muscles together with the rectal mucosa tear. The definition created by Sultan is widely used and also adapted by the Royal College of Obstetrics and Gynaecology (RCOG). Isolated internal anal sphincter tears occur rarely, and such injuries are not included in these classification systems.

Several other terms have been used across decades; such as different combinations of words denoting perineal or anal sphincter damage, including laceration, injury, tear, rupture, trauma, disruption, as well as damage. Numerous abbreviations are created to describe anal sphincter injury, by combining different words: AST, OAST, ASR, OASR, OASI and OASIS. In the International Statistical Classification of Diseases and Related Health problems (ICD-10), perineal injuries are classified in four degrees, as presented in Table 1.
Table 1

<table>
<thead>
<tr>
<th>Description</th>
<th>Martius</th>
<th>Williams Obstetrics</th>
<th>Sultan/RCOG</th>
<th>ICD-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superficial tear involving only perinal skin or vaginal mucosa</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>O 70.0</td>
</tr>
<tr>
<td>Tear involving superficial perineal muscles and fascia</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>O 70.1</td>
</tr>
<tr>
<td>Less than 50% external anal sphincter muscle is torn</td>
<td>2</td>
<td>3</td>
<td>3A OASIS</td>
<td>O 70.2</td>
</tr>
<tr>
<td>More than 50% of the external anal sphincter is torn</td>
<td>3</td>
<td>3</td>
<td>3B OASIS</td>
<td>O 70.2</td>
</tr>
<tr>
<td>Both external and internal anal sphincter are torn</td>
<td>3</td>
<td>3</td>
<td>3C OASIS</td>
<td>O 70.2</td>
</tr>
<tr>
<td>Anal sphincter muscle and rectal mucosa are torn</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>O 70.3</td>
</tr>
</tbody>
</table>

**Incidence of OASIS**

Occurrence of OASIS is used as a quality indicator of obstetric health care in OECD countries (61).

The incidence of OASIS varies largely between countries and delivery units, 1.0-5.85% (62-65). An increasing trend in OASIS incidences is documented in several countries (62,63,66-68). It has been unclear whether such trends reflect differences in populations, differences in diagnosis and registration, or differences in management of delivery between and within countries. Part of this increase has been argued to result from an improved quality of recognition, registration and reporting of anal sphincter injuries, a change in the classification systems from three degrees to four degrees, or changes in the population of delivering women; women are older and overweight is more frequent, the distribution of nulliparous women is larger than in previous decades (women deliver fewer children than before). Newborns are also heavier than in the past decades.

The studies from Finland and from Norway indicate that the size and type of a delivery unit matter, the largest (68-70) and the smallest delivery units with have the highest OASIS rates (70). A higher risk of OASIS in largest hospitals could be explained by larger amount of high-risk pregnancies, but this option does not explain the more frequent OASIS occurrence in the smallest hospitals. On the other hand,
Räisänen et al. showed that the differences between delivery units may be explained by different policy of management of second stage of delivery (69,71).

1.4 Diagnostic methods and primary repair of obstetric anal sphincter injuries (OASIS)

1.4.1 Diagnostics of OASIS

Primary diagnosis of an obstetric anal sphincter injury is important (72), an unrepaired or defect anal sphincter muscle increases the risk and prevalence of anal incontinence (23,73-75).

The diagnosis of a perineal injury is based on a careful clinical examination after delivery and consists of an inspection and digital examination. Defining the depth and degree of a perineal injury requires a rectal exploration. By palpating the anal sphincter muscle between two fingers the detection rate of sphincter injuries immediately after a delivery is very high (76). Awareness and training in recognizing OASIS improves the detection rate (76,77).

Many studies have concluded that occult anal sphincter injuries can be detected in a postpartum follow-up by endoanal or perineal ultrasound examination (23,76,78). However, these “occult” anal sphincter injuries may actually be injuries missed at delivery, and could have been detected with more careful clinical examination (76). Defects in the anal sphincter muscles detected despite primary repair may represent an insufficient primary diagnosis and repair, but may also indicate disturbed healing process after adequate primary repair. The external anal sphincter covers the internal anal sphincter (IAS), and thus, the isolated IAS injuries can be difficult to detect during a clinical examination after delivery. Such injuries can be detected in an ultrasound examination, but are rare, as less than 1% occurrence is described (23,76).

Possible false positive findings in endoanal ultrasound examination of the anal sphincter are described; in a study with a control group consisting of women delivered with cesarean only, ultrasound examination detected anal sphincter defects even in women never delivered vaginally (74).
1.4.2 Primary repair of OASIS

Good quality of the primary OASIS repair is important to achieve a good result and low risk of postpartum anal incontinence. Increased awareness increases the detection rate of OASIS (76,77). Specific education for primary repair of OASIS improves the results of primary repair and reduces the prevalence of anal incontinence (53). Careful visualization and repair of the entire injury including the internal anal sphincter is crucial to avoid defects in the anal sphincter muscles (53,73-76,79).

There are mainly two methods in use for repairing OASIS; the “end-to-end” and the “overlapping” methods, describing alternatives how to adapt the ruptured muscle ends. Randomized controlled trials comparing these repair methods show conflicting results and are therefore considered as clinically equal (80-82).

1.5 Risk factors for obstetric anal sphincter injuries (OASIS)

A large number of studies exploring obstetric anal sphincter injuries are published and available on PubMed. Large birth register studies with robust and reliable data are published during the last decade (2001-13) from the Nordic countries, Netherlands, Israel, Ireland and the U.S. including 87,267-1,673,442 deliveries (65,68,83-89). Additionally, many smaller retrospective case-control reports, exploring numerous details around the delivering woman, the infant and the obstetrical procedures are published. The results from these case-control studies are conflicting, likely to be biased due to the small number of participants.

Risk factors for OASIS can be classified as

- Maternal
- Fetal
- Obstetrical
- Delivery unit administrative and personnel factors

Risk factors could also be classified as modifiable and non-modifiable characteristics and procedures or interventions. Maternal and fetal characteristics are mostly non-modifiable, such as parity, maternal age or infant size. These characteristics are largely studied as risk factors for OASIS, as are common
obstetrical interventions such as instrumental delivery, episiotomy and epidural. Many factors or clinical procedures related to the management of second stage of labor can affect the occurrence of perineal injuries, such as maternal birth position, pushing methods, manual perineal protection and use of episiotomy technique and quality of the episiotomy cut. These factors are difficult to study due to the challenges in precise documenting and objective registering of these events and interventions. These challenges may have contributed to these second stage procedures being little studied as risk factors for OASIS. Importantly, obstetrical procedures and interventions can be modifiable, at least to some extent, in contrast to maternal and fetal characteristics.

1.5.1 Maternal risk factors associated with OASIS
Maternal risk factors include maternal characteristics that are not modifiable at the moment of delivery. Maternal features are an important part of the risk assessment of OASIS, and primiparity is one of the most important risk factors for OASIS.

Parity
Primiparous women have undoubtedly higher risk for OASIS than parous women with previous vaginal delivery; large register studies conclude 2-7-fold increased risk (65,68,86,89). This risk increment caused by primiparity is markedly higher than any other assessed maternal characteristics. Respectively, risk of OASIS is reduced with increasing birth order (68,89). However, women with previous caesarean section only, and no vaginal deliveries, have higher risk for OASIS than nulliparous women delivering first time, adjusted odds ratio (aOR) of 1.2-1.42(65,68,84,90).

Maternal age
Women with higher age have increased risk of OASIS to some extent, OR 1.2-1.3 for women over 30 years, aOR 1.2 (68) or for women over 35 years, aOR 1.09-1.6 (65), or when the youngest (ref <20 years) women are compared to the oldest (>35 or >39 years), aOR 1.6-1.74 (85,86). In the study of Gerdin et al., the effect of higher maternal age was significant for OASIS risk only when the infant birth weight was
less than 4000g; in a multivariate analyses the effect of macrosomia exceeded the effect of maternal age (91). In the study of Ampt et al. the association between OASIS and advancing maternal age was indifferent among the parity groups and different age groups (84) and in the study of Landy et al. the advancing age was a significant factor only among the nulliparous women (85).

Effect of young maternal age on OASIS risk differs in studies; in most studies women under 20 years have reduced risk (65,68,84,86), but in some studies the youngest women have increased OASIS risk (92,93).

**Maternal body mass index, height, weight and weight gain**

Body mass index (BMI) is investigated in only few studies probably because weight and height are not routinely registered in all obstetrical registries.

Maternal height has been found to inversely associate with OASIS (90,94). BMI was not related to OASIS risk after adjusting for other risk factors in the study of Räisänen et al. (86). The study of Landy et al. showed a reduced risk of OASIS with BMI >30 among nulliparous women, aOR 0.8-0.7. Among multiparous women no significant association was found between BMI and OASIS (85). Maternal overweight is also associated to an increment in infant birth weight, which is one of the strongest risk factor for OASIS.

**Maternal ethnicity**

Some studies conclude that Asian women have increased OASIS risk, (aOR 1.37-2.5) (65,84,85) and that black and Hispanic women have reduced risk (aOR 0.69) compared to white women (65). The study of Baghestan et al. showed an increased OASIS risk among both African and Asian women, aOR 1.3 and 1.6, compared to European women (68). However, the review from Wheeler et al. concludes that Asian ethnicity was not associated with increased risk for OASIS (95). The conflicting results could be explained with the various definitions of the term “Asian ethnicity” between the studies.
Previous OASIS and recurrence risk in next delivery
Anal sphincter injury during a previous delivery increases the risk for recurrent OASIS in subsequent delivery, OR 4.2-5.9 (96,97), and aOR 4.3 (98). Recurrence risk for OASIS increases with increasing infant birth weight (96-98); aOR 10.0 when the infant births weight is >4000 grams, and aOR 23.6 when the infant birth weight is >5000 grams. An instrumental subsequent delivery increases the OASIS risk strongly to 5-fold and also a large fourth degree tear in first delivery increases the risk of recurrent OASIS (96-98).

Tissue type, collagen weakness and risk of perineal injuries
A maternal tissue type that predisposes to lacerations and association with OASIS has been proposed. Such a hypothesis is however difficult to assess; as tissue type is not easy to measure or define. Some few studies have explored the relation between pelvic organ prolapse, urinary incontinence and tissue type, but OASIS is rarely explored in these studies. Joint hypermobility is believed to indicate collagen weakness, and Knoepp et al. described a protective effect of joint hypermobility against OASIS (47). Smoking reduces the risk of OASIS with 28% in all infant birth weight groups; the biological explanation may be that smoking affects collagen synthesis and thereby causes changes in perineal tissues (68,99).

1.5.2 Fetal characteristics associated with OASIS
Fetal characteristics that represent OASIS risk factors are largely non-modifiable factors, such as fetal weight, abnormal presentation or shoulder dystocia.

Birth weight
Infant birth weight is one of the most important risk factors for OASIS, as uniformly concluded by numerous studies. Macrosomia (>4000g) is associated with OASIS, aOR 2.17-9.2 (65,68,85,86,88). In deliveries with infant above 4500 grams even higher risk is observed, aOR 10.5-13.6 (85). Increasing infant birth weight increases the risk of OASIS linearly in all weight groups, with OR 1.47 per every unit of increased 500 grams (89), or aOR 1.2 per 200 g increment (84).
Even though the risk of OASIS is increased when the baby is large, the large majority (70-90%) of OASIS occurs in deliveries with an infant less than 4000 grams (65,67,84,85,88,100), and 52-56% in deliveries with infant birth weight less than 3500 grams (84,85,100).

