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

Katariina Laine, MD

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Katariina Laine, MD

Department of Obstetrics

Oslo University Hospital, Ullevål

University of Oslo

Oslo, Norway

**Department of Obstetrics, Oslo University Hospital, Ullevål
University of Oslo, Norway**

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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.

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LIST OF PAPERS

I. **Laine K, Skjeldestad FE, Sandvik L, Staff AC**. Prevalence and risk indicators for anal incontinence among pregnant women. ISRN Obstet Gynecol. In Press.

II. **Laine K, Skjeldestad FE, Sanda B, Horne H, Spydslaug A, Staff AC.** Prevalence and risk factors for anal incontinence after obstetric anal sphincter rupture. Acta Obstet Gynecol Scand. 2011;90(4):319-24.

III. **Laine K, Rotvold W, Staff AC.** Are obstetric anal sphincter ruptures preventable? – Large and consistent rupture rate variations between the Nordic countries and between delivery units in Norway. Acta Obstet Gynecol Scand. 2013;92(1):94-100.

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.

	Never	Rarely	Sometimes	Weekly	Daily
Incontinence for solid stool	0	1	2	3	4
Incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration of lifestyle	0	1	2	3	4
				No	Yes
Need to wear pad or plug				0	2
Taking constipation medicines				0	2
Lack of ability to defer defecation for 15 minutes				0	4

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 weeeks-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 ischiocaverosus muscle

- Deep: Levator ani, deep transverse perineal muscle
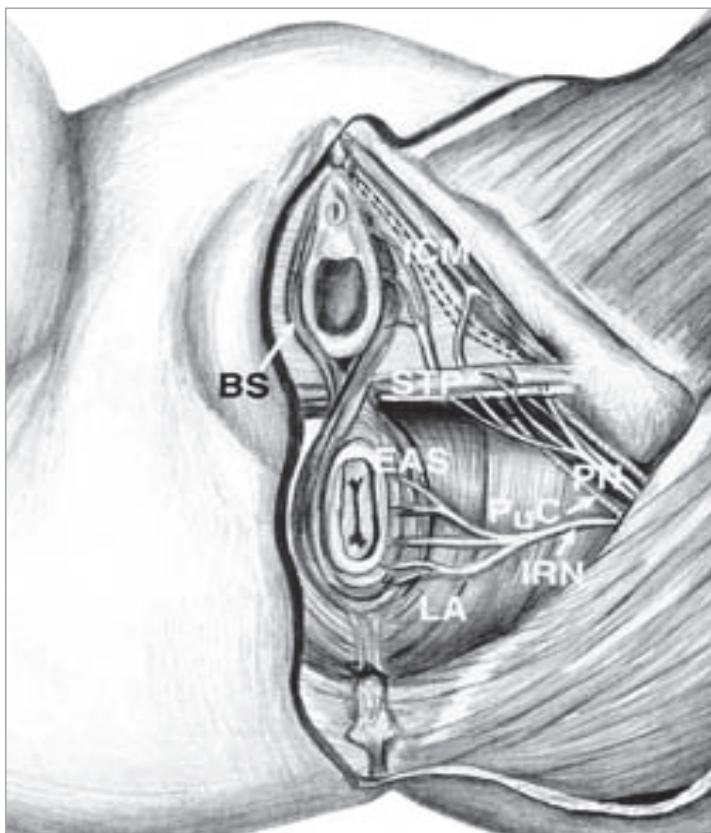
Figure 1

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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(Am J Obstet Gynecol 2002;187:64-71. Barber et al.)

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
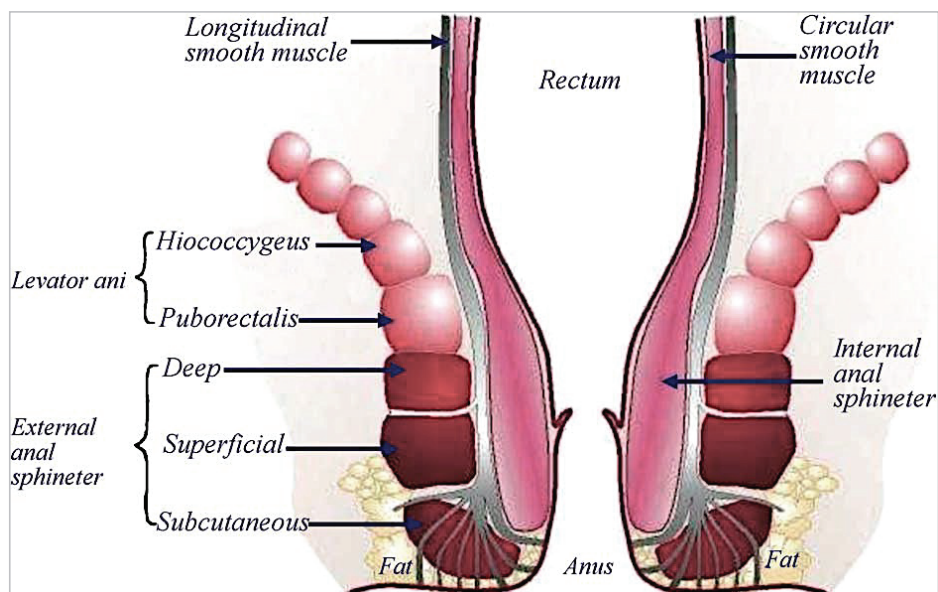
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(Rewievs in Gynaecological Practice 3. 2003, 188-195)

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

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 2	Parity	Maternal age (years) aOR	Vacuum Ref non-instrum	Forceps Ref non-instrum	Prolonged second stage	Birth weight/ macrosomia (grams)
Hehir, 2013 Ireland N=100 307 (83)	Primip 3.5% Multip 0.9%	No data	OR 2.9 3.7%	OR 7.1 8.6%	No data	No data
Ampt, 2013 Australia N=528 846 (84)	Primip 4.8% Multip 0.9%	Ref 25-29 <20 0.5, 20-24 0.7 Primip 30-34 NS 35-39 aOR 0.9 ≥40, aOR 0.7 Multip 30-39 aOR 1.17 ≥40 NS	Primip aOR 1.8-2.0 Multip aOR 2.6-2.7	Primip aOR 3.0-6.1 Multip aOR 3.4-6.1	No data	Per 200 g increment aOR 1.2
Landy, 2011 USA N=87 267 (85)	Nullip 5.8% Multip 0.6%	Ref <20 Primip 20-24 aOR 1.2 25-29 aOR 1.6 30-34 aOR 1.9 >35 aOR 1.6 Multip NS	Primip aOR 2.6 Multip aOR 4.9	Primip aOR 3.7 Multip aOR 3.0	Primip Ref < 60' 1-2 h aOR 1.5 2-3 h aOR 1.7 >3h aOR 2.0 Multip Ref <30' 30-60' aOR 2.2 1-2h aOR 2.9 >2h aOR 5.4	Ref <2500 Primip 4000-4499 aOR 5.9 ≥4500 aOR 10.5 Multip 4000-4499 aOR 9.2 ≥4500 aOR 13.6
Baghestan, 2010 Norway N=1 673 442 (68)	Ref Multip Nullip: aOR 4.8	Ref 25-29 y 20-24 aOR 0.8 30-34 aOR 1.2 >35 aOR 1.3	aOR 2.0 6.0%	aOR 3.9 8.1%	No data	Ref 3000-3499 2500-2999 aOR 0.5 4000-4499 aOR 2.7 4500-4999 aOR 4.2 >5000 aOR 5.9

Table 2 continued	Parity	Maternal age	Vacuum extraction	Forceps	Prolonged second stage	Birth weight/ macrosomia
Räisänen, 2009 Finland N=514 714 (86)	6-fold: Nullip 1.07% Multip 0.18%	Ref <19 Primip: 30-39 aOR 2.3 Multip 30-39 OR 1.34 ≥40 1.75	Primip: aOR 3.9 Multip: aOR 4.2	Primip: aOR 10.2 Multip: aOR 10.1	Ref ≤15' >60' Primip aOR 2.06 Multip aOR 7.2	Ref≤3000 Primip ≥4000 aOR 4.66 Multip >4000 aOR 5.84
Dandolu, 2005 N=258 507 USA (103)	No data	No data	15.3% OR 2.58	20.3% OR 3.84	No data	No data
Sheiner, 2003 Israel N=98 524 (88)	NS	NS	aOR 8.2	aOR 26.7	NS	aOR 2.5
deLeeuw, 2001 Netherlands N=284 783 (89)	Ref Multip Primip aOR 2.39	No data	3.0% aOR 1.68	4.65% aOR 3.53	OR 1.12 per increased 15'	OR 1.47 per increased 500 grams
Handa, 2001 USA N=2 101 843 (65)	Ref Primip Multip aOR 0.15	Ref 18-35 >35 aOR 1.09 <18 aOR 0.81	15.5% aOR 2.3	16% aOR 1.45	No data	Ref <4000 ≥4000, aOR 2.17

NS=non-significant

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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 bulbospongiosus 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). This

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

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.
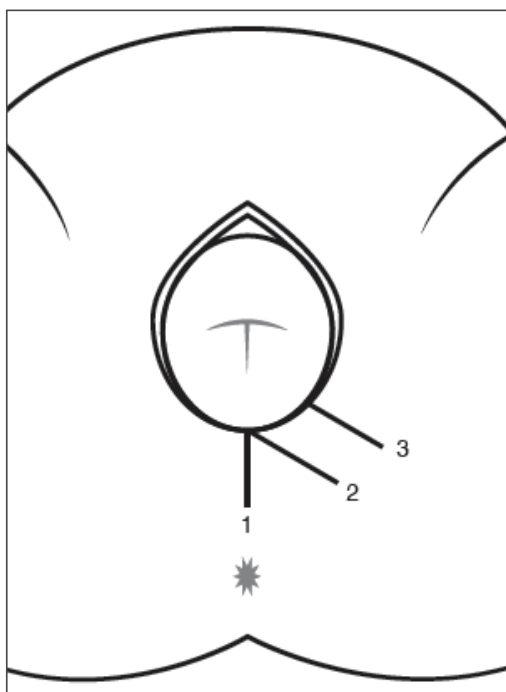
Figure 3.

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

Olivia Österberg

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

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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 to13%), 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:

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

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

- o Co-morbidity
- o Medication use
- o Marital status
- o Educational level
- o Household annual income
- o Non-domestic working activity
- o Degree of OASIS
- o Type of defect in anal sphincter muscle
- Fetal characteristics
  - o Birth weight
  - o Head circumference
  - o Apgar scores
  - o Fetal head presentation
  - o Shoulder dystocia
- Obstetrical procedures
  - o Delivery mode
  - o Epidural use
  - o Episiotomy
  - o Duration of second stage of labor
  - o 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 chracateristics 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 2851 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 out patient 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:

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- 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 perineumduring 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

Prevalence and risk indicators for anal incontinence among pregnant women

Katariina LAINE, MD[a,b], Finn Egil SKJELDESTAD, MD, PhD[c], Leiv SANDVIK, MSc, PhD[d], Anne Cathrine STAFF, MD, PhD[a,b]

[a] Department of Obstetrics and Department of Gynaecology, Oslo University Hospital, Ullevål, Norway

[b] Faculty of Medicine, University of Oslo, Norway

[c] Women's Health and Perinatology Research Group, Department of Clinical Medicine, University of Tromsø, Norway

[d] Unit of Biostatistics and Epidemiology, Oslo University Hospital, Oslo, Norway

Corresponding author: Katariina Laine

Department of Obstetrics, Oslo University Hospital, Ullevål

Pb 4965, Nydalen, 0424 Oslo, Norway

Business telephone number: + 47 22 11 98 00

Business fax number: + 47 22 11 97 75

Home telephone number: + 47 40 28 54 64

E-mail: kattiksen@yahoo.no

Finn Egil Skjeldestad: eskjelde@online.no

Leiv Sandvik: uxledv@ous-hf.no

Anne Cathrine Staff: uxnnaf@ous-hf.no

Abstract

The aim of this study was to assess the prevalence and risk factors of anal incontinence in an unselected pregnant population at second trimester. A survey of pregnant women attending a routine ultrasound examination was conducted in a university hospital in Oslo, Norway. A questionnaire consisting of 105 items concerning anal incontinence (including St.Mark's score), urinary incontinence, medication use and co-morbidity was posted to women when invited to the ultrasound examination.