**Abnormal fetal presentation**

When the infant is born in a persistent occiput posterior presentation, a larger head circumference passes the vaginal introitus than in an occiput anterior presentation, causing more pressure on the perineal structures. Persistent occiput posterior presentation increases the risk of OASIS markedly aOR 1.73-3.2 (86,89). However due to the low incidence (2%), persistent occiput presentation explains only a minor fraction of all OASIS cases (86,101). Infants in occiput posterior presentation are more often delivered with forceps or vacuum extraction, which additionally increases the OASIS risk in deliveries with the infant in abnormal presentation (101).

**Shoulder dystocia**

Shoulder dystocia is associated with increased risk of OASIS and studies show high aOR of 2.0-2.67 (65,89). This delivery complication occurs rarely, in only 0.5-2% of deliveries, and therefore is a contributing factor in only a few cases of all OASIS cases. Shoulder dystocia is also associated with high infant birth weight, which also increases the OASIS risk. In some studies assessing OASIS, cases with shoulder dystocia are excluded (85,88).

**Fetal distress and OASIS risk**

Non-reassuring fetal heart rate can cause a hurried delivery and may therefore become a risk for perineal injury. This issue is very little explored; Handa et al. found an association between fetal distress and OASIS (aOR 1.31) (65). The study of Sheiner et al. also showed an increased OR for OASIS (11.7), but it was not significant in the multivariate analyses.
1.5.3 Obstetrical interventions and OASIS

Nulliparous women need more obstetrical interventions and often one procedure leads to another. It is not easy to identify the causality relations between nulliparity and obstetrical interventions and procedures. The obstetrical procedures associated with each other can act as confounding factors, interactions or intermediate variables.

Delivery mode

Instrumental deliveries are associated with increased OASIS risk compared to spontaneous delivery. Forceps delivery is shown to represent a higher risk for OASIS than a vacuum extraction, as concluded in a Cochrane review based on 10 randomized trials (102). Similarly, in large register studies, incidences of OASIS are higher in forceps deliveries (8.1-16 %), than in deliveries by vacuum extraction 6.0-15.5% (65,68,84). Forceps performed in a high position of the presenting part increases the OASIS risk even more, in the study of Dandolu et al. low forceps delivery resulted in 20% OASIS, mid forceps 23% and high forceps resulted in 75% OASIS (103).

Also when adjusting for other variables forceps delivery is a higher risk for OASIS (aOR 2.3-26.7) than a vacuum extraction (aOR 1.45-8.2) (65,68,84-86,88,89).

Epidural

Epidural use has probably no effect on OASIS risk, and conflicting results from different studies may indicate differences by chance. In previous studies the effect of epidural has shown to be indifferent in parity groups (86), or have only slightly increasing (68), decreasing (85) or no (65) effect after adjustment for other OASIS risk factors.

Duration of second stage of delivery

Prolonged second stage of delivery (>60 min) is an independent risk factor for OASIS, aOR 1.49-5.4 (65,85,86), and is a factor strongly related to nulliparity, large infant and presentation abnormalities. Landy et al. presented the duration of second
stage of delivery in four categories, and the risk of OASIS increased in every category with increasing second stage duration.

**Pushing methods during second stage of delivery**
When pushing on commando or on natural subjective need was compared, no difference in OASIS occurrence could be observed. Coached pushing with closed glottis (Valsalva) during second stage of labor does not seem to affect the occurrence of OASIS (104). However, in this randomized trial a large number of participating women were not able to use the method they were randomized to, 15% were not able to push with closed glottis, and 34% of the women randomized to push spontaneously with open glottis pushed with closed glottis. Thus, contamination of the methods was a problem in both study arms, and can have influenced the results.

**Induction of labor and augmentation with oxytocin**
The results in studies on effect of induction of labor and oxytocin on prevalence of OASIS are conflicting, and there is probably no effect on OASIS risk (68,84,86). Induction and augmentation of labor may appear as confounding factors associated with other obstetrical factors, such as nulliparity, prolonged labor, instrumental delivery or large infant.
The table below summarizes studies from large birth registries published in 2001-2013, assessing risk factors for OASIS. Main risk factors studied are presented in the table, and only significant OR/aOR are presented. Ref: reference group chosen in the study.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Parity</th>
<th>Maternal age (years)</th>
<th>Vacuum Ref non-instrum</th>
<th>Forceps Ref non-instrum</th>
<th>Prolonged second stage</th>
<th>Birth weight/ macrosomia (grams)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hehir, 2013 Ireland N=100 307 (83)</td>
<td>Primip 3.5% Multip 0.9%</td>
<td>No data</td>
<td>OR 2.9 3.7%</td>
<td>OR 7.1 8.6%</td>
<td>No data</td>
<td>No data</td>
</tr>
<tr>
<td>Ampt, 2013 Australia N=528 846 (84)</td>
<td>Primip 4.8% Multip 0.9%</td>
<td>Ref 25-29 &lt;20 0.5, 20-24 NS Primip 30-34 aOR 0.9 ≥40, aOR 0.7 Multip 30-39 aOR 1.17 ≥40 NS</td>
<td>Primip aOR 1.8-2.0 Multip aOR 2.6-2.7</td>
<td>Primip aOR 3.0-6.1 Multip aOR 3.4-6.1</td>
<td>No data</td>
<td>Per 200 g increment aOR 1.2</td>
</tr>
<tr>
<td>Landy, 2011 USA N=87 267 (85)</td>
<td>Nullip 5.8% Multip 0.6%</td>
<td>Ref &lt;20 Primip 20-24 aOR 1.2 25-29 aOR 1.6 30-34 aOR 1.9 &gt;35 aOR 1.6 Multip NS</td>
<td>Primip aOR 2.6 Multip aOR 4.9</td>
<td>Primip aOR 3.7 Multip aOR 3.0</td>
<td>Primip Ref &lt; 60’ 1-2 h aOR 1.5 2-3 h aOR 1.7 &gt;3h aOR 2.0 Multip Ref &lt;30’ 30-60’ aOR 2.2 1-2h aOR 2.9 &gt;2h aOR 5.4</td>
<td>Ref &lt;2500 Primip 4000-4499 aOR 5.9 ≥4500 aOR 10.5 Multip 4000-4499 aOR 9.2 ≥4500 aOR 13.6</td>
</tr>
<tr>
<td>Baghestan, 2010 Norway N=1 673 442 (68)</td>
<td>Ref Multip Nullip: aOR 4.8</td>
<td>Ref 25-29 y 20-24 aOR 0.8 30-34 aOR 1.2 &gt;35 aOR 1.3</td>
<td>aOR 2.0 6.0%</td>
<td>aOR 3.9 8.1%</td>
<td>No data</td>
<td>Ref 3000-3499 2500-2999 aOR 0.5 4000-4499 aOR 2.7 4500-4999 aOR 4.2 &gt;5000 aOR 5.9</td>
</tr>
<tr>
<td>Parity Maternal age</td>
<td>Vacuum extraction</td>
<td>Forceps</td>
<td>Prolonged second stage</td>
<td>Birth weight/ macrosomia</td>
<td></td>
<td></td>
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<td>------------------------</td>
<td>-------------------------</td>
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<td></td>
</tr>
<tr>
<td>Räisänen, 2009 Finland N=514 714 (86)</td>
<td>6-fold: Nullip 1.07% Multi 0.18%</td>
<td>Ref&lt;19 Primip: aOR 3.9 Multi: aOR 4.2</td>
<td>Primip: aOR 10.2 Multi: aOR 10.1</td>
<td>Ref≤15’ &gt;60’ Primip aOR 2.06 Multi aOR 7.2</td>
<td>Ref≤3000 Primip ≥4000 aOR 4.66 Multi &gt;4000 aOR 5.84</td>
<td></td>
</tr>
<tr>
<td>Dandolu, 2005 N=258 507 USA (103)</td>
<td>No data</td>
<td>No data</td>
<td>15.3% OR 2.58</td>
<td>20.3% OR 3.84</td>
<td>No data</td>
<td></td>
</tr>
<tr>
<td>Sheiner, 2003 Israel N=98 524 (88)</td>
<td>NS</td>
<td>NS</td>
<td>aOR 8.2</td>
<td>aOR 26.7</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>deLeeuw, 2001 Netherlands N=284 783 (89)</td>
<td>Ref Multi Primip aOR 2.39</td>
<td>No data</td>
<td>3.0% aOR 1.68</td>
<td>4.65% aOR 3.53</td>
<td>OR 1.12 per increased 15’</td>
<td></td>
</tr>
<tr>
<td>Handa, 2001 USA N=2 101 843 (65)</td>
<td>Ref Primip Multi aOR 0.15</td>
<td>Ref 18-35 &gt;35 aOR 1.09 &lt;18 aOR 0.81</td>
<td>15.5% aOR 2.3</td>
<td>16% aOR 1.45</td>
<td>No data</td>
<td></td>
</tr>
</tbody>
</table>

NS=non-significant
1.6 Prevention of obstetric anal sphincter injuries (OASIS)

Obstetric anal sphincter injury is a patient safety and quality indicator in OECD countries, including an assumption that OASIS incidence can be reduced (61).

Preventing OASIS and reducing the OASIS incidence presumably reduces the occurrence of AI after delivery. Many maternal and fetal characteristics such as parity, age, BMI, birth weight and are non-modifiable and cannot be changed at the moment of delivery. The management of second stage of delivery is modifiable, and performance of many obstetrical procedures can be optimized.

Few studies have described how modifying and improving delivery procedures can notably reduce the incidence of OASIS (64,105-107). These studies have described several actions that have contributed to the reduced OASIS rate:

- Improved manual delivering techniques using two hands:
  - Protecting the perineum with one hand
  - Slowing the delivery of the baby’s head with the other hand
- Coaching the mother not to push when the baby’s head is crowning
- Choosing a maternal birth position allowing the accoucheur to visualize the perineum
- Choosing vacuum instead of forceps when instrumental delivery is indicated
- Improved episiotomy technique avoiding midline cuts

1.6.1 Manual perineal protection

Manual perineal protection is not documented in medical records or medical birth registries, and therefore difficult to investigate on a large population-based scale. Uniform definition for perineal protection is lacking, and therefore understanding of manual perineal protection methodology varies between birth attendants. Perineal protection could for some accoucheurs mean using one hand on the baby’s head to slower the delivery of the head, others would understand perineal protection as only touching the perineum, and others would interpretate the technique to involve the use of both hands.
Different perineal protection routines seem to result in different OASIS risk. A study comparing two delivery units in Finland and Sweden revealed a fivefold difference in OASIS incidence, lower in the unit with routine use of manual perineal protection (108).

Also perineal protection education for the delivery unit personnel seems to reduce the OASIS risk significantly. Two reports from the Norwegian national campaign for reduction of OASIS occurrence has been published, including 5 hospitals with 40-70% reduction of OASIS risk after implementing perineal protection procedures (64,105). In an observational study from Sweden lacking perineal protection was a risk factor for OASIS (109). In the study of Parnell et al. several manual techniques during second stage of delivery were assessed, and “easing the perineum” was associated with reduced risk of OASIS. What “easing the perineum” includes in practice, was not explained or defined in the paper (110).

It seems that manual perineal protection is to some extent forgotten or abandoned in many countries today. For instance, a survey of midwives in the UK revealed that more than half of the English midwives prefer “hands-off” delivering techniques, even in cases of a high risk woman with previous OASIS, or a nulliparous woman with a large baby (111).

Few randomized controlled trials are published on perineal protection, and only one of them had OASIS as primary outcome. In this study, Ritgen’s maneuver was compared to “standard care” and no difference in OASIS risk was observed between the groups. It is important to emphasize, that in this trial the “hands-off” delivering technique was not tested (112). In the other three published studies the outcomes were postpartum experienced perineal pain or perineal trauma in general, including all degrees (1-4) and not only OASIS (113-115). Three of the trials included all parity groups. All four trials were underpowered to investigate OASIS. Results of these studies are often misinterpreted, and especially the HOOP study (113) is referred to when hands-off delivering techniques are promoted. The HOOP-study did however never conclude that “hands-off” delivery method is recommended as routine or acceptable delivery method (116,117).
1.6.2 Episiotomy

An episiotomy, also called perineotomy, is defined as a cut of the perineum aimed to protect the delivering woman from anal sphincter injury, or to shorten the last phase of second stage of delivery to protect the infant. When performing an episiotomy correctly, the bulbospongiousus and superficial transverse perineal muscles are cut.

Different episiotomy techniques can be used, the main types are defined as mediolateral, lateral and median episiotomy (118). The difference between these techniques is the starting point and the angle of the cut (Figure 3). Unfortunately, clinicians and even textbooks use the terms of episiotomy types inconsequently, lateral episiotomy cuts are sometimes called mediolateral (118,119,119,120) and clinicians’ understanding of the definitions varies widely (119).

Midline episiotomy seems to increase the risk of OASIS (103,121,122). This is not surprising, as the direct cut downwards from the posterior fourchette more easily extends to the anal sphincter than the oblique mediolateral and lateral cuts directed away from the anus (121). Median episiotomy has been the method of choice in North America while mediolateral and lateral techniques have been used in Europe (71,86,120,123,124). Hence, episiotomy studies conducted on different continents are not necessarily comparable. Large European register studies indicate a protecting effect of mediolateral and lateral episiotomy, especially among nulliparous women and when an instrumental delivery is performed (71,86,89,124,125). The suture angle of a mediolateral episiotomy after delivery is 15-20 degrees smaller than the cutting angle, due to the distension of perineum when the baby’s head is crowning (126,127). The episiotomy cutting-angle should be large enough to achieve a protecting effect of the mediolateral episiotomy (127-131). Mediolateral episiotomies are sometimes unintentionally performed as lateral (119,120,132), or median with a too narrow cutting angle (128,129,132).

The use of episiotomy has been reduced markedly during the last decades, from 60% in 1979 to 24% in 2004 in the U.S. and from 20% to 7% in some Scandinavian countries (62,133). Episiotomy is a surgical procedure where the cut needs to be sutured, with potential for complications (bleeding, infections), and should therefore only be used when indicated, and not routinely (123,134).
The conclusion is confirmed in a Cochrane review, based on randomized controlled trials comparing restrictive and routine use of mediolateral episiotomy (134-139) or midline episiotomy (140,141). The frequencies of restrictive episiotomy (8 to 57%) and routine episiotomy (47 to 100%) overlap and vary strongly between these studies (Table 3), making it difficult to compare the results. It is important to note that none of these trials tried to compare effect of episiotomy with no episiotomy; only selective use by indication was compared to routine use of episiotomy (142). All these trials were underpowered to assess OASIS, most of them with very low number of participants (123).

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Restrictive vs routine use %</th>
<th>Number per study arm</th>
<th>OASIS %</th>
<th>Parity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mediolateral episiotomy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Murphy, 2008, Ireland (143)</td>
<td>All 52 vs 93 vac 17 vs 88 forc 64 vs 95</td>
<td>101 vs 99</td>
<td>10.9 vs 8.1</td>
<td>Nulli oper deliv</td>
</tr>
<tr>
<td>Dannecker, 2004, Germany (144)</td>
<td>41 vs 77</td>
<td>49 vs 60</td>
<td>2 vs 5</td>
<td>Nulli</td>
</tr>
<tr>
<td>Eltorkey, 1994, Saudi-Arabia (138)</td>
<td>53 vs 83</td>
<td>100 vs 100</td>
<td>0 vs 0</td>
<td>Prim</td>
</tr>
<tr>
<td>Belizan, 1993, Argentina (135)</td>
<td>30.1 vs 82.6</td>
<td>778 vs 777</td>
<td>1.2 vs 1.5</td>
<td>Both</td>
</tr>
<tr>
<td>House, 1986, UK (139)</td>
<td>Prim 32 vs 79 Multi 22 vs 43</td>
<td>94 vs 71</td>
<td>Prim 0 vs 4 Multi 0 vs 4</td>
<td>Both</td>
</tr>
<tr>
<td>Sleep, 1984, UK (137)</td>
<td>10 vs 51</td>
<td>498 vs 502</td>
<td>0.2 vs 0.2</td>
<td>Both</td>
</tr>
<tr>
<td>Harrison, 1984, Ireland (136)</td>
<td>8 vs 89</td>
<td>89 vs 92</td>
<td>0 vs 6</td>
<td>Nulli</td>
</tr>
<tr>
<td><strong>Median episiotomy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rodriguez, 2008, Colombia (141)</td>
<td>24 vs 100</td>
<td>222 vs 223</td>
<td>6.8 vs 14.3</td>
<td>Nulli</td>
</tr>
<tr>
<td>Klein, 1992, Canada (140)</td>
<td>Prim 57 vs 81 Multi 31 vs 47</td>
<td>353 vs 350</td>
<td>Prim 13.3 vs 12.5 Multi 0</td>
<td>Both</td>
</tr>
<tr>
<td><strong>Comparison of median and mediolateral episiotomy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coats, 1980, UK (121)</td>
<td>163 vs 244</td>
<td>11.6 vs 2%</td>
<td>Prim</td>
<td></td>
</tr>
</tbody>
</table>

Interestingly, a 50% reduction of OASIS incidence was reported when episiotomy use was increased from 12% to 20% in a single delivery unit during a 5
year period in Australia (145). An Israeli study showed an increased OASIS incidence after a markedly reduced episiotomy rate in a delivery unit (146). Räisänen et al. described large OASIS incidence differences between delivery units and a higher episiotomy rate on a delivery unit seemed to protect against OASIS (71). These observations can indicate that when episiotomy use is reduced, the episiotomy rate can become too low. The study may also indicate that there may be several differences in clinical management of second stage of labor between delivery units, including differences in awareness on perineal protection, or differences in the clinical experience of the birth attendants regarding performance of perineal protecting interventions.

Figure 3.

Episiotomy types:
1: median
2: mediolateral
3: lateral

1.6.3 Maternal birth position

Birth position is not usually registered in medical records or birth registries, and therefore difficult to assess in large register studies. Birth position is also difficult to investigate, as the duration of second stage of delivery can last quite a long time, and many women change their position several times during this stage. The woman’s
need for alteration of birth position can make it difficult to register one exact birth position at second stage of labor, and this also challenges randomized controlled trials investigating delivery positions.

A Cochrane review did not show any difference in OASIS incidence when upright birthing position was compared to non-upright positions (147). In these studies, “upright” positions included very heterogenic body positions, such as standing, kneeling, squatting and “all-fours”, and these positions were compared to lithotomy and recumbent positions (“non-upright” positions). The authors of this Cochrane review comment that the included studies were of poor quality and therefore the results should be interpreted cautiously. Due to the uncertainty of the effect of birth position on maternal health and delivery complications, conclusion from this Cochrane review was that women should be encouraged to find the most comfortable birthing position.

Gåreberg et al. analyzed birth positions and found a four-fold increased incidence of OASIS in standing compared to sitting birth position. The authors concluded that midwife’s ability to visualize perineum was difficult when the delivering woman was standing, and therefore this might contribute to increased OASIS risk (148). Additionally, when a woman delivers in a standing or squatting position, she can probably push harder than if in the lithotomy or lateral position. An accelerated force due to more rapid delivery of the presenting fetal part is likely to cause more damage to the perineal tissues, and thereby increase the risk of OASIS.

It is reasonable to argue that the birth attendant must be able to reach the woman’s perineum in order to perform an adequate manual perineal protection and to slower the delivery of the baby’s head. Therefore, a birthing position allowing sufficient perineum overview and access may be more important in preventing OASIS than the birth position per se (64,105,108,109).

### 1.6.4 Perineal massage and warm packs

In a randomized controlled study from Australia, including only nulliparous women, use of warm packs on perineum was compared to standard care during the end of second stage of labor. The authors found a 50% reduced OASIS incidence in the
intervention group (4.2% vs 8.7%) (149), however, the study was underpowered to assess OASIS with only 717 randomized participants. In addition, the duration of the warm pack intervention of 5-11 minutes seems too short to give a plausible biological mechanistic explanation for such an OASIS reducing effect, unless use of warm package also included some sort of manual perineal protection.

In a study from the US, 1211 women, including all parity groups, were randomized to three study groups with three different methods; warm compresses on perineum, or perineal massage with lubricant performed by midwife or not touching the perineum before baby’s head was crowning. This study could not show any difference in OASIS incidence between the randomized groups (115). However, also this study was underpowered to assess OASIS, as the primary outcome was not OASIS, but perineal trauma in general. OASIS incidences in these two studies were very different, in the Australian study the intervention group 4.2% and standard care 8.7%, while in the US study only 1.2% (both study arms), which makes the studies difficult to compare.

Another Cochrane review based on four randomized controlled trials concluded that perineal massage during pregnancy performed by the woman or her partner reduced the use of episiotomy in deliveries of nulliparous women, but not the incidence of OASIS or other perineal trauma (first and second degree tears) (150).

1.6.5 Predicting OASIS
Attempts to create risk-scoring systems to predict OASIS antenatally have not been successful (151-153). A risk calculator can provide an OASIS risk in percent, but the utilization in a clinical situation is limited (94). OASIS is an infrequent event, affecting some few percent of delivering women, and predicting with antenatal measurable factors to select the individuals who are going to suffer from OASIS remains imprecise. As an example: although fetal macrosomia is a risk factor for OASIS; most of the OASIS will occur in women delivering an infant with normal weight.
1.7 Complaints after obstetric anal sphincter injuries (OASIS)

The most important complaint associated with OASIS is anal incontinence, which is thoroughly presented in section 1 in this thesis. Other complaints after OASIS are less studied and more research is needed in this field.

1.7.1 Perineal pain after OASIS

Few studies have assessed postpartum pain and discomfort among women with OASIS compared to women without OASIS. In a randomized controlled trial, postpartum perineal pain was more frequent among women with OASIS compared to women without OASIS, when compared to women with intact perineum, second degree tear or episiotomy. In this RCT, women with OASIS reported more perineal pain 1-10 days and 3 months after delivery than women without OASIS (154). Similar results was reported in the studies of Andrews et al. and Macarthur et al., women with OASIS reported more perineal pain than women with episiotomy, second and first degree tears or intact perineum 2-3 months after delivery (155,156).

1.7.2 Sexual dysfunction after OASIS

Women with OASIS report more dyspareunia than women without OASIS (4,5,154,157). Women with OASIS delayed starting sexual activity after delivery compared to women without OASIS (154,158,159), and still after 1 year, women with OASIS were less sexually active than women without OASIS (160). Dyspareunia was markedly more frequent among women with previous OASIS than in the control group without OASIS (29% as compared to 13%), in the study of Mous et al., even 15 years after delivery (4). Anal incontinence during sexual intercourse was reported by 13-17% of the women with OASIS (4,51) and among 1% of the controls (4).