Results Prevalence of self-reported anal incontinence (St. Mark's score ≥ 3) was lowest in the group of women with a previous cesarean section only (6.4%) and highest among women with a previous delivery complicated by obstetric anal sphincter injury (24.4%). Among nulliparous women the prevalence of anal incontinence was 7.7%, and was associated to low educational level and co-morbidity. Prevalence of anal incontinence increased with increasing parity. Urinary incontinence was associated to anal incontinence in all parity groups.

Conclusions Anal incontinence was most frequent among women with a history of obstetric anal sphincter injury. Other obstetrical events had a minor effect on prevalence of anal incontinence among parous women. Prevention of obstetrical sphincter injury is likely the most important factor for reducing bothersome anal incontinence among fertile women.

Introduction

Anal incontinence is a bothersome ailment associated with many health complaints and discomfort in daily life; hygienic problems, limitations in occupational and social life, sexual dysfunction, reduced quality of life and altered self-esteem. Anal incontinence (AI) is defined as involuntary loss of flatus or feces [1]. Prevalence and severity of anal incontinence is measured by patient self-reporting, no objective assessment methods exist.

Obstetric anal sphincter injury (OASIS) is one of the main causes for female AI reported in non-pregnant women. Additionally, multiple vaginal deliveries can increase the risk of AI regardless of anal sphincter injury [2,3]. Age, obesity and medical conditions such as diabetic neuropathy and gastrointestinal disorders also increase the risk of anal incontinence [2,4,5].

Prevalence of anal incontinence among women differs largely (2-28%) in previous studies, and differs between different study populations [4-6]. Postpartum studies show a high prevalence of AI in women having suffered OASIS, 38-59% [6-8]. Women attending gynecological out patient clinics have higher prevalence of AI (16-28%) compared with the general female population (4.4%)[2,5]. Women with pelvic floor disorders have higher prevalence of AI than women without pelvic floor disorders. Community based studies show differences in prevalence of AI between age groups, with increasing prevalence by increasing age [4,5,9]. Most frequent AI is found among nursing home residents (50-60%), among the oldest women with frequent additional complaints and co-morbidity [10].

Few previous studies have assessed the prevalence of anal incontinence among pregnant women and few studies have included nulliparous women [11,12].

The aim of this study was to assess the prevalence and risk factors for anal incontinence in an unselected female population across parity groups in second trimester of pregnancy.

Material and methods

This study is part of a comprehensive perineum research study, which was approved by the Regional Committee for Medical Research Ethics in South-Eastern Norway (ref S-08810d/20941) and the institutional Personal Data Officer.

This study was conducted as a survey of pregnant women attending free of charge routine ultrasound examination at second trimester, from September 2009 to August 2010, in a large university hospital in Oslo, Norway. The pregnant women attending the ultrasound screening in our hospital represent a non-selected population from the entire Oslo area. All pregnant women in Norway are offered a free of charge second trimester routine ultrasound examination in gestational week 18-20, and 98% attend. In our hospital, this routine ultrasound is performed by specially educated midwives at the fetal medicine unit. The hospital receives admission notes from the local general practitioners when the woman is pregnant in the first trimester. The invitation to participate in our study, the questionnaire and informed consent was included as a part of the invitation to the routine ultrasound appointment. Midwives performing the routine ultrasound examination reminded the women about the study and collected the questionnaire and the signed informed consent. From the 7256 women who were posted a questionnaire, 973 women were not found in our postpartum labor ward database: they did either not achieve 18 weeks pregnancy (pregnancy loss), they did not deliver in our hospital or they had moved out of Oslo area or Norway, resulting in 6283 women eligible for study participation. We received 2851 filled-out questionnaires from the participants. Four women returned two questionnaires (twice during the same pregnancy),

and one woman returned the questionnaire shortly after the index delivery. Thus, five filled-out forms were excluded from the analyses and the study group consisted of 2846 (of 6283 invited) women, resulting in a response rate of 45%.

The questionnaire consisted of 105 questions concerning anal and urinary incontinence, general health condition, drug-use and worries concerning pregnancy and delivery. The major part of the questions were chosen from validated questionnaires such as: Due, U [13], St. Mark's [14], NUGG [15], HUNT[16] and Cambridge worry scale (CWS)[17,18]. Additionally, we collected demographic data, obstetrical history, educational level, household income and country of origin of the participant.

Anal incontinence was identified by self-reported leakage of gas, loose or solid stools, lack of ability to defer defecation for 15 minutes (fecal urgency), use of pads or plugs and alteration of lifestyle described in St. Mark's score. We defined anal incontinence as a St. Mark's score 3 or above (of maximal score 24). Women with St. Mark's score from 0 to 2 were analyzed as a control group (no or infrequent AI). Fecal incontinence was defined as self-reported leakage of loose or solid tools. Urinary incontinence was defined as self-reported symptoms of stress or urge urinary incontinence.

Parity was adjusted to history of cesarean delivery. Thus, women with cesarean delivery only (never having delivered vaginally before) were categorized as "vaginal primiparous".

The data were analyzed by using PASW (Predictive Analytics SoftWare, SPSS Inc., version 19.0, Chicago, IL). Continuous data were categorised and the independent variables are presented as frequencies. Univariate analysis was performed to identify significant risk factors for anal incontinence. Univariate analyses were performed by Chi-square test. A significance level of 5% was chosen in all analyses. Variables with P≤0.05 were included in a multivariate logistic regression analysis. The results from this regression analysis are

presented as adjusted odds ratios (aORs) for AI with 95% CI. For each model the assumptions

underlying a valid logistic regression analysis were checked and found to be adequately met.

Results

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

infrequent AI with 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.

Urinary incontinence was reported by 19% (547/2846) of the women. Urinary

incontinence (UI) was significantly associated to reported anal incontinence among all parity

groups, 32.4% of the women with AI also reported UI (P<0.001). Prevalence of UI was

threefold among parous women compared to nulliparous women, and increased slightly with

increasing vaginal parity (P<0.001) (data not shown).

The majority of the 2846 women had answered the questionnaire when they were in

the second trimester (84%), 12.2% in the first trimester and 1.2% in the third trimester.

Most of the participating women were nulliparous 63% (1792/2846). The majority of the

participating women were Norwegian (77.5%). Non-Western origin was reported by 13.5% of

the women. Mean age of the participating women was 31 years. Mean height was 168 cm,

mean weight 66.7 kg. Mean BMI was 23.6, range 16.0-42.4. Smoking was infrequent; only

2% (57/2851) women reported that they smoked during this pregnancy (Table 1).

There was a significant difference in prevalence of AI among women with different

obstetric history. Prevalence of AI (defined as St. Mark's score of 3 or above) increased with

increasing vaginal parity (data not shown).

Nulliparous women

Of the nulliparous women, 7.8% (139/1792) reported anal incontinence. In the univariate analysis, non-Western background, low household income, being unmarried or single, lowest educational level, age 35 or more, answering the questionnaire in the first trimester (as opposed to second trimester), dermatological disease, ulcerative stomach disease, hypertension, rheumatoid arthritis and muscle-skeletal complaints were significantly associated with anal incontinence among the nulliparous women (Table 1, Table 2).

In the multivariate analysis, low educational level, dermatological disease and rheumatoid arthritis remained significant factors for AI (Table 2).

Parous women

After excluding the 140 women with previous cesarean delivery only, the subgroup of vaginal parous women consisted of 914 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 AI, whereas the group of women with more than one previous vaginal delivery, as many as 14.5% (29/200) reported AI (P=0.004).

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 AI. Previous delivery with OASIS was reported by 41 women (4.5%), and was strongly associated with AI.

In the univariate analysis, previous delivery with OASIS, non-Western background, low household income, being unmarried or single, lowest educational level, age 35 or more, BMI 25 or more, dermatological disease and use of pain killers were significantly associated with anal incontinence among the parous women (Table 1 and Table 2).

In the multivariate analysis, previous delivery complicated with OASIS and

dermatological disease remained significant risk factors for AI (Table 2). The risk of AI was threefold among women with previous OASIS compared to women without (24.4% and 8.1%, respectively).

The higher risk of AI associated with previous OASIS remained threefold in the more severe forms of AI, if defining AI as self-reported St. Mark's score of 5 or above (12.2% and 3.8%) or if 7 or above (7.3% and 2.3%) instead of 3 or above (Table 3).

Women with previous cesarean only

The subgroup of parous women with previous cesarean only (n=140), and no vaginal deliveries, was also analysed separately. In this subgroup the prevalence of AI 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 (data not shown).

Women with dermatological disease

Women who reported having a dermatological disease reported also more anal incontinence than women without this disease (Table 2). 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.

Discussion

This population-based study showed that previous obstetric anal sphincter injury was the strongest risk factor for self-reported AI among pregnant parous women. Among the nulliparous women, a low educational level and co-morbidity were associated with anal

incontinence. The group of women with previous deliveries with cesarean section only, had the lowest prevalence of AI, indicating that pregnancy per se may not represent a major risk factor for AI. These findings support the notion that the process of vaginal delivery may be more damaging to the anal continence mechanisms than pregnancy per se.

We found a surprisingly high frequency of self-reported AI among nulliparous women (7.8%). Low socioeconomic status (low income, low education) is a well-known reason for lower health status and increased morbidity, and previous studies show that self-rated health predicts morbidity well [19-21], therefore, there is now reason to doubt the correctness of the self-reported AI. Socioeconomic differences have been found in occurrence of almost all conditions and illnesses [20,21]. This might explain part of the results for the group of nulliparous pregnant women in our study, where low educational level remained significant risk factor for AI in the multivariate analysis.

A previous OASIS was the strongest risk factor for self-reported anal incontinence in all analyses in parous women, with and without adjusting for other factors, and in all categories of severity of anal incontinence. In our study, women with previous OASIS reported a lower prevalence of AI than women in previous studies on non-pregnant women [6-8,22]. All the participants in our study were pregnant, and the low prevalence of AI among women with previous OASIS might indicate that fewer women with severe complaints of AI embark on a new pregnancy [23]. The risk of AI increased with increasing number of vaginal deliveries, a result similar to previous studies. Interestingly, previous delivery with a macrosomic infant (>4000 g) was not associated with self-reported AI during pregnancy in our study, neither was a previous delivery with vacuum extraction or forceps. This is in contrast to some previous studies, where previous forceps delivery and macrosomy are reported risk factors for AI [8,24,25]. In our study of pregnant women, maternal age was not a significant risk factor for AI in the subgroup of parous women, probably because our study

group was young, the oldest participant was 45 years old, and age related increased risk of anal incontinence is probably more important in older age groups[2,5,25]. Women with overweight (BMI 25-29.9) and obesity (BMI> 30) were more likely to suffer from anal incontinence than women with normal BMI (<25) in our study, but in the multivariate analysis this effect disappeared, due to the strong effect of previous OASIS. The large effect of OASIS exceeded all other factors (except dermatological illness).

Many previous studies of AI describe only the frequency of the different components of AI only. We chose to describe the prevalence of AI as a score, to be able to perform multivariable analyses of the assessed variables in our study. The reason to choose the St. Mark's score 3 as cut-off for AI, was to be able to compare the results from this study to our previous study [6] and also to our future study, a follow-up of the participating women after delivery. As a limit of 3 for defining AI may be questioned for clinical relevance, we repeated all statistical analyses were repeated with different cut-offs (4, 5 and 7) for St. Mark's score, for all parity groups. The main conclusions remained unaltered, OASIS was the most important predictor for AI (for all these cut-offs for St. Mark's score) among parous women, low socioeconomic status and co-morbidity were the most important indicators for AI among nulliparous women. Variables with a p-values over 0.05 were also included in the primary analyses to ensure that no risk factors were missed among our registered variables, but no such factors were revealed.