1.7.3 Delivery method after previous obstetric anal sphincter injury

As presented in the section 1.5, the risk of a new OASIS is increased in the subsequent delivery for women with a previous OASIS, as compared to women without a previous OASIS (96-98). A high percentage of women with a previous
OASIS are delivered by caesarean in the next pregnancy (49%) (161). Some studies indicate that women after OASIS wish to postpone the following childbirth, however, they seem to have same number of subsequent pregnancies (161). Although the risk of recurrent OASIS is increased after previous delivery with OASIS, a recurrent OASIS is an infrequent event. Therefore large studies of anal incontinence risk after a recurrent injury are lacking (161,162). Subsequent vaginal deliveries without a new OASIS may also increase the risk of anal incontinence, especially among women with defects in the anal sphincter, or symptoms of anal incontinence after first delivery (25,163-165). In the study of Sangalli et al. women with a fourth degree tear had increased prevalence of anal incontinence, while women with third degree tear did not develop more symptoms after a subsequent vaginal delivery (166). As the recurrence risk for OASIS is markedly elevated if the baby is large, the counseling following an OASIS delivery should take into account estimated birth weight. Therefore, women with previous OASIS should be offered antenatal counseling and careful planning of the delivery during pregnancy. Women with a normal functioning anal sphincter after OASIS; with no symptoms of anal incontinence, seem to not at increased risk for deteriorating symptoms of anal incontinence if delivering vaginally in a next pregnancy (162).

1.8 Treatment and long term prognosis of anal incontinence

Treatment of anal incontinence is challenging, and no superior method with good long-term results can be pointed out. In the treatment of anal incontinence, 50% reduction of incontinence episodes is considered as a successful treatment in most studies. Secondary surgical treatment of anal sphincter injury has relatively poor results, and thus, non-surgical treatment is the first choice in attempt to help the patient with anal incontinence.

Non-operative treatment of anal incontinence

Lifestyle change is a part of the non-surgical, conservative management of anal incontinence. Regular bowel habits may help the incontinent patient to participate in social and non-domestic activities. Dietary counseling includes instructions of fiber
intake to form stools, to avoid diarrhea and achieve predictable bowel movements and complete emptying of the rectum (44,49). Adequate pelvic floor muscle training instructed by a physiotherapist can improve continence by strengthening the pelvic floor muscles. Biofeedback can improve the control over pelvic floor muscles (44,49). All these methods can slightly help against the anal incontinence symptoms, but most often they do not provide total healing and long term results are poor.

**Operative treatment of anal incontinence**

Sacral nerve stimulation (neuromodulator) with a subcutaneous stimulator is a suitable treatment for anal incontinence in selected patient groups. More than 50% reduction in anal incontinence episodes was reported by 80-90% of the patients at 3-5 years follow-up, and 30-40% reported complete anal continence, but longer follow-up studies are lacking. The patients reported also increased quality of life (167,168). Anal sphincter defect was a negative predictive factor and may indicate lower effect of this treatment (169).

Perianal bulking injections with different injectable biomaterials (collagen, silicon, autologous fat) are surgical treatment alternatives that may help patients with moderate soiling symptoms and not severe anal incontinence (44). Long-term follow-up studies of these novel methods are lacking (170).

Secondary surgical repair of a defect anal sphincter is challenging. A retracted sphincter ani muscle can be shortened and atrophic after not being used for a substantial time. Long-term results of secondary sphincteroplasty are disappointing, as follow-up studies show that continence deteriorates and the majority of the treated women were incontinent after 5-10 years (171,172). Anal sphincter device and muscle transplantation are alternatives that have been tried out, but the results are not promising (44,49).

Few patients with anal incontinence can achieve complete anal continence with the existing treatments, except by colostomy, which is indicated and used in the most severe cases of anal incontinence.
Degree of OASIS and anal incontinence

Larger sphincter damage increases the risk of anal incontinence 2-10-fold (22,27,75,173), and women with larger anal sphincter injury more often have ultrasound detectable defects in the sphincter muscles (75,78,174).

Long-term prognosis

Longitudinal follow-up studies show that anal incontinence after delivery often persists and many studies conclude that the anal function after OASIS deteriorate with time (4,7,25). Women with a history of OASIS have persistent and more frequent anal incontinence than women without OASIS (26,27,175-177). However, some few women report resolving of symptoms, while some women develop de novo symptoms over time (4,175,178).

Despite the fact that studies on anal incontinence are heterogeneous and difficult to compare, the main and consistent message is that anal sphincter injury is the most important risk factor for female anal, fecal and flatal incontinence, with negative effects on women’s quality of life. Secondary treatment of such injuries and associated anal incontinence symptoms is challenging and the long term prognosis is poor. Therefore, primary prevention of OASIS seems to be the crucial effort to reduce anal incontinence problems, thereby improving female health and quality of life.
2 AIMS OF THE THESIS

The main aims of this thesis were to assess

- the prevalence of female anal incontinence in a non-selected pregnant population and among women one year after delivery complicated with obstetrical anal injuries (OASIS)
- the reduction of incidence of OASIS after re-introduction of perineal protection techniques.

Specifically, we aimed to assess

1. the prevalence of anal incontinence in an unselected pregnant female population
2. the risk factors for anal incontinence in a female population of fertile age
3. the prevalence of anal incontinence among women with OASIS
4. the incidence of OASIS before and after implementation of improved perineal protection methods in a delivery unit
5. the incidence of OASIS in subgroups of women defined by risk factors
6. the risk factors for OASIS before and after reduced OASIS incidence in a delivery unit
7. the OASIS incidence in Nordic countries across the last decades.
3 MATERIALS AND METHODS

3.1 Data and population

The data in paper 1 were collected from questionnaires and consisted of self-reported information from the survey of the pregnant participants. Data were obtained from the medical birth registries in Paper 3 and from the Oslo University Hospital obstetrical database and patients’ individual medical records in paper 2 and 4.

Summary of study populations:

<table>
<thead>
<tr>
<th>Main study outcome</th>
<th>Population</th>
<th>Source</th>
<th>Design</th>
<th>Study period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper 1 Anal incontinence</td>
<td>2 846 pregnant women</td>
<td>Questionnaire</td>
<td>Survey</td>
<td>August 2009-August 2010</td>
</tr>
<tr>
<td>Paper 2 Anal incontinence</td>
<td>591 women with OASIS</td>
<td>Hospital obstetrical database, individual medical records</td>
<td>Retrospective clinical observational study</td>
<td>2003-05</td>
</tr>
<tr>
<td>Paper 3 OASIS incidence</td>
<td>574 175 deliveries</td>
<td>Medical Birth Registries</td>
<td>Retrospective register study</td>
<td>2004 and 2010</td>
</tr>
<tr>
<td>Paper 4 OASIS incidence</td>
<td>31 709 vaginal deliveries</td>
<td>Hospital obstetrical database, individual medical records</td>
<td>Retrospective cohort study</td>
<td>2003-05 2008-10</td>
</tr>
</tbody>
</table>

Outcomes and independent variables

Main outcomes in this thesis were incidence of obstetric anal sphincter injuries and prevalence of anal incontinence.

Independent variables included

- Maternal characteristics
  - Parity
  - Age
  - Weight, height, BMI
  - Western or non-western origin
Co-morbidity
Medication use
Marital status
Educational level
Household annual income
Non-domestic working activity
Degree of OASIS
Type of defect in anal sphincter muscle

- Fetal characteristics
  - Birth weight
  - Head circumference
  - Apgar scores
  - Fetal head presentation
  - Shoulder dystocia

- Obstetrical procedures
  - Delivery mode
  - Epidural use
  - Episiotomy
  - Duration of second stage of labor
  - Induction of labor

3.2 Definitions

Obstetric anal sphincter injuries (OASIS)
Third and fourth degree tears were analyzed together as OASIS in Papers 1, 3 and 4. In Paper 2 third and fourth degree perineal tears were analyzed separately, to assess the effect of a larger injury on prevalence and severity of anal incontinence.

Parity - nulliparity, primiparity and multiparity
Pregnant women who have never delivered before are named nulliparous, and after their first delivery they become “primiparous”. In Paper 1 women are assessed while they are pregnant and named “nulliparous” if it was their first pregnancy. In Paper 2,
3 and 4 women are named “primiparous”, because their characteristics are explored after this index delivery. Parity was adjusted according to history of caesarean section and women who have been delivered with caesarean only, are named “vaginal primiparous” in this thesis. Women with one or several previous vaginal deliveries before the studied index delivery are in this thesis named “parous” or “multiparous”, after having delivered at least one child.

Medical birth registries
The national birth registries in the four studied Nordic countries include information of all deliveries collected by a mandatory notification from all hospitals, delivery units as well as home deliveries. These birth registries include numerous details of maternal, fetal and obstetrical factors related to maternal health before and during pregnancy, fetal health and size, and interventions and complications during delivery providing a database to a broad spectrum of issues. The Nordic medical birth registries are evaluated to be of good quality (179,180) and suitable for research, and a large number of studies are published based on these registries. The Danish, Finnish and Swedish medical births registries present a quality declaration on their respective web sites. The birth registries are based on data collected and registered in obstetrical databases located in the delivery units/hospitals.

Paper 1 and Paper 2
Papers 1 and 2 assess the prevalence of anal incontinence in two different female populations. Prevalence and severity of anal incontinence was assessed with St. Mark’s score in both studies. In Paper 1 pregnant women completed the questionnaire with items of incontinence themselves, as in Paper 2 the information concerning anal incontinence was collected by interview performed by a gynecologist during a postpartum outpatient appointment.
Prevalence of anal incontinence during pregnancy

The study in Paper 1 was a survey of pregnant women attending routine ultrasound examination at second trimester. The questionnaire included items of incontinence, co-morbidity and medication use.

The invitation to participate in our study, including the questionnaire and informed consent, was posted with the invitation to the routine ultrasound appointment. From the 7,256 women who were posted a questionnaire, 973 women were not found in our postpartum labor ward database; they may have experienced early pregnancy loss after the invitation was posted, and did not achieve 18 weeks pregnancy or they did not deliver in our hospital, or moved out of the Oslo area or from Norway. Thus, 6,283 women were eligible for study participation. Five of the 2,851 returned questionnaires were excluded; four women returned two questionnaires (twice during the same pregnancy), and one woman returned the questionnaire after the index delivery. After the exclusion the response rate was 45%, and the study group consisted of 2,846 (of 6,283 invited) women.

The questionnaire items were assembled from different validated questionnaires:

- St. Mark’s (10)
- NUGG (181)
- Due (182)
- HUNT-study (183)
- Cambridge worry scale (184,185)

In addition to demographic data, the questionnaire included items for country of origin for the participant, educational level and household income, obstetrical history, symptoms of anal incontinence or urinary incontinence and worries during pregnancy.

Anal incontinence after OASIS

The study was a retrospective clinical observational study. The information concerning anal incontinence was collected during a postpartum outpatient appointment one year after delivery complicated with OASIS.
Women with OASIS during delivery in years 2003-2005 were identified from the labor ward database and checked with the hospital discharge register, and 13 cases of OASIS not registered with OASIS in the labor ward protocol were found. The individual medical records were controlled carefully by reading the surgical reports to verify correct OASIS diagnoses and degree of the tear. The medical records revealed that 22 cases were incorrectly registered as OASIS (false positives) and were excluded from the analyses. After these corrections the study population consisted of 591 women with OASIS.

All patients with OASIS were invited to a one-year clinical follow-up. Clinical information about endoanal ultrasound examination, anal- and urinary incontinence at one year postpartum outpatient follow-up was collected from the individual patient records.

St. Marks’s incontinence score was used to evaluate the severity of anal incontinence. If the St. Mark’s form was not filled out during the one-year follow-up consultation, it was filled out by the PhD student and co-workers by retrieving the information from the medical records. When some of the items in St. Mark’s were not mentioned in the records from the consultation, this variable was registered as a 0 score.

**Paper 3 and Paper 4**

Papers 3 and 4 assess changes of OASIS incidence in four Nordic countries, in different delivery units and specifically in one large university hospital in Oslo.

**OASIS incidence in the four Nordic countries**

The study in Paper 3 was a retrospective register study based on medical birth registries in four Nordic countries.

Data on OASIS incidence were obtained from medical birth registries in Denmark, Finland, Norway and Sweden across the time periods the registries have existed in respective countries. The Norwegian Birth Registry is the oldest of these four registries, and presents delivery data from 1968 (186). The Finnish OASIS data were collected to the Finnish Hospital Discharge Register in 1987-2003 and from
2004 to the Finnish Medical Birth Register (187), but were now available in the birth register. The available time period that included OASIS information in the Medical Birth Register database in Denmark was 1997-2010, and Sweden 1973-2010 (188,189).

The OASIS incidences across the decades were presented from the four countries. Highest and lowest OASIS incidences from individual delivery units in respective countries were also presented to illustrate the differences between delivery units in the four countries.

The main maternal and fetal characteristics and obstetrical interventions from the years 2004 and 2010 from all deliveries (574,175) registered in Denmark, Finland, Norway and Sweden were presented to describe the study population. Most of the collected data was freely available online, and lacking data (episiotomy rates in Sweden) were received from the register after request.

Reduced incidence of OASIS in a university hospital

The study in Paper 4 was conducted as a retrospective cohort study. Two cohorts of delivering women during in two time periods (years 2003-2005 and 2008-2010) were studied. After exclusion of caesarean sections and preterm deliveries (< week 32) the study population consisted of 31,709 vaginal deliveries. Obstetrical anal sphincter injury was registered for 907 women during this time period in the study population. The two cohorts represent time periods before and after implementing of an intervention program to improve manual perineal protection techniques during delivery. The study population was stratified according to parity and the incidence of OASIS during the two periods was compared.

3.3 Statistics

Continuous data were dichotomized or categorized and the independent variables are presented as frequencies and means, where appropriate. Chi square test was used in all studies. Univariate and multivariate regression analyses were used in Papers 1, 2 and 4. Univariate analyses were performed by Chi-squared test. Adjusted odds ratio (aOR) with 95% CI is reported from the logistic regression analysis. A p-value of <
0.05 was chosen as level of statistical significance in all analyses but to secure that no confounding factors are missed, also variables with close to this value were tested (p <0.1).

Among the variables with obvious biological correlation to each other, such as infant birth weight and head circumference, or fetal weight and pregnancy duration, only one of them was kept in the final model, to avoid unnecessary adjustment (190). Variables with large proportion of missing values were excluded from the analyses. Stratified analyses were performed according to parity in Papers 1 and 4. Episiotomy use was analyzed separately in different delivery methods in Paper 4.

Statistical analyses were performed using SPSS (Statistical Program of Social Sciences, version 16.0, Chicago, IL) and PASW (Predictive Analytics SoftWare, SPSS Inc., version 19.0, Chicago, IL).

### 3.4 Ethical considerations

The “Perineum study” (including several studies) was evaluated and accepted by the Regional Committee for Medical Research Ethics in South-Eastern Norway (REK) in 2009 (ref S-08810d/20941). The study followed the Helsinki declaration and the Norwegian Health Research legislation and was approved by the institutional Personal Data Officer. Informed consent was obtained from the women participating in the study presented in Paper 1. No patient consent was necessary in the two retrospective studies in Paper 2 and 4. Paper 3 included only anonymous and aggregated data from publicly available Medical Birth Registries and no ethical committee consent was needed. Studies 2 and 4 were evaluated both by the regional ethical committee and the Oslo University Hospital as internal clinical quality control studies with no personal data violation and with possibility to present aggregated anonymous data.
4 SUMMARY OF RESULTS

4.1 Paper 1

Prevalence and risk indicators for anal incontinence among pregnant women

Prevalence of self-reported anal incontinence (defined as St. Mark’s score 3 or more) in the entire study group was 8.4% (238/2846). Most of the women (80.3%) reported complete anal continence (2268/2846) with St. Mark’s score 0, and 11.3% (322/2846) women reported St. Mark’s score 1 or 2.

Inability to control flatus was the most frequent complaint, reported by 18.0% (513/2846). Of these, 385 women reported episodes of flatus incontinence without fecal incontinence. Fecal incontinence was reported by 6.0% (171/2846) and fecal urgency by 3.2% (90/2846) of the women.

Prevalence of anal incontinence increased with increasing vaginal parity, and with a history of OASIS. Therefore, women with different parity were analyzed separately (stratified).

Nulliparous women

Of the nulliparous women, 7.8% (139/1792) reported anal incontinence. In the multivariate analysis, low educational level, dermatological disease and rheumatoid arthritis were significant factors for anal incontinence.

Parous women

Overall anal incontinence among parous women was 9.8% (90/914). In the group of women with one previous vaginal delivery, 8.5% (61/714) reported anal incontinence, whereas the group of women with more than one previous vaginal delivery, as many as 14.5% (29/200) reported anal incontinence.

When the women with previous OASIS were excluded from the analysis, 7.8% (53/681) women with one previous vaginal delivery reported anal incontinence, and of the women with at least two vaginal deliveries, 14.1% (27/192) reported anal incontinence.

Of the parous women, 15.9 % had previously delivered at least one
macrosomic (>4000g) infant (145/914), 156 reported previous delivery with vacuum extraction and 24 women reported a previous forceps delivery. An obstetric history with instrumental delivery or a macrosomic infant was not associated with anal incontinence. Previous delivery with OASIS was reported by 41 women (4.5%), and was strongly associated with anal incontinence.

In the multivariate analysis, previous delivery complicated with OASIS and dermatological disease were significant risk factors for anal incontinence. The risk of anal incontinence was threefold among women with previous OASIS compared to women without (24.4% and 8.1%, respectively). The higher risk of anal incontinence associated with previous OASIS remained threefold in the more severe forms of anal incontinence, if defining anal incontinence as self-reported St. Mark’s score of 5 or above (12.2% and 3.8%) or 7 or above (7.3% and 2.3%).

**Women with previous cesarean only**
The subgroup of parous women with previous cesarean only (n=140), and no vaginal deliveries, was analyzed separately. In this subgroup the prevalence of anal incontinence was lowest (6.4%, 9/140) compared with all other parity groups, but was too small to further analysis of risk factors. When the analyses were repeated with this subgroup of women added to the subgroup of nulliparous women, the conclusions remained unaltered.

**Women with dermatological disease**
Women who reported having a dermatological disease reported also more anal incontinence than women without this disease. There was a significant association between dermatological disease and several other complaints; allergy, migraine and headache, constipation and psychological problems. Women who reported dermatological problems also more frequently reported use of vitamins, allergy medication, and stomach and bowel regulators. These women also reported more worries on the Cambridge worry scale than the women without dermatological problems.
4.2 Paper 2

Prevalence and risk factors for anal incontinence after obstetric anal sphincter rupture

In this study we assessed the prevalence and risk factors for anal incontinence first year after a delivery complicated with obstetric anal sphincter injury. All women with a delivery complicated by OASIS were invited to a postpartum follow-up. Prevalence and severity of anal incontinence was measured with St. Mark’s score. Women with St. Mark’s score 0 were defined as complete anal continent, whereas score 3 or above was interpreted as anal incontinence.

The study population:

- Among 18 145 deliveries in 2003-2005, 591 women were identified with OASIS.
- The majority of OASIS were third degree (93%), and 7% of the tears were fourth degree tears
- Of these 591 women, 77% (455) attended the offered postpartum follow-up 10 months after delivery. There were no significant differences in maternal and obstetric risk factors between women who attended and those who did not attend.

Prevalence of anal incontinence:

- Anal incontinence was reported by 38% (171/455) of the women with OASIS; 21% with St. Mark’s score ≥3 and 17 % with score 1-2. The main complaint was the inability to control gas (affecting 33%; 151/455). Fecal incontinence was reported by 6% (26/455) and urgency for defecation by 9% (43/455) of the women.
- Prevalence of anal incontinence among women with fourth degree tear was significantly higher than among women with third degree tear (51.4 % and 18.4 %, respectively, p<0.001).

Defects in the sphincter muscles detected by the endoanal ultrasound examination:
• Endoanal ultrasound examination was performed in 78% (357/455) of the women and a persistent defect in the anal sphincter muscles was found in 33% (118/357).

• 16.5% of the women had a defect in external anal sphincter muscle (EAS) (59/357), an isolated internal anal sphincter muscle (IAS) defect was found in 5.6% (20/357) and 11.5% of the women had defects in both the internal and external anal sphincter muscle (39/357).

• A defect in the IAS (either isolated or combined with EAS) was found at the postpartum control in 39 women who were primarily diagnosed to have a tear in the EAS only.

• A persistent defect in the sphincter muscles was more frequent among women with a fourth degree tear than among women with a third degree tear (83.2% and 28.4%, respectively), a defect in EAS only (23.3 and 15.9 %) or in IAS only (13.3 vs. 4.9%), (p<0.01).

• Almost half of the women with a fourth degree tear had a persisting defect in both EAS and IAS (46.6%) whereas 7.6% of the women with a third degree tear had defect in both muscles (OR 10.5; 95% CI: 4.6-24.1).

• Women with ultrasound detected defects in the anal sphincter muscles reported anal incontinence more frequently than women without diagnosed defects. Prevalence of AI among women with defect in EAS, IAS or both was 30.5%, 35.0% and 64.1%, respectively.

Risk for/risk factors for anal incontinence:

• In univariate analyses, anal incontinence (St. Mark’s score ≥3) was associated with higher maternal age, macrosomia and fourth degree perineal tear, using continent women as reference group (St. Mark’s score 0).

• In multivariate analyses, only fourth degree tear remained significant in prediction of anal incontinence in women with OASIS (OR 5.6, 95% CI: 2.6-12.0).
4.3 Paper 3

Are obstetric anal sphincter ruptures preventable? - Large and consistent rupture rate variations between the Nordic countries and between delivery units in Norway

Large variations of OASIS incidence were observed during the last decades in the four studied Nordic countries. Until year 2004 the OASIS incidence increased constantly in all four countries, however, in Finland markedly lower incidence was observed during the whole study period. After 2004 the OASIS incidence in Norway started a remarkable decline from year to year and was halved by 2010, from 4.2% to 2.3%. This reduction happened after introduction of a national plan for reduction of OASIS incidence, including re-introducing manual perineal protection techniques. In this study the changes in the OASIS incidence in four Nordic countries; Denmark, Finland, Norway and Sweden, over the last years were assessed.

Cesarean rate, mean maternal age, distribution of primiparous women, frequency of instrumental deliveries, mean infant birth weight and proportion of macrosomic newborns was calculated from all deliveries, whereas OASIS and episiotomy rate was calculated from vaginal deliveries only.

Population characteristics in the four Nordic countries during the study period:

- Main maternal characteristics such as mean maternal age and distribution of primiparity were almost similar for the four Nordic countries for these two years.
- Distribution of primiparous women and frequency of macrosomic babies was highest in Sweden, but the differences to other Nordic countries were small.

Differences between the four Nordic countries in use of obstetrical interventions, during the years 2004 to 2010.