Similarly to our previous study of non-pregnant women, urinary incontinence was reported by 19.2% of the participants [6]. Prevalence of urinary incontinence was threefold among women who reported AI compared to women without AI, in both nulliparous and parous subgroups of women (P<0.001). This might indicate that some women are in higher overall risk for incontinence, possibly associated with tissue type, or the pathophysiological mechanism may be the same for both diseases.

Strengths and weaknesses of the study

Strength of this study is that the pregnant population was unselected, and consisted of all

parity groups, including nulliparous women. The majority of previous studies on female anal

incontinence have assessed non-pregnant women 6-24 months after delivery.

Another strength of this study is that we also assessed co-morbidity and medication

use in addition to obstetrical history. To our knowledge, no previous studies have assessed

anal incontinence and co-morbidity among women of fertile age. Among nulliparous women,

co-morbidity seems to have association to anal incontinence. Further research is needed to

explore whether this is a consistent finding across population groups and to explore which

mechanisms that could underlie such an association.

A weakness in our study is that the response rate among the invited women was less

than 50%, the intimate questions might partly explain the low response rate, such as was the

experience in the study of van Brummen et al [26]. Low response rate can cause self-selection

bias among the study participants. Similar selection bias was observed in the Norwegian

MoBa study, where higher educated women more likely agreed to participate [27]. However,

the effect of such selection bias was found low in the MoBa study [28], and we have no

reason to believe our response rate of 45% negatively affected our study either. Low

prevalence of co-morbidity and medication use may indicate that the participants did not have

lower health status than non-participants or the general population in Oslo.

Bias of women with a previous OASIS and complaints of AI having been more eager

to participate the study is unlikely, since the prevalence of AI in the subgroup of women with

previous OASIS was lower (24.4%) than in previously reported studies (from Norway) [6,7].

We compared the study population's basic clinical data with an anonymous electronic

database covering all patients delivering in the same time period as the participants in this

study. The distribution of nulliparous women in our study population was higher than in the overall delivery population in our hospital (63% and 52%, respectively). We did not find any differences in mean age between responders and non-responders, but the distribution of women with non-Western background was higher among the non-responders (data not shown), as expected, as the questionnaire and patient information was in Norwegian.

All data in this study was based on self-reporting from the participants, and thus information of their obstetric history can include errors. It is likely that women remember correctly the number of previous deliveries, delivery mode and infant birth weight, but not all women are aware of having suffered of OASIS [7] when they leave the hospital after delivery. Lacking information of OASIS might strengthen our conclusions of OASIS being a strong risk factor for AI: if women unaware of previous OASIS reported AI and were analyzed as no previous OASIS, the risk of AI after OASIS is even higher than calculated in this study. On the other hand, if more women who were unaware of having OASIS reported no AI, our results would show too strong effect of OASIS as a risk factor to AI.

We found an association between self-reported dermatological disease and self-reported AI for all parity groups, which has not been reported before. We can only speculate reasons for this association; women that have AI may also be more sensitive to dermatological bother than others, perhaps associated with the fecal incontinence with affection of perianal skin. Possibly, there could be a common tissue specific risk for both AI and dermatological conditions. Women who reported dermatological problems also reported more worries; another explanation could be that these women were in general more sensitive to different symptoms and signs. In a further study more detailed questions about the type of dermatological disease would be of interest when assessing co-morbidity in relation to symptoms of AI.

We have performed a large number of analyses due to a large number of detailed

information about obstetric history and maternal characteristics. The study population is relatively young, and thus, frequency of co-morbidity and medication use was very low among the participants, which can give results by chance. Therefore, all analyses were also performed without co-morbidity and medication use. This did not alter the conclusions; low educational level among nulliparous and OASIS among parous women were the most important factors associated to AI.

We conclude that among parous women, previous OASIS is the most important risk factor for anal incontinence and other obstetrical events only had a minor effect on development of AI. As OASIS is a modifiable risk factor, which frequency may rapidly be altered after introduction of obstetrical perineal support programs [29-32], prevention of obstetrical sphincter injury is likely the most important factor for reducing bothersome anal incontinence in fertile women. Efforts to reduce incidence of OASIS should be high prioritized in all delivery units.

References

Tables

Table 1. Anal incontinence defined in St.Mark's score in subgroups of women. Values are given in frequencies (numbers) or mean/median.

	Nulliparous (n=1792)		Parous (n=914)	
	St.Mark's 0-2	St.Mark's 3-16	St.Mark's 0-2	St.Mark's 3-16
Number of women	1653	139	824	90
Born in	P<0.001		P<0.001	
Western country (Western Europe, North America, Oseania)	93.2 (n=1448)	6.8 (n=106)	91.6 (n=717)	8.4 (n=66)
Non Western country (Asia, Africa, Eastern-Europe, Turkey, South or Central America)	86.1 (n=198)	13.9 (n=32)	81.7 (n=107)	18.3 (n=24)
Household income, USD	P=0.04		P=0.002	
91 000 or more	93.2 (n=1257)	6.8 (n=91)	92.0 (n=698)	8.0 (n=61)
Less than 91 000	90.0 (n=316)	10.0 (n=35)	82.9 (n=97)	17.1 (n=20)
Marital status	P=0.004		P=0.02	
Married	92.8 (n=632)	7.2 (n=49)	89.7 (n=503)	10.3 (n=58)
Co-habitating	92.6 (n=945)	7.4 (n=76)	93.0 (n=305)	7.0 (n=23)
Unmarried/living alone/single	82.5 (n=66)	17.5 (n=14)	75 (n=15)	25 (n=5)
Maternal educational level	P<0.001		P=0.008	
University 5 years or more	93.1 (n=707)	7.7 (n=136)	93.2 (n=398)	6.8 (n=29)
College/University 4 years	93.2 (n=685)	6.8 (n=50)	90.5 (n=294)	9.5 (n=31)
High school	91.3 (n=219)	8.8 (n=21)	84.5 (n=98)	15.5 (n=18)
Elementary/secondary school	69.8 (n=30)	30.2 (n=13)	81.3 (n=26)	18.8 (n=6)
Working	P=0.57		P=0.09	
Full-time, more than 90%	92.5 (n=1301)	7.5 (n=106)	91.3 (n=619)	8.7 (n=59)
Part-time 40-90%, sick-leave, studying, housewife	93.4 (n=297)	6.6 (n=21)	87.3 (n=186)	12.7 (n=27)
Maternal age mean/median (years)	30.1/30.0	30.6/30.0	33.0/33.0	32.9/34.0
Maternal age	P=0.04		P=0.82	
Less than 35 years	92.8 (n=1427)	7.2 (n=111)	90.3(n=523)	9.7 (n=56)
35 or more years	89 (n=226)	11.0 (n=28)	89.9 (n=301)	10.1 (n=34)

Prevalence of anal incontinence

BMI, mean	23.6	23.8	23.6	24.7
BMI	P=0.64		P=0.03	
16-24.9	92.4 (n=1201)	7.6 (n=99)	91.7 (n=594)	8.3 (n=54)
25-44.4	91.7 (n=443)	8.3 (n=40)	86.9 (n=226)	13.1 (n=34)
Smoking	P=0.93		P=0.73	
No	92.3 (n=1595)	7.7 (n=133)	90.1 (n=810)	9.9 (n=89)
Yes	92.7 (n=38)	7.3 (n=3)	92.9 (n=13)	7.1 (n=1)
Pregnancy duration when answered	P=0.04		P=0.13	
First trimester (6-12 weeks)	88.4 (n=175)	11.6 (n=23)	93.9 (n=124)	6.1 (n=8)
Second or third trimester (13-38)	92.5 (n=1437)	7.5 (n=116)	89.7 (n=672)	10.3 (n=77)
Obstetrical history				
OASIS			P=0.001	
No			90.8 (n=793)	9.2 (n=80)
Yes			75.6 (n=31)	24.4 (n=10)

Table 2. Risk of anal incontinence defined in St.Mark's score 3-16 compared to women with St.Mark's score 0-2. Crude OR and adjusted OR with confidence intervals. Adjusted OR is presented for significant variables only.

	Nulliparous (n=1792)		Parous (n=914)	
	Crude OR	aOR (95% CI)	Crude OR	aOR (95% CI)
Born in/Maternal origin				
Western (Western Europe, North America, Oseania)	1	1	1	1
Non Western (Asia, Africa, Eastern-Europe, Turkey, South or Central America)	2.21 (1.45-3.37)	1.54 (0.85-2.78)	2.44 (1.46-4.06)	1.04 (0.44-2.46)
Household income, NOK /USD				
500 000 or more 91 000	1	1	1	1
Less than 500 000	1.53 (1.02-2.30)	1.07 (0.63-1.80)	2.36 (1.36-4.08)	1.40 (0.63-3.14)
Marital status				
Married	1	1	1	1
Co-habitating	1.04 (0.71-1.51)	1.16 (0.76-1.77)	0.65 (0.39-1.08)	0.78 (0.46-1.36)
Unmarried/living alone/single	2.74 (1.43-5.22)	2.08 (0.91-4.74)	2.89 (1.01-8.24)	2.06 (0.54-7.89)

Prevalence of anal incontinence

Maternal educational level					
University 5 years or more		1	1	1	1
College/University 4 years		0.99 (0.66-1.48)	0.91 (0.60-1.40)	1.45 (0.85-2.45)	1.42 (0.81-2.49)
High school		1.30 (0.77-2.21)	1.16 (0.65-2.09)	2.52 (1.34-4.72)	1.85 (0.86-3.99)
Elementary/secondary school		5.89 (2.90-11.97)	3.88 (1.46-10.32)	3.17 (1.21-8.31)	1.00 (0.21-4.03)
Maternal age					
Less than 35 years		1	1	1	
35 or more years		1.59 (1.03-2.47)	1.62 (1.01-2.62)	1.06 (0.67-1.65)	
BMI					
16-24.9		1		1	1
25-44.4		1.10 (0.75-1.61)		1.66 (1.05-2.61)	1.36 (0.81-2.29)
Pregnancy duration when answered					
First trimester (6-12 weeks)		1	1	1	
Second or third trimester (13-38)		0.61 (0.38-0.99)	0.53 (0.32-0.90)	1.78 (0.84-3.77)	
Illness/disease					
Dermatological disease	No	1	1	1	1
	Yes	1.97 (1.15-3.40)	2.39 (1.36-4.20)	2.85 (1.51-5.40)	3.02 (1.51-6.02)
Ulcerative stomach	No	1	1		
	Yes	2.60 (1.13-6.00)	2.42 (0.95-6.15)		
Hypertension	No	1	1	1	
	Yes	2.60 (1.13-6.00)	2.05 (0.77-5.48)	0	
Rheumatoid arthritis or other muscular-skeletal problems	No	1	1	1	
	Yes	2.77 (1.36-5.62)	2.45 (1.14-5.31)	1.83 (0.74-4.51)	
Kidney/urinary problems	No	1		1	
	Yes	1.36 (0.85-2.18)		1.87 (0.94-3.72)	
Medication					
Pain killers	No	1		1	1
	Yes	1-10 (0.50-2.43)		2.40 (1.02-5.66)	1.80 (0.62-5.20)
Obstetrical history					
OASIS	No			1	1
	Yes			3.20 (1.51-6.76)	3.83 (1.68-8.73)

Prevalence of anal incontinence

Previous macrosomy, >4000 g	No	1	
	Yes	0.80 (0.42-1.51)	
Previous vacuum extraction	No	1	
	Yes	0.58 (0.29-1.15)	
Forceps	No	1	
	Yes	0.83 (0.19-3.58)	

Table 3. Distribution of St. Mark's score among parous women with OASIS and without OASIS.