- In Norway, the use of instrumental delivery increased by 15.0% (from 8.7% to 10.0%, p< 0.001, of all deliveries).
During the same period, the use of forceps increased in Norway by 34.4% (from 1.28% to 1.72%, p<0.001, all deliveries) and vacuum extraction by 11.2% (from 7.4% to 8.2%, all deliveries, p< 0.001).

In Finland, the use of instrumental delivery increased by 26.1%, from 6.9% to 8.7%.

In Norway, the use of episiotomy increased by 7.3% (from 17.8% to 19.1%, p<0.001).

In Finland, the use of episiotomy was reduced by 25% (from 32% to 24% vaginal deliveries, p< 0.001).

In Denmark, the use of episiotomy decreased by 49.0% (from 9.8% to 5.0%, p< 0.001).

In Sweden, the use of episiotomy was reduced by 28.4% (from 8.1% to 5.8%, p< 0.001).

Episiotomy use was threefold in Finland and Norway compared to Denmark and Sweden where episiotomy was rarely used during the study period.

Of the four Nordic countries, the frequency of instrumental delivery was highest in Norway (10.0%) and lowest in Denmark (7.8%) in 2010.

Denmark had a significantly higher caesarean section rate in 2010 than the other three countries (p<0.001), as well as a higher OASIS incidence.

Incidence of OASIS in the Nordic countries:

- In Norway, the incidence of OASIS was reduced by 48% (from 4.2% to 2.3%, vaginal deliveries, p<0.001) from 2004 to 2010.

- In Finland, the OASIS incidence increased by 43% (from 0.7% to 1.0%, p<0.001).

- In Sweden, a 24% reduction in the incidence of OASIS was observed from 2004 to 2009 (from 4.2% to 3.2%, p<0.001), but the OASIS incidence increased again slightly to 3.6% in 2010 (p<0.001).

- In Denmark, the OASIS incidence increased by 16.7% (from 3.6% to 4.2%, p<0.001)
- Denmark was the Nordic country with the highest OASIS incidence in 2010 (4.2%).

Incidence of OASIS between the delivery units:
- All the presented Norwegian delivery units have reduced the OASIS incidence from 2004 to 2010, p<0.001.
- OASIS incidence was threefold when the units with the highest OASIS incidence were compared to units with the lowest incidence. This difference was shown through all presented study years (2008, 2009 and 2010). This difference in OASIS incidence between the delivery units remained significant over the studied years.
- In Denmark, the OASIS incidence varied from 2.9% to 5.6% between delivery units during the study years, in Finland from 0.1% to 2.1% and in Sweden from 2.0% to 5.7% (only delivery units with more than 1500 annual deliveries were taken into account, data from the national birth registries, respectively).

4.4 Paper 4

Incidence of obstetric anal sphincter injuries after training to protect the perineum: cohort study

In this study the incidence of OASIS was assessed in two time periods, 2003-2005 and 2008-2010 Oslo and a 50% reduction in the OASIS incidence was observed during these years. A training program for improved manual perineal protection techniques was implemented between the study periods.

Population characteristics across the study years:
- Changes in population characteristics between the two time periods were small
- The prevalence of older women (>35 years) was slightly higher in the second period (2008-10)
- Use of vacuum extraction, episiotomy, epidural and induction of labor was more frequent in the second period.
OASIS incidence:

- Overall incidence of anal sphincter injury in vaginal deliveries was significantly reduced by 50%, from 4.0% (591/14787) in the first time period (2003-5) to 1.9% (316/16922) in the second time period (2008-10). The reduction of the incidence of OASIS was of similar magnitude across all studied subgroups of women, defined by risk factors; the reduction was similar in primi- and multiparous women and in spontaneous deliveries and in instrumental deliveries.

- In spontaneous deliveries the OASIS incidence was reduced from 3.1% (409/13037) to 1.5% (215/14711) and in vacuum assisted deliveries from 9.7% (152/1565) to 4.7% (98/2075). Forceps is less used in our department, but a significant OASIS reduction was also observed in forceps deliveries from 16.2% (30/185) to 2.2% (3/136).

Primiparous women

In a multivariate regression analysis, large infant birth weight, instrumental delivery, prolonged second stage and occiput posterior presentation were significant risk factors for OASIS in the first study period. In the second study period, when the incidence of OASIS was reduced, only instrumental delivery and foetal occiput posterior presentation remained significant risk factors for OASIS.

Frequency of episiotomy use in spontaneous deliveries of primiparous women was reduced from the first time period to the second, and increased in instrumental deliveries. When adjusted for risk factors in the multivariate analysis, episiotomy appeared as a protective factor for OASIS in both time periods for primiparous women.

When analyzing the time period solely as an explanatory variable for OASIS, the first time period emerged as one of the most important “risk factors” with high OR for OASIS. Without adjusting for any other variables, OR for OASIS in the logistic regression analysis for the first study period as compared to the second was 2.10 (95% CI 1.76 to 2.40).
Multiparous women

In the multivariate regression analysis, macrosomia and instrumental delivery were significant risk factors for OASIS in the first time period, but not in the second. In the second time period, none of the identified risk factors for OASIS were significant for multiparous women. However, OASIS cases were few (n=53) in this subgroup of women. In the multivariate analysis the effect of episiotomy was non-significant in both time periods. However, multiparous women with episiotomy were very few in this study and interpretation of the results should be undertaken cautiously.

The risk of OASIS was markedly reduced from the first to the second time period and the time period for the delivery was one of the most important “risk factors”; OR for OASIS in the logistic regression analysis for the first time period as compared to the second was 2.31 (95% CI 1.65 to 3.25).

Women with previous cesarean section only

Primiparous women with a previous caesarean section only, and no previous vaginal delivery, had an increased OASIS risk compared to women with no previous delivery OR=2.2 (95% CI 1.6 to 3.1), both in the first time period (11.5% and 5.9%, respectively, p=0.001) and in the second (6.7% and 2.9%, respectively, p=0.001). Also in this subgroup, the OASIS incidence was reduced with 50% after implementation of the perineal protection program. When the various study analyses were performed without this small subgroup of vaginal primiparous women with one previous caesarean only, the study conclusions remained unaltered, as expected due to the small number of women in this subgroup.
5 DISCUSSION

5.1 Methodology

In this thesis, retrospective observational design and a patient survey were used as methods for studying the main aims. Randomized controlled trial (RCT) is considered as superior to observational methodology to evaluate the effect of an intervention, such as perineum support on OASIS. However, an RCT may not be possible to perform when studying effects of isolated interventions in an obstetric population, mainly due to the clinical population heterogeneity and complexity of the delivery situation. Patient recruitment to an RCT is time consuming and resource demanding. In order to create homogenous study arms, many patients must be excluded. Therefore the participants in randomized trials are often healthier and have fewer risk factors for the studied outcome than the general population one wishes to study, which makes the results less generalizable. The paradox may be that the “healthiest” patients often are participants in trials testing treatment for the more seriously ill patients. An RCT is suitable in comparing the effect of clearly defined interventions, such as different surgical methods or medication. During surgery, the patients are either in general anesthesia or given analgesia, they are immobilized and not making/having wishes how the operation should be performed. In contrast, delivering women are healthy and a labor is not surgery, women have plans and wishes as how to deliver and are moving/changing position during the many hours a delivery takes. Also, at the moment of birth it is not easy to restrict or control all potential affecting factors in order only investigate one variable, such as birth position or pushing methods.

Despite a careful planning of a randomized controlled trial, the (medical) staff might not be able to follow the allocation arm, but may continue using methods as they are used to. Non-compliance of the personnel is known challenge in medical research, also in obstetrics (191,192). In a trial of Klein et al, some physicians were not able to restrict episiotomy use at all, although the study aim was to compare restrictive episiotomy use with routine use (140,154,193). In another randomized trial nulliparous women were allocated to routine or restrictive episiotomy use during
operative vaginal delivery. Episiotomy rate in the restrictive use group varied largely between delivery methods; of the women delivered with vacuum extraction, 17% had an episiotomy, in forceps deliveries 64% of women had episiotomy (143). This difference also indicates that clinicians evaluate the clinical need of episiotomy and use it on high risk patients. Women with episiotomy and women without episiotomy are therefore not comparable due to their very different OASIS risk profile. Such biased studies may therefore lead to the potential erroneous conclusion that episiotomy per se mediates higher risk for OASIS.

Due to the challenges and limitations related to randomized controlled trials in obstetrics, observational studies are often used to acquire knowledge. Observational studies may even be more suitable in obstetrical research; with large unselected population more reliable, generalizable and robust information is obtained to assess outcomes as OASIS with multiple risk factors. In large observational studies based on for example birth registries including all deliveries, selection bias can be avoided, when both low- and high risk patients are included, and different risk groups can be analyzed separately. A study with a too low number of participants is in high risk of results by chance.

Assessing obstetrical risk factors for OASIS is challenging due to the chain of factors and interventions; nulliparous women have a longer duration of labor and need more pain relief, they have a longer duration of second stage of labor, which can further become prolonged caused by epidural and thereby need for episiotomy or instrumental assistance increases. Components in this chain of events and features during labor and delivery are tightly related to each other, and it is not easy to determine which factor is a consequence of another. Need for obstetrical interventions is even stronger when the infant is large, which is also an independent risk factor for OASIS. Most of these obstetrical interventions during labor and delivery are performed on nulliparous women. Compared to nulliparous women, a parous woman only rarely needs an instrumental delivery, episiotomy or epidural, for example in case of a large baby and a “difficult” delivery. Due to these facts a nulliparous woman is in much higher risk of perineal laceration and OASIS than a
parous woman, and therefore nulliparous and parous women were analyzed separately in this thesis.

When the primary outcome is an infrequent event, such as OASIS, the number of study participants needed is larger than when frequently occurring outcomes are explored. For example perineal lacerations (degree 1-4) during delivery in general are frequent (60-80% of women suffer from such lacerations during a vaginal delivery), but only a small fraction of these are anal sphincter injuries (degree 3-4), 4-5% of all vaginal deliveries. Therefore, studies assessing perineal lacerations in general (degrees 1-4), or other frequent outcomes, such as intact perineum or postpartum perineal pain experience, are not suited to simultaneously assess OASIS risk, as they are often underpowered assessing OASIS as outcome variable (113-115). Similarly, studies designed to explore urinary incontinence may be underpowered to investigate anal incontinence. It is tempting to expand the number of outcomes after a study is conducted, and in the desire of publishing, it is not unusual that researchers produce publications of several outcome variables from a study originally designed to investigate another main outcome, resulting in underpowered studies.

5.2 Strengths and weaknesses

A strength in Paper 1 was that both nulliparous and parous women were invited to participate, and the questionnaire was filled out before delivery. Thus information regarding anal incontinence among nulliparous women was obtained, a group rarely investigated in previous studies, as mostly only postpartum anal incontinence has been assessed in previous reports. A weakness in the study was that the response rate in the survey was only 45%, and a self-selection bias cannot be excluded in the study. In the Norwegian Mother and Child Cohort Study (MoBa), including more than 100 000 respondents, the response rate was of similar magnitude (43%), which was considered as non-problematic in studies assessing associations between risk factors and outcome (194,195). Also in a previous large population based study on anal incontinence had a response rate of this magnitude was (29). Low response rate
in health surveys is a known problem, and rates less than 50% are not unusual (29,194,195).

In the clinical observational study of women with OASIS, 77% of the invited women attended the follow-up and there was no difference in the maternal or obstetrical risk factors between the attendants and non-attendants. Unfortunately, logistical problems occurred in this clinical retrospective study; the ultrasound equipment was not always available at the outpatient clinic. Thus the endoanal ultrasound examination was performed in 78% of the women who attended follow-up. Of the whole study population with OASIS, 60% (357/591) had a documented endoanal ultrasound examination. Clinical characteristics between women who were examined and those who were not examined did not differ, indicating that selection bias was avoided and the results therefore representative for the entire group of women with OASIS (Paper 2).

Strength in the study in Paper 3 is that the data is based on national birth registries including the entire population, and therefore resulting in a large unselected study population. The birth registries are based on information registered and collected on the delivery units, and are lacking some clinically important data such as use of manual perineal protection, type of episiotomy and indication for episiotomy. Such non-reported factors may act as confounding factors that cannot be controlled or adjusted for in any statistical analyses.

Lacking information on episiotomy type and indication for episiotomy in obstetric databases and birth registries complicate the assessment of episiotomy effect on OASIS risk, and the effect of episiotomy can be difficult to interpret in statistical analyses. Different frequency of episiotomy in instrumental deliveries and spontaneous deliveries in Paper 4 illustrate the feature of episiotomy: it is used by indication, after the accoucheur’s consideration of clinical need for it, and it is not a variable or event occurring by chance. When episiotomy is used restrictively only during complicated deliveries, a “confounding by indication” may occur. Comparing women with episiotomy with women without episiotomy is in potentially biologically erroneous, because their OASIS risk profile is different and therefore the need for episiotomy is different. Episiotomy is not per se a risk factor, but a surgical
procedure aimed to reduce complications. Therefore parity groups and delivery methods were analyzed separately when the effect of episiotomy on OASIS risk was assessed in Paper 4. A strength was also that the comparison of two time periods was conducted in one hospital, reducing the confounding caused by the varying obstetrical routines between different delivery units.

The marked difference in OASIS risk profiles between nulliparous and parous women was taken into account and stratified analyses were performed for different parity groups. Additionally, women with previous cesarean section only (with no vaginal deliveries), were defined as vaginal primiparous and pooled with nulliparous women in the analyses. Likewise, it is also a strength of the analyses performed in Paper 1 that the assessment of anal incontinence was stratified for parity, as nulliparous and parous women might have different risk factors.

**Study design and patient selection**

**Anal incontinence**

In this thesis, a survey was chosen to investigate prevalence of anal incontinence among pregnant women. When assessing complaints that are not objectively measurable such as anal incontinence, a subjective patient report is necessary to quantitate the symptoms. Paper 1 presents the first part of a longitudinal study assessing the effect of pregnancy and delivery on anal incontinence; data from a follow-up study after delivery in a selection from the same cohort are under analysis. A study group consisting of women attending routine ultrasound examination in second trimester enabled recruitment of nulliparous women, as well as parous women who were planning to deliver in the study hospital.

Among the study respondents, nulliparous women (63%) were overrepresented as compared to overall distribution of nulliparous women (52%) in this hospital. The distribution of non-western women (mostly with immigrant background) among the study respondents was 13%, which is somewhat lower than the overall number of women in this group in this hospital. There was no difference in the mean age between the respondents and mean age of delivering women in
general in the hospital. Thus, the participation rate in the study was as expected, but some degree of selection bias cannot be excluded (Paper 1).

To assess the association between OASIS and anal incontinence after delivery, a retrospective clinical observational study was conducted. This design allowed collecting detailed data from individual patient records and reliable investigation of maternal and fetal characteristics as well as obstetric interventions related to anal incontinence. The prevalence of anal incontinence among the women who did not attend (23%) postpartum follow-up is unknown. However, there was no difference between the attendants and dropouts regarding the maternal characteristics, obstetrical interventions or degree of anal sphincter injury, indicating that the results are valid for the women with OASIS during the study period. A weakness of the study was that all women had OASIS; a control group with women without OASIS would have been the optimal design. However, this study was a retrospective observational study based on a patient group in a clinical follow-up after a complication (OASIS), and no control group was available. Secondly, it is challenging to recruit healthy women without indication to a clinical examination including endoanal ultrasound (Paper 2).

In this thesis, in the two studies presenting data on anal incontinence in Paper 1 and 2, two different methods for obtaining data on self-reported anal incontinence were used. In Paper 1, the participant filled out a questionnaire by herself, whereas in Paper 2 the clinician filled out the St. Mark’s score form when interviewing the patient during an outpatient appointment. These two methods were not compared in one group of women at same time point, whether these methods differed in anal incontinence scores in the same women was not studied.

A benefit with a survey was the opportunity to invite a large number of women to participate, while the study including clinical examination limits the number of participants due to the resource demanding design.

OASIS
Strength in the study in Paper 3 is that the data is based on national birth registries including the entire population, and therefore resulting in a large unselected study
population. A register study based on four large birth registries was chosen to assess
time trends in OASIS incidence between four Nordic countries, allowing
observations across several decades. A limitation is that a health registry may include
missing values and errors that occur during the registration process, but in this study,
only data on annual figures of main obstetrical variables were assessed, thus minor
errors on individual level did not cause a problem for study validity. Additionally,
the Nordic birth registries are considered reliable, producing data of good quality and
suitable for research (179,196). A large register study offers an opportunity to
observe main trends of both outcomes and risk factors in a population over time. The
unselected study population included all deliveries during the study period, and thus,
selection bias was avoided. Number of deliveries included was large (574 175), and
represents an unselected population from all age and parity groups, both spontaneous
and instrumental deliveries. The number of annual deliveries in each country varied
from 56 874 to 113 324 during the study years. Such a large number of deliveries
generate robust data to assess the observed differences in OASIS incidence between
countries and changes in trends over time (Paper 3).

Two cohorts of delivering women were chosen to observe different OASIS
incidence between two time periods; before and after implementation of an
intervention (Paper 4). In order to study effect of a treatment or intervention, a
randomized controlled trial (RCT) is considered the golden standard and when
studying various preventive interventions for OASIS, the ideal would have been to
perform an RCT. Cause and effect cannot be judged in a cohort or observational
study; only associations can be described. A limitation in Paper 4 is that an RCT was
not conducted to assess the effect of an intervention, and only associations are
reported. However, the large number of deliveries in one hospital and the marked
reduction of OASIS incidence in a short time period indicate that the intervention
probably is the cause of the change in OASIS incidence, when the changes in the
delivering population during the study period were small. Similarly, in Paper 3 the
reduction of OASIS incidence in Norway is observed simultaneously with the
national plan for implementing improved delivery techniques to reduce OASIS risk.
The study population in Paper 4 consisted of 31,709 parturients and included 907 women with OASIS during the 6 years study period. These delivering women represented all parity and age groups, a notable proportion of immigrant women of many ethnical groups, a large number of vaginal instrumental assisted deliveries and a wide spectrum of different infant birth weights. Healthy, normal and high-risk women deliver in this hospital. This makes the results generalizable to almost any other population in the world, where health service includes help from a birth attendant.

**Health questionnaires**

Information on self-rated health condition can be obtained in an interview performed by a health care professional, either during a consultation or by telephone, or the patient can fill in a questionnaire by herself in privacy.

When the assessed complaint is of an embarrassing type, such as anal incontinence, it may be a benefit that women can fill out a questionnaire in privacy, as in the study in Paper 1. On the other hand, without assistance from a health care worker, misunderstanding of the questions or response alternatives can result in answers not adequately reflecting the patient symptoms, or failure to reply. A possible weakness in the survey was self-reporting errors that cannot be controlled. It is likely that women remember how many children they have delivered, and which delivery mode was used, but they may have insufficient information about the extent of perineal laceration. However, self-reporting of personal health condition is considered as a reliable method of assessing morbidity and it is therefore reasonable to assume that these young women have managed to report their health condition correctly (197). In this thesis, items assessing symptoms and complaints in the questionnaire were from previously validated questionnaires (Paper 1).

**Defining anal incontinence**

The international consensus of definition of anal incontinence does not include any precept of how to define anal incontinence by using anal incontinence scoring systems, such as St. Mark’s incontinence scores. In previous publications, anal
incontinence is often quantitatively described as frequency of the different components of anal incontinence (fecal, flatal or urgency). In this thesis the total summary of scores from the St. Mark’s incontinence score was used to enable the analysis of anal incontinence risk factors in a multivariate analysis. Due to the complex feature of obstetrics, many factors may impact on the occurrence of OASIS (the main risk factor for anal incontinence), and a multivariate regression analysis is necessary when assessing reasons for anal incontinence, as presented in Paper 1 and 2.

As long as no exact definition of St. Mark’s score for anal incontinence exists, a threshold of St. Mark’s score 3 or above was chosen in this thesis. This score may include different combinations of complaints, for example weekly incontinence for flatus or stools only, or rarely occurring incontinence of flatus, stools and alteration of lifestyle. A St. Mark’s score \( \geq 3 \) as threshold for anal incontinence included also women with several components of anal incontinence occurring rarely, a considerable problem to cope with in the daily life. Using a summarized St. Mark’s incontinence score, instead of merely quantitating separate symptoms, allows a comparison of the participating women in Paper 1 and 2, as well as also allowed the option of a future comparison of the results in the follow-up study of the participants in Paper 1 after delivery (see Further studies, section 7).

In some previous studies, severity of anal incontinence is classified as mild and severe. In this thesis, using the word “mild” is consciously avoided, due to the the stigmatizing feature of the word; calling anal incontinence “mild” depreciates the impact this complaint may have in a woman’s life.

**Registration of OASIS**

Numerous problems in documentation of OASIS occurrence have been suggested to explain the large differences in OASIS incidence between countries and delivery units, such as registration and reporting differences or heterogeneous classification of perineal tears. Insufficient clinical training and education in diagnosing OASIS may result in misclassification of OASIS at delivery. The four studied Nordic countries have similar health care systems. These countries also have similar pregnancy and
labor care, and the education of health care workers is similar. Therefore, there is no reason to believe that large differences in OASIS incidence can be a result of heterogeneous diagnostic skills, registration or classification. In the four studied Nordic countries data from all deliveries are carefully documented in individual patient records, the hospital obstetrical database and hospital discharge register and transferred to medical birth registries. This process is secured with a mandatory document to the birth registry, and is in most delivery units generated automatically from the obstetrical database.

A strength of Paper 4 was the validity of the outcome (OASIS); all cases of OASIS were verified by checking the individual patient records. Additionally, both labor ward database and the hospital discharge register were used to identify all cases of OASIS during the study period.

5.3 Interpretation of results

Anal incontinence

Previous OASIS was the most important risk for anal incontinence among the 2846 women who participated in the survey presented in Paper 1. Other indicators for strong pressure against perineal structures, such as delivery of a large infant or history of instrumental delivery were not associated with anal incontinence. Large infant and instrumental delivery are risk factors for perineal injuries, but did not appear as risk factors for anal incontinence, not even when the OASIS cases were excluded and the multivariate regression analysis was performed without them. Nulliparous women and parous women with one previous vaginal delivery without OASIS reported similar prevalence of anal incontinence (7.8%), indicating that one uncomplicated vaginal delivery has no effect on anal incontinence. Prevalence of anal incontinence was increased among women with two (14.1%) or more (13.7%) vaginal deliveries, while women with previous OASIS reported the highest prevalence of anal incontinence. Lowest anal incontinence prevalence was reported by the women who were delivered with cesarean only (6.4%). These results indicate that pregnancy itself is not a risk factor for anal incontinence, and if a woman had managed to go through one vaginal delivery without OASIS, her risk for anal
incontinence is not increased, but is similar with a nulliparous woman. Compared to nulliparous women, one uncomplicated vaginal delivery did not add the woman’s anal incontinence risk, whereas one previous delivery with OASIS increased the anal incontinence risk to threefold.