	Parous women without previous OASIS	Parous women with previous OASIS
	n=873	n=41
St. Mark's 0	81.4 (n=711)	63.4 (n=26)
St. Mark's 1-2	10.4 (n=91)	12.2 (n=5)
St. Mark's 3-16	8.1 (n=71)	24.4 (n=10)
St. Mark's 5-16	3.8 (n=33)	12.2 (n=5)
St. Mark's 7-16	2.3 (n=20)	7.3 (n=3)

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II

MAIN RESEARCH ARTICLE

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

KATARIINA LAINE[1,2], FINN EGIL SKJELDESTAD[3], BIRGITTE SANDA[1], HILDEGUNN HORNE[1], ANNY SPYDSLAUG[1] & ANNE CATHRINE STAFF[1,2]

[1]Department of Obstetrics and Department of Gynecology, Oslo University Hospital, Ullevål, [2]Faculty of Medicine, University of Oslo, Oslo, and [3]Department of Obstetrics and Gynecology, Institute of Clinical Medicine, University of Tromsø, Tromsø, Norway

Abstract

Objective. To study prevalence and risk factors for anal incontinence (AI) after obstetric anal sphincter rupture. *Material and methods.* This was a retrospective clinical observational study. Among 14 959 vaginal deliveries, 591 women were diagnosed with obstetric anal sphincter ruptures (3.9%) at one Norwegian University Hospital in 2003–2005. Patients were examined and interviewed approximately 10 months after delivery. Anal continence was classified with St. Mark's incontinence score (0, complete anal continence; ≥ 3, anal incontinence), and defects in anal sphincter muscles were diagnosed by endoanal ultrasound. Prevalence of anal incontinence was assessed in relation to obstetrical and maternal characteristics as well as the correlation between anal incontinence and ultrasound-detectable defects of sphincter muscle. *Results.* Anal incontinence with a St. Mark's score of ≥ 3 was reported by 21% of women with obstetric anal sphincter rupture, with inability to control gas as the most prevalent symptom. Women with AI were more likely to report urinary incontinence compared with women having no AI. In a multiple regression analysis of maternal and obstetrical risk factors, fourth degree sphincter tear was the only significant risk factor for AI. Anal incontinence was more frequent in patients diagnosed with than without ultrasound-identified anal sphincter muscle defects at 10 months postpartum follow-up. *Conclusion.* Anal as well as urinary incontinence after delivery with obstetric anal sphincter rupture is common, and prenatal obstetric and maternal variables could not predict anal incontinence. Fourth degree perineal tear and a persistent ultrasound-detected defect in the anal sphincter muscles are associated with AI.

Abbreviations AI, anal incontinence; CI, confidence interval; EAS, external anal sphincter; IAS, internal anal sphincter; OASR, obstetric anal sphincter rupture; OR, odds ratio; UI, urinary incontinence

Introduction

Anal incontinence (AI) is defined as involuntary loss of flatus, liquid or solid stool (1) and is associated with significant morbidity and a negative impact on quality of life (2). Anal incontinence can lead to sexual dysfunction, hygienic problems, poor self-esteem and restrictions to social life and occupational activity.

Obstetric anal sphincter rupture (OASR) is assumed to be the most important risk factor for female anal incontinence (3–5), and high prevalence for AI (range 30–60%) is reported among women having undergone OASR (4,6). Other risk factors are probably also important, including damage to the pudendal nerve during delivery (7), ageing (8–11), rectal and anal surgery, as well as diseases such as diabetes and neurological disorders (12,13). In the general female population, the prevalence of AI is reported to range from 0.4 to 7.7%, but for patients attending gynecologic outpatient clinics, the AI rates are reported to vary from 5.6 to 15.9%, the latter in an urogynecological clinic setting (14).

Anal incontinence has been assessed with many very similar scoring systems, but only St. Mark's score has the advantage of including an urgency component in the AI score (15–19).

The aims of the study were to assess risk factors and prevalence of AI after obstetric anal sphincter rupture in a clinical setting at a Norwegian University hospital.

Material and methods

This retrospective study is part of a perineum research study that was evaluated and accepted by the Regional Committee for Medical Research Ethics in South-Eastern Norway (REK; ref. S-08810d/20941). All parts of the study have followed Norwegian Health Research legislation as well as institutional requirements and have been approved by the institutional Personal Data Officer. No patient consent was necessary in this retrospective substudy part, as it was evaluated both by the REK and by the Oslo University Hospital as an internal clinical quality control study with no personal data violation and with the possibility of presenting aggregated anonymous data.

Through 2003 to 2005, a total of 18 145 women delivered at the Department of Obstetrics, Oslo University Hospital, Ullevål, Norway. After exclusion of women with cesarean section, 600 cases of OASR were identified, among 14 959 women who delivered vaginally, by reviewing the diagnostic listing kept at the delivery wards. All 600 medical records were examined (both electronic and paper medical records for each patient) by a senior obstetrician (KL), and 22 false positive cases (with no OASR) were identified and excluded. The hospital electronic discharge diagnosis register identified 13 additional patients with OASR (ICD-10 codes O70.2 and O70.3), which were confirmed as cases after review of patient records. In total, 591 cases of OASR were identified, resulting in a prevalence of 3.9% among vaginal deliveries. All OASR surgical repair procedures were carefully evaluated in the medical charts to ascertain that all 591 study patients were correctly diagnosed with the correct degree of obstetric anal sphincter tear. Potential maternal, obstetric and fetal risk factors for OASR and AI were collected from the perinatal database and medical records, as follows: maternal age, marital status, parity, ethnicity, educational level, height, weight gain during pregnancy, body mass index (early and late in pregnancy), pregnancy duration, epidural use, episiotomy, delivery mode, fetal presentation, shoulder dystocia, duration of second stage labor, infant birthweight and head circumference, Apgar scores and degree of perineal tear (third or fourth).

Overall parity was corrected to vaginal parity. Fifty-nine of the study patients had one cesarean delivery (and no vaginal delivery) prior to the index delivery and were recoded as primiparas.

The anal sphincter tears were clinically diagnosed peroperatively using the standard classification of third or fourth degree perineal laceration (20) and routinely registered in the medical records. All women with OASR were primary operated immediately after delivery by end-to-end adaptation as standard method, either in the delivery room or in the operating theatre, by a resident doctor assisted by a consultant or a consultant alone. Clinical follow-up after OASR included treatment to avoid constipation and referral to pelvic muscle training with a physiotherapist from 6 weeks postpartum and to urogynecological outpatient examination 12 months after delivery. Lactulose was administrated postpartum during hospital stay and continued use was recommended after discharge.

Two experienced gynecologists performed outpatient postpartum OASR examinations, including routine gynecological examination, inspection and palpation of perineum and vagina and digital rectal exploration in order to assess anal sphincter muscle thickness, tonus and contractility. Endoanal two-dimensional ultrasound examination was performed to assess defects in external (EAS) and internal anal sphincter muscles (IAS). A B-K Medical HAWK 2101 EXL ultrasound machine with an endoanal probe (type 2050, 12 MHz) was used. All women were examined in the lithotomy position. The puborectalis muscle appears as a U-shaped sling and served as a reference point before moving the probe caudally. The IAS appears as a hypoechoic circle surrounding the anal mucosa, and the EAS appears as a hyperechoic circle surrounding the IAS. The gynecologists interviewed the women on anal and urinary incontinence (stress or urge), dyspareunia and sexual activity. Severity of anal incontinence was assessed with St. Mark's score, categorized as complete anal continence (score = 0) and AI (score ≥3), following definitions in two earlier Scandinavian studies (6,13). Cases with St. Mark's score 1–2 were analysed separately and defined as 'uncertain AI' due to uncertain clinical significance of the lowest scores. In cases lacking St. Mark's formula, the scores were determined from the medical records.

Statistical analyses were performed using SPSS version 16.0 (SPSS Inc., Chicago, IL, USA). Continuous data were categorized, and the independent variables are presented as frequencies, means or medians, where appropriate. Univariate analyses were performed by χ^2-test. Adjusted odds ratio (OR) 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.

Results

The scheduled outpatient follow-up after OASR was attended by 455 of the 591 women with OASR (77%), on average (mean and median) 10 months postpartum.

There were no significant differences with respect to maternal and obstetric risk factors between women who attended and women who did not attend scheduled follow-up. In our study, the majority of OASRs were third degree (93%), and 7% of the tears were fourth degree tears. The overall frequency of vaginal instrumental delivery as a percentage of this hospital's total deliveries (including cesarean sections) was 9.5% (8.5% delivered by ventouse and 1% by forceps), whereas the frequency of episiotomies was 20% (of all deliveries). In our study population of 591 women with OASRs, 75% occurred during spontaneous deliveries and 25% during instrumental deliveries. Most of the fourth degree tears occurred during spontaneous delivery (70%; 26 of 37), 24% (9 of 37) during ventouse, 3% (1 of 37) during forceps and 3% (1 of 37) after failed ventouse followed by forceps delivery.

At outpatient follow-up of women with OASR, the main complaint was the inability to control gas (affecting 33%; 151 of 455). Fecal incontinence was reported by 6% (26 of 455) and urgency for defecation by 9% (43 of 455) of the women. Total prevalence of anal incontinence was reported by 38% (171 of 455) of the women with OASR; 21% with St. Mark's score $\geq$3 and 17% with score 1–2.

In univariate analyses, AI (St. Mark's score $\geq$3) was associated with higher maternal age, macrosomia and fourth degree perineal tear (Table 1), using continent women as the reference group (St. Mark's score 0). Prevalence of AI after fourth degree tear and third degree tear was 51.4 and 18.4%, respectively ($p < 0.001$). In multivariate analyses, only fourth degree tear remained significant in prediction of AI in women with OASR (OR 5.6, 95% CI 2.6–12.0).

Endoanal ultrasound examination was recorded in 78% (357 of 455) of the women attending the follow-up, and demonstrated a defect in the anal sphincter muscles in 33% (118 of 357) of the women having undergone OASR. Clinical characteristics of those not examined with ultrasound did not differ from those who were examined.

One-third of the patients had an ultrasound-detectable defect (118 of 357) in the anal sphincter muscles. All defects identified by ultrasound examination were partial; no women had a total discontinuity of the sphincter muscles. The endoanal ultrasound examination revealed that 16.5% of the women had an isolated EAS muscle defect (59 of 357), whereas 11.5% had defects in both the IAS and EAS muscle (39 of 357). An isolated IAS defect was found in only 5.6% (20 of 357). A defect in the IAS (either isolated or combined with EAS) was detected by ultrasound at the postpartum follow-up in 39 women who were clinically diagnosed during OASR repair to have a tear solely in EAS during delivery.

Significantly more women with ultrasound-detected anal sphincter defects reported AI compared with women without diagnosed defects (Table 2). Prevalence of AI among women with a defect in EAS, IAS or both was 30.5, 35.0 and 64.1%, respectively.

Ultrasound-identified sphincter muscle defect was more frequent in women having undergone fourth degree tears compared with women having undergone third degree tears (83.3 vs. 28.4%), both for EAS only (23.3 vs. 15.9%) and for IAS only (13.3 vs. 4.9%), $p < 0.01$. After a fourth degree tear, the frequency of a persisting ultrasound-identified defect in both EAS and IAS was 10-fold compared with women having undergone third degree OASR (46.6 vs. 7.6%; OR 10.5; 95% CI 4.6–24.1).

Among the women who at follow-up reported anal incontinence (St. Mark's score 3 or higher, $n = 96$), 52% had a documented defect in the anal sphincter muscles, whereas 32% had no apparent defect identified by the endoanal ultrasound and 16% were not examined by ultrasound, due to equipment being unavailable.

Sixty-four per cent of women (289 of 455) reported that they had performed pelvic floor muscle exercises after discharge from hospital. There was no association between AI and pelvic floor exercise (data not shown), but adherence to exercise frequency and exercise intensity was not assessed.

Symptoms of stress and urge incontinence were analysed together as urinary incontinence (UI) and reported by 19% (87 of 455) of the women having undergone OASR. Prevalence of UI was doubled with AI (28.1%) compared with women having no anal incontinence (14.8%). Double incontinence (both UI and AI) was reported in 26% (45 of 171) of women with OASR, with no difference between women with AI defined as St. Mark's score $\geq$3 (28%: 27 of 96) and in the group with score 1–2 (24%: 18 of 75).