In addition to OASIS, low education appeared as a risk factor for anal incontinence. This is however not surprising, as previous studies report higher prevalence of health complaints in general among people with lower socioeconomic status. Unexplainable and novel finding was the association between dermatological disease and anal incontinence.

In Paper 2 only women with previous OASIS were investigated. Prevalence of postpartum anal incontinence was associated with fourth degree tear and defects in the anal sphincter muscles. Women with larger obstetric anal sphincter injuries (fourth degree) more often had detectable defects in the sphincter muscles at the postpartum follow-up than women with a third degree injury. A defect in the internal anal sphincter was detected in 39 (of 357 ultrasound examinations) women who were primarily diagnosed with an injury in the external anal sphincter only, representing insufficient primary diagnosis. Such defects in the anal sphincter muscles detected one year after delivery may represent a disturbed healing process or an incomplete primary repair.

Preventing OASIS, and especially the larger injuries (fourth degree) during delivery will probably reduce the number of women suffering from anal incontinence postpartum and later in life. Higher risk with persisting anal sphincter defects among women with fourth degree tears may represent an insufficient primarily diagnosis and repair, and highlights the importance of proper diagnosis and primary repair at delivery.

OASIS

Paper 3 showed that the OASIS incidence was reduced with 50% during the study years in Norway. Although all Norwegian delivery units have managed to reduce the OASIS incidence during the last years, threefold difference between the delivery units was observed. Interestingly, the difference in OASIS frequency between the
delivery units remained the same over the study period, despite a reduced incidence among all these units. The delivery units with highest OASIS incidences had the highest rates both before and after the overall OASIS reduction in Norway. Differences in the population of delivering women cannot explain the differences in OASIS incidence, as the delivery populations are quite similar across the majority of hospitals in Norway. Similar pattern of consistent variations in OASIS frequencies was observed in the other Nordic countries, with threefold difference in OASIS incidence between the best and worst performing delivery units. This finding may indicate that there is a real difference in the management of the second stage of labor between hospitals, affecting the frequency of OASIS.

During the years when the OASIS incidence was halved in Norway (2004-10), the incidence increased in Denmark, whereas it slightly was reduced and then increased again in Sweden. The OASIS incidence increased significantly in Finland over the study years, but the incidence was constantly 75% lower than in Denmark and Sweden. It has been speculated that the low incidence of OASIS in Finland would be a result of underreporting and misclassification of OASIS, and it has been suggested that such a low frequencies are “too good to be true”. After the marked reduction in OASIS incidence in Norway in 2010, where some delivery units managed to achieve the same low level of OASIS incidence as Finland, it seems more accepted that the low incidence of OASIS from Finland may be correctly recorded and due to appropriate delivery techniques. Tradition of using manual perineal protection during second stage of delivery in Finland has continued in Finland, while hands-off delivering techniques have become acceptable in other countries (111).

The large reduction of OASIS incidence in Norway was observed after a national campaign in 2004-06 to reduce OASIS risk by implementing better delivering techniques. Since no such reduction was observed in the neighbor countries, the reduction in Norway is unlikely to be by chance, or a trend without a cause. A sudden change in OASIS reporting routines to the medical birth register or altered diagnostic skills is also unlikely. A conscious underreporting of OASIS cases is an unlikely explanation for the reduction in a public health care system where
individual health care workers are not suffering of economical or other sanctions when complications occur. Such underreporting would also imply that 50% of Norwegian midwives and doctors were underreporting OASIS cases, which is highly unlikely. Also, the majority of deliveries in Norway are supervised by more than one professional birth attendant. This reduces the risk of conscious underreporting of OASIS, as it would be evaluated as professional misconduct not compatible with the ethical values of any health professional.

Variations in obstetrical practices among delivery units, such as choice of instrument during assisted vaginal delivery (vacuum or forceps), use of manual perineal protection and use of episiotomy type as well as episiotomy frequency could potentially explain some of the differences in OASIS incidence between delivery units (63,70,71,86,106,108). A measurable difference between the Nordic countries was observed in the episiotomy use. In Norway and Finland, with the lowest OASIS incidences, the episiotomy rate was threefold compared to Denmark and Sweden, the latter countries having a significantly higher (2-3-fold) OASIS risk. The episiotomy use in Denmark and Sweden might have become too infrequent in regard to OASIS prevention. Although episiotomy should not be used routinely, but only selectively by indication, there are no studies indicating that less than 6% episiotomy rate is beneficial compared to 20-30%, when OASIS is the outcome variable. Previous studies have shown that too low episiotomy rate may result in increased risk of OASIS (71,145).

In Paper 4, the OASIS risk was reduced with 50% consistently across all assessed risk groups regardless of parity, delivery method or infant birth weight. The reduction was statistically significant, and almost exactly of same magnitude in all risk groups. The reduction was achieved after a careful training of the labor ward staff, both midwives and doctors, in the use manual perineal protection, slow down the delivery of the baby’s head and instructing the mother not to push. The training included hands-on training on pelvic models and hands-on guiding in labor room during delivery. Correct use of episiotomy, selectively by indication and with a technique avoiding medial cuts was also in focus during training period. Correct episiotomy use and technique was a part of the training program.
During the study period the delivering population remained mainly unaltered, but the use of instrumental deliveries was increased. Instrumental delivery is a known risk factor for OASIS, and despite of the increased occurrence of instrumental deliveries, the risk of OASIS was reduced in this large delivery unit. Episiotomy use was reduced during spontaneous deliveries, while episiotomy rate in instrumental deliveries was increased across the study period. This observation indicates that episiotomy use can be reduced during spontaneous delivery, but is more frequently necessary during an instrumental delivery, to protect the perineum from injuries extending to anal sphincter.

The described changes happened simultaneously with the training of the staff to improved delivery techniques. The effect of episiotomy is difficult to separate from the effect of manual perineal protection, but a combination of correct use of episiotomy and routine use of manual perineal protection seemed to result in reduced risk of OASIS in low risk and high risk deliveries (Paper 4).

The results show that the use of episiotomy was increased over the two study periods in high-risk deliveries, the instrumental deliveries, whereas episiotomy use was reduced in deliveries with lower risk for OASIS, the spontaneous deliveries. This finding may be a result of the increased awareness and focus on perineal care to reduce OASIS, and it probably indicates that the accoucheurs are capable of selecting the patients in high risk for OASIS. The education of the delivery unit staff by offering hands-on training and guidance resulted in a standardization of the delivering technique and increased skills of perineal protection.

The perineal protection program has contributed to the marked and persisting reduction in the OASIS incidence in this large delivery unit. Similarly, the historical variations in OASIS incidence between the Nordic countries and Norwegian delivery units support the importance of delivery routines as a major defining factor for the OASIS risk and thereby also for the risk of postpartum anal incontinence risk.

To further assess the effect of manual perineal protection and episiotomy on OASIS risk, a cluster-randomized trial might be the best design to test different interventions. In a cluster-randomized trial many problems from individual patient randomizing can be avoided when the OASIS incidences on entire delivery units are
analyzed as clusters. By implementing different delivery techniques in different hospitals the OASIS incidence during a study period measures the effect of an intervention on OASIS risk.

**Generalizability of the results**
The main results concerning anal incontinence are consistent with findings from other countries and can be considered as highly generalizable to cultures similar to the North European, where mean number of children per woman is less than two, maternal age at delivery is relatively advanced, and a public health care system is available to everyone.

Using two-hand technique to reduce perineal tears and simultaneously instructing the delivering woman not to push is an intervention that can be implemented in any country or culture where obstetrical care is offered during delivery. No expensive medication or equipment is needed; one birth attendant can perform the protecting maneuvers, making this method feasible in both developed and developing countries.
6 CONCLUSIONS

This thesis showed that obstetric anal sphincter injury is the most important reason for anal incontinence in a female population of fertile age. Other factors, such as co-morbidity, medication use, pregnancy and one previous vaginal delivery had only a minor effect on risk of anal incontinence (Paper 1).

Women with fourth degree anal sphincter tears are at higher risk for anal incontinence than women with third degree tears. A fourth degree tear increases the risk for persisting defects in the anal sphincter, indicating either problems in the healing process, failure at primarily diagnosis or insufficiently repaired anal sphincter injury at delivery. Women with persisting defects in the anal sphincter muscles were at higher risk for anal incontinence than women without such defects, incompletely repaired anal sphincter was a risk for anal incontinence (Paper 2).

The increasing trend of OASIS incidence during the last decades was observed in four Nordic countries, albeit significantly at much lower level in Finland than in the other three countries. This increase continued until the year 2004, and after that a marked reduction of OASIS incidence was observed in Norway during the study period 2004-10. The reduction during this period was 48%, and it appeared simultaneously with the national plan for reducing occurrence of OASIS. National strategy to implement improved delivering techniques reduced the risk for OASIS (Paper 3).

Incidence of OASIS was reduced with 50% after a training program for improving delivery technique during second stage of delivery. The reduction was similar in all subgroups of women and in all parity groups regardless of delivery method or infant birth weight. Manual perineal protection together with selective use of episiotomy is likely to reduce the risk of OASIS, as no other factors were notably altered during the study period. The intervention needed is of minimal cost and low-resource demanding, as compared to previous routines, as one midwife alone in the labor room can perform perineal support during delivery. The same procedure can be performed during an instrumental delivery and the reduction of OASIS risk is similar in instrumental and non-instrumental deliveries (50%). Use of episiotomy on the
correct patients and with a correct technique is likely to contribute in reduction of OASIS risk (Paper 4).

In conclusion, this thesis postulates that by reducing the incidence of OASIS it is possible to reduce the prevalence of anal incontinence among women, immediately after delivery and later in life, as OASIS was identified as the major risk factor for anal incontinence. Therefore, protecting the perineum during delivery to avoid OASIS will very likely prevent the women’s risk of suffering from anal incontinence after delivery. In addition to the important primary prevention of OASIS during delivery, it is important to acknowledge that all OASIS are not likely to be prevented. It is therefore important, if the anal sphincter injury occurs, that the extent of the injury is recognized. Identification of and correct primary repair of an OASIS is important to reduce the risk for anal incontinence.

The main message of this thesis is that it is possible to dramatically reduce the incidence of OASIS by using a perineal protection program, thereby also dramatically reducing the largest risk factor for anal incontinence in fertile women. Protecting the perineum during delivery to avoid OASIS can prevent the women’s risk of suffering from anal incontinence after delivery. Secondly, if the anal sphincter injury occurs, the extent of the injury is important to recognize, so that the primary repair can be performed correctly.
7 FURTHER STUDIES

This PhD study has generated data and ideas for several future research projects, such as:

- **Anal incontinence after OASIS: a longitudinal study**
  Follow-up study of the population presented in Paper 1. Of the 2,846 women who returned the questionnaire during their pregnancy, 41 suffered from OASIS at delivery. These 41 women and 20 randomly chosen controls to each of them have received a follow-up questionnaire 1 year after delivery with questions including symptoms of anal incontinence, urinary incontinence and sexual function.

- **Changes in the incidence of perineal lacerations across last decade**
  To assess possible changes in the incidence of first and second degree perineal tears and intact perineum during the last decade 2001-2012 in Oslo University Hospital Ullevål.

- **Changes in episiotomy use across last decade**
  Register study comparing three delivery units in a university hospital to assess any changes in episiotomy use during the last decade when the OASIS incidence was reduced.
8 ERRATUM
9 REFERENCE LIST


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10 PAPERS I-IV