Discussion

Anal incontinence nearly 1 year postpartum could not be predicted with prenatal variables in this study of women having undergone OASR. Fourth degree perineal rupture was the only significant risk factor for AI in a multivariate regression analysis in this patient group. Furthermore, women with fourth degree perineal rupture were significantly more often diagnosed with persisting defects in anal sphincter muscles than women having undergone a third degree rupture (21–25).

The strength of our study is the population-based design, the large sample size, the high follow-up rate (77%) and a relatively long time interval from delivery with OASR to follow-up examination. The study population is non-selected, and the University Hospital delivered approximately 80% of the delivering women in the city of Oslo over the study period. The time interval from delivery to follow-up is probably important in relation to perceived symptoms (26). The time interval from delivery with OASR to follow-up examination in our study was 6–12 months, which is much longer than the 6–12 week postpartum interval used in many other published studies on AI after OASR (2,4,6,20,24,25,27,28). Most

Table 1. Maternal, fetal and obstetrical clinical characteristics of study participants by St. Mark's anal incontinence score; continent women compared with women having anal incontinence score ≥3 (score 0, continent vs. score ≥3, anal incontinence).

Characteristics	Percentage with St. Mark's score 0 (*n* = 284) (%)	Percentage with St. Mark's score ≥3 (*n* = 96) (%)
Maternal age (years) *p* = 0.05		
18–29	44.4	30.2
30–34	15.5	18.8
35–45	40.1	51.0
Ethnicity *p* < 0.55		
Western	73.9	77.1
Non-western	26.1	22.9
Parity (vaginal) *p* < 0.47		
0	79.2	75.0
≥1	20.8	25.0
Delivery mode *p* < 0.30		
Spontaneous	70.4	65.6
Ventouse	26.1	28.1
Forceps	3.5	6.2
Episiotomy	29.6	34.4
Duration of stage II (min) *p* < 0.96		
0–9	16.5	15.6
10–29	23.6	22.9
30–59	31.0	28.1
60–135	28.9	33.3
Infant birthweight (g) *p* < 0.05		
1 300–2 999	8.1	6.2
3 000–3 499	29.6	16.7
3 500–3 999	35.2	38.5
4 000–5 750	27.1	38.5
Head circumference (cm) *p* < 0.19		
24–34	20.4	15.6
35	24.3	17.7
36	30.6	32.3
37–41	24.7	34.4
Perineal rupture *p* < 0.01		
Third degree	95.8	80.2
Fourth degree	4.2	19.8

Table 2. Anal sphincter muscle defects diagnosed by ultrasound at postpartum examination and relation to St. Mark's anal incontinence score.

Defects	*n*	St. Mark's score 0 (%)	St. Mark's score 1–2 (%)	St. Mark's score >3 (%)
No defects	239	71.1	15.9	13.0
External anal sphincter muscle	59	52.5	16.9	30.5
Internal anal sphincter muscle	20	35.0	30.0	35.0
External and internal anal sphincter muscles	39	20.5	15.4	64.1

women in Norway are on paid maternity leave for many months postpartum, and complaints of AI might be easier to manage than if working outside the home (6). Therefore, a longer follow-up time after OASR, such as in our study, might give a more precise estimate regarding anal incontinence.

It is possible that a group of women chose not to attend the scheduled outpatient control due to less severe complaints than the remaining OASR group, thus introducing a possible selection bias in the follow-up cohort. However, there was no skewed distribution in maternal and obstetric characteristics among women who attended (77%) and did not attend (23%) the follow-up examination. Since fourth degree sphincter tear was the only significant risk factor for AI, it is unlikely that non-attendees suffered more often from AI, as there were no significant differences in frequency of fourth degree tear between attendees (8.1%) and non-attendees (4.4%). It is also unlikely that the patients were specifically followed up elsewhere. The follow-up consultation fee is very low in

Norway, and differences in income and social background are unlikely to represent a selection bias in this study.

There is no agreement for definition of severity of AI, and very different categorizing entities are used. Nazir et al. (6) used the frequency of complaints to define the severity of AI and Wexner score ≥2 (AI less than once per week but once or more than once per month) was defined as AI (19). Nordenstam et al. (13) defined fecal leakage with any frequency or loss of flatus more than once per week as severe AI, whereas loss of flatus once per week or less was considered as mild incontinence. In contrast, much higher incontinence scores have been used to define AI (2,29) than in our study. In our view, scores higher than 4 or 8 (Wexner or St. Mark's) represent very severe AI, as these high scores imply frequent complaints, such as weekly or daily gas and fecal leakage. Anal incontinence occurring this often is likely to represent a major burden for many women.

We categorized the patients into three groups of St. Mark's scores to evaluate degree of AI. Only the categories 'no AI' (score 0) and 'AI' (score ≥3) are shown in Table 1, as the majority of differences between no AI (score 0) and 'uncertain AI' (score 1–2) were not significant. We defined St. Mark's score 1–2 as 'uncertain' AI (6), comprising complaints such as gas leakage, faecal incontinence or impact in daily life occurring 'sometimes' or 'rarely'. In our study, one-fifth of all women with OASR reported AI, whereas uncertain AI was reported by 17% after OASR. If defining AI as St. Mark's score ≥5 (or ≥8), 9.2% (or 2.6%) of the women with OASR reported AI. Using these alternative thresholds for AI did not change the conclusions of this study; fourth degree OASR was still the only significant risk factor for AI (data not shown). Women with irritable bowel syndrome may also report low St. Mark's score independently of OASR (15), but we believe that such symptoms would be equivalently distributed in our study population and therefore not hamper our conclusions.

Interestingly, we showed that symptoms of UI were doubled in women reporting AI compared with women without AI. This association could be due to intrapartum damage or patient-related characteristics, such as support tissue weakness leading to both AI and UI.

Instrumental delivery, especially forceps delivery, is reported to increase the risk of AI (1,30). We could not demonstrate an association between instrumental delivery or other antenatal maternal and obstetric variables (such as age, education, ethnicity, pregnancy weight gain, maternal height, body mass index, pregnancy duration, induction of labor, episiotomy and delivery mode) and AI.

The ultrasound-detected sphincter muscle defects at the outpatient follow-up after OASR may result from an unsuccessful primary surgery, from a poor healing process with secondary defects or due to non-identified multiple sphincter injury at delivery (with a clinical repair of only one of the defects), or any combination of these alternatives. In our study, 39 patients had an ultrasound-detectable defect in IAS not diagnosed during primary operation.

Our study did not include a control group without OASR, as routine follow-up with postpartum endoanal ultrasound is not performed in women without a diagnosis of OASR. We cannot assess the incidence of de novo AI after delivery in this study, as we did not register prepregnancy AI symptoms.

In summary, our large and population-based study showed that it is not possible to predict AI with prenatal findings. Clinically, a reduction in the incidence of fourth degree perineal tear might reduce the prevalence of both anal and urinary incontinence after delivery, thus reducing a major health problem for delivering women. Careful diagnosis of OASR with good primary surgical technique immediately after delivery will probably also reduce the prevalence of AI after delivery. Prevention of OASR by good clinical practice during delivery may lead to reduced prevalence of AI and improved quality of life, both postpartum as well as later in life.

Funding

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AOGS | MAIN RESEARCH ARTICLE

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

KATARIINA LAINE[1,3], WENCHE ROTVOLD[4] & ANNE CATHRINE STAFF[1,2,3]

Departments of [1]Obstetrics and [2]Gynaecology, Oslo University Hospital, Ullevål, Oslo, [3]Faculty of Medicine, University of Oslo, Oslo and [4]Department of Obstetrics and Gynaecology, Østfold Hospital Trust, Fredrikstad, Norway

Abstract

Objective. To study changes in the incidence of obstetric anal sphincter rupture (OASR) during recent years in Denmark, Finland, Sweden and Norway and hospital-based incidence in recent years in Norway. *Design.* Retrospective birth register study. *Setting.* Unselected population of delivering women in four Nordic countries. *Sample.* All deliveries (574 175) registered in Denmark, Finland, Norway and Sweden, 2004–2010. *Methods.* Parity data, including maternal, obstetrical and fetal characteristics, were obtained. The incidence of OASR was calculated from vaginal deliveries. A chi-squared test was used to analyse differences between countries and time periods. *Main outcome measures.* Incidence of OASR. *Results.* During the study period, the OASR incidence in Finland was notably lower (0.7–1.0%) than in the other three Nordic countries (4.2–2.3%). A significant and constant reduction in OASR incidence was observed in Norway only (from 4.1 to 2.3%, from 2004 to 2010, $p < 0.001$). This reduction occurred simultaneously with introduction of a national intervention program of improved delivery techniques that aimed to reduce the incidence of OASR. No major alterations in maternal or fetal risk factors for OASR or registration routines could explain this rapid reduction in the rate of OASR. Differences in the incidence of OASR between Norwegian delivery units were significant, with a threefold difference when comparing the units with lowest and highest incidences. *Conclusions.* Obstetric anal sphincter rupture seems to be preventable to a considerable extent, as indicated by the rapid and lasting reduction of OASR incidence after implementation of perineal protection programs in Norway. Improved delivery techniques should be implemented in all delivery units to prevent OASR as much as possible.

Abbreviations: OASR, obstetric anal sphincter rupture; RCT, randomized controlled trial.

Introduction

Obstetric anal sphincter rupture (OASR) is a complication that most often occurs unexpectedly during a normal delivery. As women with OASR have an increased risk for anal and fecal incontinence, pain and sexual dysfunction, OASR may have an impact towards reducing a woman's quality of life after delivery (1–3).

The frequency of OASR has been selected as one of the health-care quality indicators in Organisation for Economic Co-operation and Development countries (http://www.

> **Key Message**
>
> Obstetric anal sphincter rupture (OASR) seems to be preventable to a considerable extent, as indicated by the rapid and lasting reduction of OASR incidence after implementation of perineal protection programs in Norway. Improved delivery techniques should be implemented in all delivery units to prevent OASR as much as possible.

oecd.org/dataoecd). The risk factors for OASR have been well studied, and primiparity, a large infant and instrumental vaginal delivery have been shown to be most important (4–6). An increasing incidence of OASR has been observed in the four largest Nordic countries during the most recent decades (5–8). Several reasons for this development are proposed, namely increased infant size, older mothers, increased use of instrumental deliveries, better quality and accuracy of diagnosis and registration of OASR, and changed clinical routines during the second stage of delivery (9–12). The impact on OASR rates ascribed to alteration in the use of perineal support during the second stage of delivery has been less studied. Manual perineal protection during the second stage of delivery became less practiced during the 1980s in many countries, simultaneously with the promotion of "natural delivery" as a better experience for the delivering woman. Alternative birth positions became popular, and traditional perineal protection with the accoucheur's hands became more difficult to perform when the delivering woman maintained standing and squatting birth positions. These changes in clinical delivery routines might have had an impact on the increasing occurrence of OASR in the Nordic countries (5,7,9,10,12).

The role of episiotomy in reducing OASR risk is controversial, but the type of episiotomy used is important. Median episiotomy has been known to increase the OASR risk (13), but large register studies reveal a protective effect with selective use of mediolateral or lateral episiotomy during delivery for primiparous women and especially with instrumental delivery (6,14–19).

Reducing the occurrence of OASR during delivery could diminish the prevalence of anal incontinence after delivery and thus might have a positive long-term impact on women's health. The Norwegian National Board of Health and the Norwegian Directorate of Health criticized the high incidence of OASR in Norwegian delivery units in 2004, and required hospitals, midwives and obstetricians to reduce the OASR rate by implementing improved delivery techniques. The main argument for the criticism from the Board of Health was the notably higher rate of OASR in Norway compared with a neighboring country, Finland, during the most recent decades (Figure 1; 7). Improvement of delivery techniques was recommended, including manual perineal protection. Training of the accoucheurs in both diagnosis and primary repair of OASR was also recommended. Promising results of reduced OASR rates from the first five hospitals with successful training programs for the delivery staff have been published (10,12).

The health-care systems are similar for the four Nordic countries, and this allows comparison between these countries as regards OASR rates. Low-fee public health care is
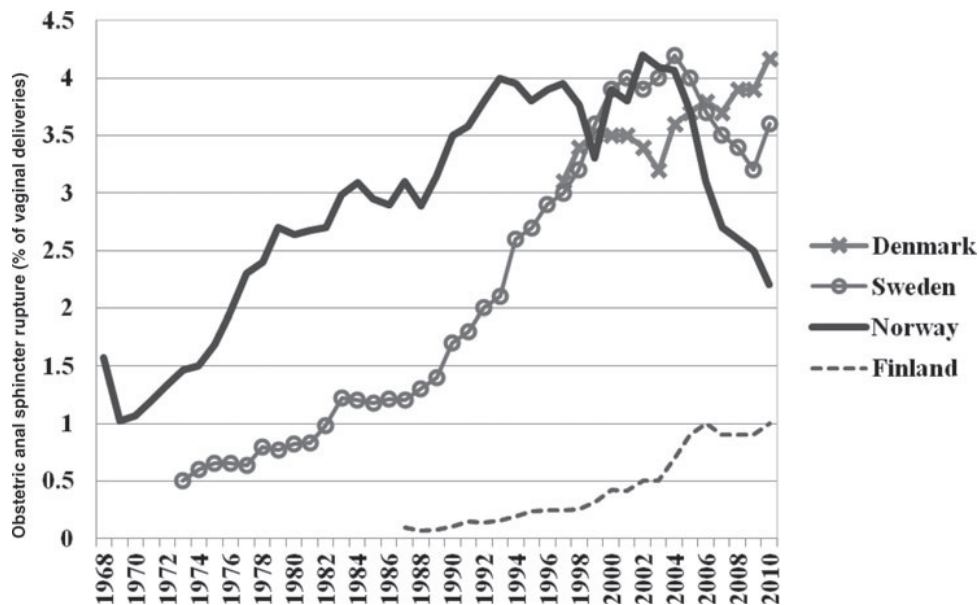
Figure 1. Incidence of obstetric anal sphincter rupture (as a percentage of vaginal deliveries) throughout the most recent decades in four Nordic countries.

provided to everyone, and almost all women deliver in public hospitals, with home deliveries being uncommon (<1%). Midwives are responsible for spontaneous deliveries, and an obstetrician is called to the delivery room when needed.

The aim of this study was to assess changes in the incidence of OASR in four Nordic countries (Denmark, Finland, Norway and Sweden) over the most recent years, as well as the incidence of OASR for individual delivery units within Norway.

Material and methods

Data were obtained from the national medical birth registries in Denmark, Finland, Norway and Sweden. The available periods with OASR information in the databases were as follows: Denmark, 1997–2010 (Medical Birth Register, National Board of Health; http://www.sundhedsstyrelsen.dk); Finland, 1987–2010 (Hospital Discharge Register 1987–2004 and Medical Birth Register 2004–2010; http://www.stakes.fi); Norway, 1968–2010 (Medical Birth Registry of Norway, National Institute of Public Health; http://www.mfr.no) and Sweden, 1973–2010 (Medical Birth Register, National Board of Health and Welfare; http://www.socialstyrelsen.se). The OASR incidences across the decades are presented from this.

A study period from 2004 to 2010 was chosen to present the main maternal and fetal characteristics and obstetrical interventions. For Norway, additional data from 12 delivery units were obtained from the Norwegian medical birth registry for the years 2004 and 2008–2010.

Third and fourth degree perineal tears [International Classification of Diseases (ICD)-9 664.2 and 664.3, ICD-10 O70.2 and O70.3], including all degrees of anal sphincter muscle injury, were analysed together as OASR. Data on the number of deliveries and the main obstetric, fetal and maternal factors, such as cesarean section, instrumental delivery, episiotomy, OASR, macrosomic infant, mean maternal age and distribution of primiparas, were collected. Cesarean sections were excluded in order to calculate the OASR and episiotomy rates in vaginal deliveries only. The chi-squared test was used to analyse differences between the countries and periods studied. A p-value <0.05 was considered significant. The data were analysed by using PASW (Predictive Analytics SoftWare, version 19.0; SPSS Inc., Chicago, IL, USA).

Results

The incidence of OASR reduced significantly (by 48%) from 2004 to 2010 in Norway (from 4.1 to 2.3%, $p < 0.001$; Figure 1). In Sweden, a 24% reduction in OASR rates was observed from 2004 to 2009 (from 4.2 to 3.2%, $p < 0.001$), but the OASR rate increased slightly in 2010 to 3.6% ($p < 0.001$). No similar reduction of OASR rates was registered in Denmark, which was the Nordic country with the highest OASR rate in 2010 (4.2%). In Finland, the OASR rate increased from

0.7% in 2004 to 1.0% in 2010, but the rate has been stable and the lowest in the Nordic countries over the last reported six years (Figure 1).

Maternal, fetal and obstetrical characteristics (cesarean section rate, OASR rate, episiotomy use, distribution of primiparous women, mean maternal age, instrumental deliveries, use of forceps, mean birthweight and distribution of macrosomic babies) for the respective countries are presented in Table 1 for 2004 and 2010. Main maternal and fetal characteristics, such as mean maternal age, distribution of primiparity and birthweight, were very similar for the four Nordic countries for these two years. The frequency of obstetrical procedures differed, however, between the countries. Denmark had a significantly higher cesarean section rate in 2010 than the other three countries ($p < 0.001$). The frequency of instrumental vaginal delivery in 2010 was highest in Norway (9.9%) and lowest in Denmark (7.8%). During the six-year period from 2004 to 2010, the frequency of instrumental delivery increased significantly by 15.0% in Norway (from 8.7 to 10% of all deliveries, $p < 0.001$). During the same period, the use of forceps increased in Norway by 34.4% (from 1.28 to 1.72% of all deliveries, $p < 0.001$; Table 1) and vacuum extraction by 11.2% (from 7.4 to 8.2% of all deliveries, $p < 0.001$).

Episiotomy was rarely used in Denmark and Sweden during the study period (5.0 and 5.8% of all vaginal deliveries in 2010, respectively; Table 1). Use of episiotomy increased by 7% in Norway from 2004 to 2010 (from 17.8 to 19.1%, $p < 0.001$), simultaneously with the 48% reduction in OASR rates (from 4.2 to 2.3% of vaginal deliveries). In the same time period, use of episiotomy was reduced in Finland from 32 to 24% (vaginal deliveries, $p < 0.001$), while the OASR rate increased slightly from 0.7 to 1.0% ($p < 0.001$).

The Norwegian delivery units with the lowest and highest OASR rates are presented in Figure 2. All the presented delivery units have reduced their OASR rates over the past years. However, there are notable and time-consistent variations in the OASR rates between the Norwegian delivery units. Figure 2 shows that the OASR rate in 2010 was threefold higher in the delivery units with the highest rates compared with those with lowest rate ($p < 0.001$). This difference in OASR rates between the delivery units remained significant over the studied years. Units with a structured and documented perineal protection program had lower OASR rates than the mean Norwegian OASR rates, as illustrated by the seven delivery units depicted to the left of the national OASR rate average for Norway (Figure 2). Notable differences in the OASR rates between the delivery units were also observed in the three other countries. In Denmark, the OASR rates 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

Table 1. Population characteristics, obstetric interventions and obstetric anal sphincter ruptures in four Nordic countries in 2004 and 2010.

Characteristics	Denmark	Finland	Norway	Sweden
Number of deliveries, vaginal and cesarean				
2004	62 874	56 878	56 889	99 571
2010	62 682	60 421	61 536	113 324
Cesarean section rate (% of all deliveries)				
2004	20.5	16.6	15.4	16.8
2010	21.2	16.3	16.8	16.9
Number of women with obstetric anal sphincter rupture				
2004	1772	262	1982	3447
2010	2012	518	1142	3361
Obstetric anal sphincter rupture (% of vaginal deliveries)				
2004	3.6	0.7	4.1	4.2
2010	4.2	1.0	2.3	3.6
Episiotomy (% of vaginal deliveries)				
2004	9.8	32.0	17.8	8.1
2010	5.0	24.1	19.1	5.8
Primiparous women (% of all deliveries)				
2004	42.9	42.2	41.2	44.8
2010	44.1	42.2	42.9	44.9
Mean maternal age (years), all deliveries				
2004	30.6	30.1	29.6	30.2
2010	30.6	30.1	29.7	30.3
Instrumental delivery (% of all deliveries)				
2004	8.1	6.9	8.7	9.4
2010	7.8	8.7	10.0	9.2
Forceps (% of all deliveries)				
2004	n.a.	0.1	1.3	n.a.
2010	n.a.	0.0	1.7	n.a.
Mean birthweight (g), all deliveries				
2004	3485	3518	3533	3530
2010	3466	3490	3491	3509
Macrosomia >4000 g (% of all deliveries)				
2004	18.8	18.6	20.8	19.6
2010	17.0	16.7	17.8	18.5
Macrosomia >4500 g (% of all deliveries)				
2004	3.7	3.0	4.3	4.0
2010	3.0	2.5	3.2	3.6

Abbreviation: n.a., information not available in medical birth registry.

deliveries were taken into account; data from the national birth registries, respectively).

Discussion

A large (48%) and lasting reduction in the OASR rate was observed only in Norway among the four large Nordic countries throughout a seven-year period. Owing to the reduction in

OASR rates from 4.2 to 2.3% in Norway, it may be estimated that over 4600 OASRs have been avoided since 2004.

Among the four Nordic countries, only Norway, to our knowledge, had introduced a national program aimed at reducing the incidence of OASR. The notable OASR reduction in Norway has been rapid and occurred simultaneously with implementation of perineal protection programs in many delivery units. Figure 2 shows that by 2010 some delivery
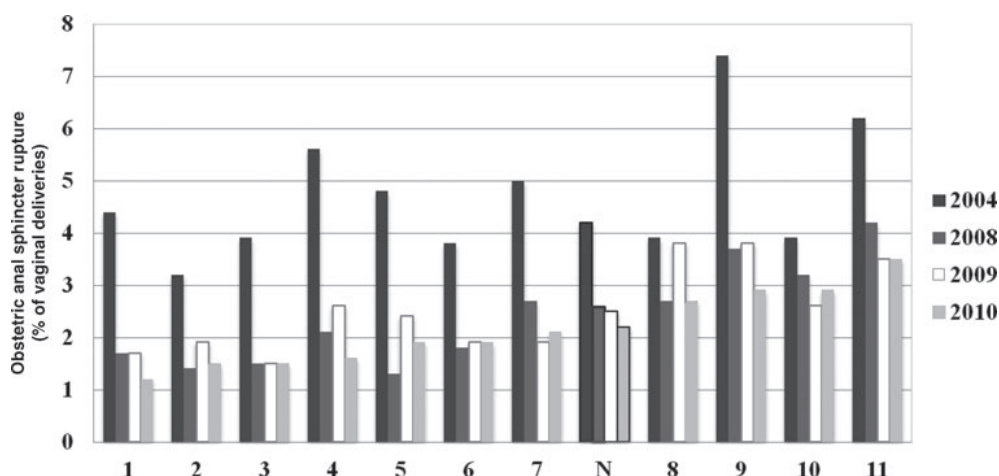
Figure 2. Incidence of obstetric anal sphincter rupture (OASR; as a percentage of vaginal deliveries) for four years in 11 Norwegian delivery units and the mean incidence of OASR for Norway (N). The hospitals with the lowest (1–7) and highest OASR rate (8–11) in Norway in 2010 are presented.

units in Norway had almost reached the same very low level of OASR rates as the neighboring country Finland. The incidence of OASR has also increased significantly in Finland over the most recent decades, but has remained low over the last few years, and is still lower than in the other Nordic countries. In Denmark, the OASR rates are still increasing from year to year and, to our knowledge, no national intervention program to reduce OASR occurrence has been launched in Denmark.

The changes in maternal and fetal characteristics from 2004 to 2010 were small (Table 1) and cannot explain the marked reduction in the OASR rates in Norway. The changes in maternal and fetal characteristics over the last decades that could have had an impact on the OASR rates are similar for all the studied Nordic countries. The mean maternal age has been increasing, and newborns are larger than during previous decades (as shown by Laine et al.; 7). Use of vaginal instrumental delivery is increasing, as are cesarean section rates in all four Nordic countries (7). Variation in the frequency of instrumental delivery cannot explain the differences in OASR rates between the four countries. On the contrary, Norway has the highest and Denmark the lowest rate of instrumental vaginal delivery, while the OASR rates are of opposite magnitude for these two countries. In fact, the rates for both vacuum extraction and forceps delivery increased in the seven-year study period in Norway, concurrently with the 48% OASR rate reduction. Interestingly, Denmark has the highest OASR rates among the four Nordic countries, but also the highest cesarean section rate and lowest vaginal instrumental delivery rate. In Sweden, the large

hospitals with the highest OASR rates also had the highest cesarean section rates (http://www.socialstyrelsen.se), demonstrating that more frequent cesarean section rates are not necessarily associated with lower OASR rates for vaginal deliveries.

Episiotomy rates were fourfold higher when Finland and Norway (the two countries with the lowest OASR rates in 2010) were compared with Denmark and Sweden. This could partly explain the differences in OASR rates. Episiotomy should be used only when indicated and not routinely; however, episiotomy rates lower than <10% (of vaginal deliveries), as in Denmark and Sweden, might be too low and may possibly contribute to the higher rates of OASR (15,19,20).

A weakness in this study is that perineal protection is not routinely registered in medical records or in the medical birth registries, and we were not able to assess its role directly in this register study. Another weakness is that a register-based study includes possible failures of registration and missing data. However, data from the mandatory and population-based Nordic birth registries are considered to be of good quality (21,22). Definition and diagnostics of perineal laceration are similar in the Nordic countries, and diagnostic differences or under-reporting of OASR are not likely to explain the registered differences in the OASR rates between or within the countries. A sudden change in reporting routines from the midwives and doctors in Norway resulting in almost 50% under-reporting in 2010 compared with 2004 is very unlikely. The most likely cause of the rapid 48% reduction in OASR registration rates in Norway is therefore a real reduction in OASR occurrence.

There is no reason to assume that the consistent OASR rate variations between the Nordic countries are by chance. Country-wise and time-trend OASR data, together with the maintained perineal-supporting Finnish delivery tradition with the lowest OASR rate and the Norwegian development over the last years, could be interpreted in favor of introducing manual perineal protection for reducing the OASR incidence. Reports from Finland indicate that manual perineal protection is still a routine during the last part of the second stage of delivery (5,9), while a trend of "hands off" has become accepted in, for example, the United Kingdom (23). Our personal experience is that perineal support became less routinely performed in Norway from the 1980s. Also, institutional data from Norway are consistent with a positive effect of perineal support. As seen in Figure 2, the seven delivery units with the lowest OASR rates in Norway are those that have implemented a structured training program for manual perineal protection for the delivery staff, and five units have published their data (10,12). We therefore believe that variations in the use of manual perineal protection and episiotomy can have contributed to the observed reduction in OASR rates over the most recent decades in Norway and to the observed differences in OASR rates between the Nordic countries.

A randomized controlled trial (RCT) would be the gold-standard method to study the exact effect of manual perineal protection during delivery on OASR occurrence. However, conducting an RCT during the second stage of delivery is challenging. Some of the most important challenges in conducting an RCT include difficulties in recruitment of patients, varying compliance of delivering staff, contamination of methods in different study arms and blinding (of staff or patients). Most of the previously published RCTs concerning perineal protection did not have OASR as a primary outcome, but other outcomes, such as perineal injuries in general (including first and second degree tears) or postpartum perineal pain, and were therefore underpowered to assess OASR (24). These studies failed to describe standardized methods used in perineal manipulation, and no structured education of the participating staff was described.

The rapid and consistent decrease in OASR incidence in Norway after the introduction of perineal support programs would justify the general implementation of such a procedure. Ethically, one can question whether at present it would even be correct to perform an RCT comparing routine perineal support or not, as the clinical "experience" in Norway over the last few years indicates that perineal protection is beneficial. "Clinical equipoise" has been defined as when there is genuine uncertainty within the expert medical community about the preferred treatment (25,27), and it is an ethical requisite when comparing two treatment allocations. The rapid effect of the intervention programs in delivery units in Norway suggests a potential lack of "equipoise" in an RCT, where the women allocated to "no perineal support" would receive inferior treatment compared with those allocated to "perineal support."

We conclude that the OASR rates can be reduced, with an effect on the prevalence of anal incontinence, thereby improving women's health. Hospitals with high OASR rates should learn from the units that have managed to reduce their rates, so that all women can be offered optimal manual perineal protection during delivery.

Funding

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IV

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

Katariina Laine,[1,2] Finn Egil Skjeldestad,[3] Leiv Sandvik,[4] Anne Cathrine Staff[2,5]

ABSTRACT

Objective: To compare the incidence of obstetric anal sphincter injuries (OASIS) in two time periods, before and after implementing a training programme for improved perineal support aimed at reducing the incidence of obstetric anal sphincter injuries. The secondary aim was to study incidence of obstetric anal sphincter injuries in subgroups defined by risk factors for OASIS.

Design: Population-based cohort study.

Setting: University hospital setting in Oslo, Norway.

Participants: Two cohorts of all delivering women in the largest hospital in Norway during two time periods (2003–2005 and 2008–2010) were studied. After excluding caesarean sections and preterm deliveries (< week 32), the study population consisted of 31 709 deliveries, among which 907 women were identified with obstetric anal sphincter injury.

Primary and secondary outcome measures: Incidence of OASIS in two time periods. Maternal, obstetrical and foetal risk factors for OASIS were collected from the hospital obstetric database. Univariate analyses and multivariate logistic regression analyses, presenting adjusted ODs for OASIS, were performed.

Results: The OASIS incidence was significantly reduced by 50%, from 4% (591/14787) in the first time period to 1.9% (316/16 922) in the second. This reduction could not be explained by changes in population characteristics or OASIS risk factors during the study years. The reduction of incidence of OASIS between the two study periods was consistent across subgroups of women; regardless of parity, delivery method and infant birth weight.

Conclusions: A marked reduction in the incidence of OASIS was observed in all studied subgroups of women after implementing the training programme for perineal protection. Further, this reduction could not be explained by the differences in patient characteristics across the study period. These findings indicate that the training programme with improved perineal protection markedly reduced the risk of OASIS.

For numbered affiliations see end of article

Correspondence to
Dr Katariina Laine;
kattiksen@yahoo.no

INTRODUCTION

Obstetric anal sphincter injury is a serious maternal complication during a vaginal delivery with reported incidences varying from 1% to 6%,[1–5] and occurs even in otherwise uncomplicated deliveries. Obstetric anal sphincter injuries (OASIS) may cause pain, discomfort and anal incontinence (AI).[6–8]

Risk factors for OASIS have been widely studied, with several hundred studies

currently available in PubMed, assessing maternal, obstetric and foetal risk factors. Numerous factors have been investigated and focus has often been on factors that are not modifiable, such as maternal age, height, weight, ethnicity, foetal weight and head size. Most previous studies conclude that primiparity, large infant birth weight and instrumental delivery increase the risk of OASIS, but when exploring factors such as maternal age (young or advanced), ethnicity, epidural use and episiotomy, the results are conflicting.[9–14] Risk factors unrelated to the delivering woman or the infant size, such as the accoucheurs' management of the second stage of delivery, have been less investigated.

The incidence of OASIS varies between countries and delivery units.[2–5][15] A steadily increasing incidence of OASIS has been reported in the Nordic countries over the last decades,[2][5][15][16] albeit still at a very low rate in Finland.[2] Factors such as alterations in patient population over time (increasing maternal age, larger infants and increased use of instrumental delivery) have been studied, but such factors cannot alone explain the increasing incidence of OASIS.[5][15]

In 2004, the Norwegian National Board of Health criticised the delivery units for a high incidence of OASIS, at that time being 4.5% of vaginal deliveries, and required that hospitals should implement programmes to reduce the OASIS incidence. Programmes to introduce manual perineal protection in the second stage of delivery were implemented in many Norwegian hospitals, and a reduction in OASIS incidence was achieved.[17][18] In the Obstetric Department at Oslo University Hospital, Ullevål, attempts to reduce the incidence of OASIS were developed in steps, starting in 2006 with more focus on the OASIS issue in clinical meetings, whereas practical training to improve protection of perineum during the second stage of delivery started in 2008. Such training programmes have previously been described in two studies.[17][18]

The primary aim of the present study was to compare the incidence of OASIS across two time periods, before and after implementing a training programme for perineal protection during second stage of delivery, aimed at reducing the incidence of OASIS. A secondary aim was to study the incidence of OASIS in subgroups of women defined by risk factors.

METHODS

The study was conducted as a retrospective cohort study, in the largest delivery unit in Norway, at a university hospital with an unselected patient population in Oslo, with 7000 deliveries annually. Two cohorts from two time periods were studied, 2003–2005 and 2008–2010, before and after the intervention of a training programme for manual perineal protection during the second stage of delivery.

Databases and participants

Data were obtained from the hospital obstetric database, the electronic hospital discharge register, individual electronic and paper-based medical records, and from the manually assembled labour protocols at the delivery unit, during the time period from 2003 to 2010. Two cohorts were chosen to the study, 2003–2005 and 2008–2010.

Women with obstetric anal sphincter injuries were identified from the labour protocols at the delivery unit and validated against individual electronic and paper-based medical charts (by the first author: KL). Surgery notes for the perineum repair in the medical record for each case were carefully read, and false-positive cases were excluded (n=22). In addition, patients with the diagnosis OASIS (ICD-10 code O70.2 or O70.3) were identified from the electronic hospital discharge register and 13 additional patients with OASIS were identified. After excluding women delivered with caesarean section, preterm deliveries (< week 32), triplets and quadruplets, the study population comprised 31 709 deliveries, of which 907 women with OASIS.

Definition and diagnostics of OASIS

Obstetric anal sphincter injury was defined as any degree of injury in the anal sphincter muscle (3A, 3B, 3C and 4th degree perineal tears, identified by the diagnoses O70.2 and O70.3 in the ICD-10 system).[19]

In Norway, spontaneous deliveries are attended by midwives whereas instrumental deliveries are handled by physicians. To increase safety during delivery for both the mother and the infant, the procedure at our department requires at least two accoucheurs (two midwives or one midwife and a physician) attending the second and third stage of each delivery. If the midwife suspects OASIS, a physician attends the labour room and evaluates and classifies the degree of perineal tear. The written procedure of the department is that a standardised surgical OASIS repair (end-to-end technique) is always performed under direct surveillance of an experienced obstetrician or gynaecologist (consultant).

Risk factors for OASIS

Information on maternal, obstetrical and foetal risk factors for OASIS was collected, including maternal age, parity, year of delivery, labour induction, delivery method, duration of second stage of labour, epidural use, episiotomy, persistent occiput posterior presentation, shoulder dystocia, infant birth weight and infant head circumference.

The intervention programme

The need to reduce the incidence of OASIS was discussed among delivery personnel in clinical meetings from 2006. An intervention programme was implemented from 2008, including both midwives and physicians at the Department of Obstetrics and Gynaecology. An external midwife was hired in from another hospital (where a similar programme was previously successfully implemented) to educate a group of trainer-midwives, who then further educated the entire midwife-staff.

Physicians (both registrars and specialists) were educated in the perineal supporting technique and supervised by KL. First part of the training included a practical hands-on training on a pelvic delivery model and the second part included hands-on supervision in labour room during the second stage of delivery. The perineum protection programme consisted of four components during the last part of second stage of delivery, when the baby's head is crowning: slowing the delivery of the baby's head with one hand, supporting perineum with the other hand and squeezing with fingers (first and second) from the perineum lateral parts towards the middle in order to lower the pressure in middle posterior perineum, and asking the delivering woman not to push. The fourth part of the intervention was education in correct performing of episiotomy. At our department, episiotomy is performed only when indicated, for example due to foetal distress or imminent severe perineal tear. The main focus of this intervention step was to avoid median cuts of episiotomy technique, when performed, due to the augmented risk of OASIS associated with median episiotomies.[20]

Comparison of groups

The clinical characteristics of the study participants in the first (2003–2005) and second (2008–2010) time period were compared in order to identify possible population differences of delivering women between the two time periods (table 1).

Statistical analysis

Incidence of obstetric anal sphincter injuries was calculated from vaginal deliveries only and the data were stratified according to parity. Parity was adjusted to vaginal parity; women with one previous caesarean delivery only (never having delivered vaginally before) were categorised as 'vaginal primiparous' (n=440).

The risk factors for OASIS were calculated and presented separately for the two cohorts. Continuous data were categorised and the independent variables are presented as frequencies. Univariate analysis was performed to explore the significant risk factors. Variables with $p \leq 0.10$ were included in the multivariate analysis. Univariate analyses were performed by χ^2 test. A significance level of 5% was chosen in all analyses. Adjusted ORs (aORs) for OASIS with 95% CI are reported from multivariate logistic regression analyses. The data were analysed by using PASW (Predictive Analytics SoftWare, SPSS Inc, V.19.0, Chicago, Illinois, USA).

RESULTS

Overall incidence of anal sphincter injury in vaginal deliveries was significantly reduced by 50%, from 4%

Table 1 Clinical characteristics and obstetric interventions for the whole study population. Data are presented in frequencies (and numbers). p Values from χ^2 test

Time period	Primiparous women		Multiparous women	
	2003–2005	2008–2010	2003–2005	2008–2010
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
Risk factors				
Age (years)	p<0.001		p<0.001	
15–29	48.3 (n=3885)	43.8 (n=3872)	27.4 (n=1849)	21.4 (n=1730)
30–34	39.3 (n=3164)	40.8 (n=3604)	42 (n=2823)	40.7 (n=3287)
35–51	12.4 (n=1002)	15.4 (n=1361)	30.6 (n=2064)	37.9 (n=3068)
Birthweight (g)	p=0.003		p=0.60	
720–2999	16.4 (n=1321)	16.4 (n=1446)	11.8 (n=794)	11.6 (n=938)
3000–3499	37.9 (n=3050)	39.2 (n=3470)	32.5 (n=2191)	32 (n=2591)
3500–3999	33.2 (n=2670)	33.8 (n=2983)	36.3 (n=2447)	37.5 (n=3029)
4000–4499	11 (n=885)	9.3 (n=821)	15.6 (n=1049)	15.4 (n=1247)
4500–5850	1.5 (n=125)	1.3 (n=117)	3.8 (n=255)	3.5 (n=280)
Delivery method	p<0.001		p=0.45	
Spontaneous	81.5 (n=6558)	78.3 (n=6918)	96.2 (n=6479)	96.4 (n=7793)
Ventouse	16.5 (n=1331)	20.4 (n=1802)	3.5 (n=234)	3.4 (n=273)
Forceps	2 (n=162)	1.3 (n=117)	0.3 (n=23)	0.2 (n=19)
Episiotomy, all vaginal deliveries	p<0.001		p=0.066	
	31.4 (n=2528)	36.2 (n=3203)	7.3 (n=492)	8.1 (n=656)
Episiotomy, spontaneous deliveries	p=0.006		p=0.98	
	24.7 (n=1620)	22.7 (n=1569)	6.1 (n=396)	6.1 (n=477)
Episiotomy, instrumental deliveries	p<0.001		p<0.001	
	60.8 (n=908)	85.1 (n=1634)	37.4 (n=96)	61.3 (n=179)
Duration second stage (min)	p=0.057		p=0.45	
0–29	34.1 (n=2736)	32.5 (n=2864)	84.9 (n=5696)	85.4 (n=6895)
30–59	41 (n=3290)	41.6 (n=3673)	12.5 (n=839)	11.9 (n=957)
60–205	24.9 (n=1994)	25.9 (n=2288)	2.6 (n=174)	2.7 (n=219)

Reducing risk of OASIS

(591/14787) in the first time period (2003–2005) to 1.9% (316/16 922) in the second time period (2008–10). The reduction of the incidence of OASIS was of similar magnitude across all studied subgroups defined by risk factors, for both primiparous and multiparous women (table 2).

The incidence of OASIS over the study years is displayed in figure 1, demonstrating a reduced incidence of OASIS, which in time follows the implementation of the perineum support programme for the staff.

Figure 1 also demonstrates a similar reduction of OASIS incidence for the different delivery methods (operative and spontaneous vaginal delivery) between the two study periods: in spontaneous deliveries the OASIS incidence was reduced from 3.1% (409/13 037) to 1.5% (215/14711) and in ventouse 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).

Table 2 Incidence of OASIS in different subgroups of women. Data are presented in frequencies (and numbers). p Values from χ^2 test

	Primiparous women			Multiparous women		
Time period	2003–2005	2008–2010		2003–2005	2008–2010	
OASIS	6.1 (489/8051)	3 (263/8837)		1.5 (102/6736)	0.7 (53/8085)	
Risk factors						
Age (years)			P			P
15–29	5.5 (212/3885)	2.8 (107/3872)	<0.001	1.4 (25/1849)	0.5 (9/1730)	0.01
30–34	6.7 (212/3164)	3.3 (118/3604)	<0.001	1.6 (45/2823)	0.7 (22/3287)	0.001
35–51	6.5 (65/1002)	2.8 (38/1361)	<0.001	1.6 (32/2064)	0.7 (22/3068)	0.004
Birthweight (g)						
720–2999	3 (39/1321)	1.6 (23/1446))	0.016	0.4 (3/794)	0.5 (5/938)	0.63
3000–3499	4.4 (135/3050)	2.6 (90/3470)	<0.001	0.8 (18/2191)	0.4 (10/2591)	0.049
3500–3999	7.2 (192/2670)	3.4 (101/2983)	<0.001	1.3 (33/2447)	0.6 (19/3029)	0.006
4000–4499	11.2 (99/885)	4.8 (39/821)	<0.001	3.2 (34/1049)	0.7 (9/1247)	<0.001
4500–5850	19.2 (24/125)	8.5 (10/117)	0.017	5.5 (14/255)	3.6 (10/280)	0.28
Delivery method						
Spontaneous	4.8 (318/6558)	2.5 (170/6918)	<0.001	1.4 (91/6479)	0.6 (45/7793)	<0.001
Ventouse	10.8 (144/1331)	5 (90/1802)	<0.001	3.4 (8/234)	2.9 (8/273)	0.75
Forceps	16.7 (27/162)	2.6 (3/117)	<0.001	13 (3/23)	0 (0/19)	0.10
Episiotomy, all deliveries						
Yes	6.6 (166/2528)	3 (96/3203)	<0.001	2 (10/492)	1.8 (12/656)	0.80
No	5.8 (323/5523)	3 (167/5634)	<0.001	1.5 (92/6244)	0.6 (41/7429)	<0.001
Episiotomy, spontaneous deliveries						
Yes	4 (65/1620)	2.2 (34/1569)	<0.003	1.3 (5/396)	1.3 (6/477)	1
No	5.1 (253/4938)	2.5 (136/5349)	<0.001	1.4 (86/6083)	0.5 (39/7316)	<0.001
Episiotomy, instrumental deliveries						
Yes	11.1 (101/908)	3.8 (62/1634)	<0.001	5.2 (5/96)	3.4 (6/179)	0.45
No	12 (70/585)	10.9 (31/285)	0.64	3.7 (6/161)	1.8 (2/113)	0.34
Duration second stage (min)						
0–09	4.6 (13/281)	3.3 (9/273)	0.42	0.9 (20/2335)	0.4 (10/2390)	0.058
10–29	4 (99/2455)	2.9 (74/2591)	0.02	1.5 (50/3361)	0.5 (21/4505)	<0.001
30–59	5.5 (180/3290)	2.5 (93/3673)	<0.001	2.9 (24/839)	1.7 (16/957)	0.09
60–205	9.7 (193/1994)	3.8 (87/2288)	<0.001	4 (7/174)	2.3 (5/219)	0.32
Epidural						
Yes	6.5 (228/3494)	3 (128/4267)	<0.001	2 (20/1008)	0.8 (12/1419)	0.015
No	5.7 (261/4557)	3 (135/4570)	<0.001	1.4 (82/5728)	0.6 (41/6666)	<0.001
Shoulder dystocia						
Yes	15.8 (12/76))	14.1 (9/64)	0.78	5.7 (5/87)	4.1 (3/73)	0.64
No	6 (477/7975)	2.9 (254/8773)	<0.001	1.5 (97/6649)	0.6 (50/8012)	<0.001
Occiput posterior presentation						
Yes	11.4 (20/176)	6.9 (17/245)	0.11	0.7 (1/150)	1.7 (4/237)	0.39
No	6 (469/7875)	2.9 (246/8592)	<0.001	1.5 (101/6586)	0.6 (49/7848)	<0.001
Induced labour						
Yes	5.5 (75/1365)	3 (50/1650)	0.001	1.3 (12/903)	0.7 (9/1269)	0.18
No	6.2 (414/6686)	3 (213/7187)	<0.001	1.5 (90/5833)	0.6 (44/6816)	<0.001

OASIS, obstetric anal sphincter injuries.
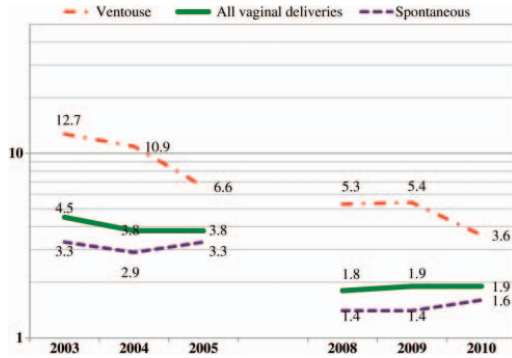
Figure 1 Frequency of obstetric anal sphincter injuries (%) for different delivery methods during the study years.

Population characteristics across the study years

Overall changes in population characteristics between the two time periods were small, but the prevalence of older women (>35 years) was significantly higher in the second period (2008–10), and use of ventouse delivery, episiotomy, epidural and induction of labour was more frequent (table 1). Primiparous women comprised 85% of the women with OASIS, but represented only 53.3% of the overall study population.

Primiparous women

In a univariate analysis, higher infant birth weight, larger infant head circumference (data not shown), prolonged second stage of labour, instrumental delivery, shoulder dystocia and persistent occiput posterior presentation were significant OASIS risk factors for primiparous women in the first study period (table 3). In the second study period, the same OASIS risk factors remained significant, except for a prolonged second stage of labour (table 3).

Looking at the various explanatory variables (such as age, maternal body mass index, foetal weight, etc) and analysing time period solely as an explanatory variable for OASIS (due to the perineal protection programme introduced in the second time period), we observed that the first time period emerged as one of the most important 'risk factors' with high OR for OASIS in our study. Without adjusting for any other variables, OR for OASIS in the logistic regression analysis for the first study period as compared with the second was 2.10 (95% CI 1.76 to 2.40).

In a multivariate regression analysis (table 4), 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 (table 1). When adjusted for risk factors in the multivariate analysis, episiotomy appeared as a protective factor for OASIS in both time periods for primiparous women (table 4).

Primiparous women with a previous caesarean section only, and no previous vaginal delivery (n=440), 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 programme. 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.

Multiparous women

In a univariate analysis for multiparous women (table 5), instrumental delivery, prolonged second stage of delivery, shoulder dystocia, large infant head circumference (data not shown) and birth weight were significant risk factors for OASIS in both time periods. 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 with the second was 2.31 (95% CI 1.65 to 3.25).

In the multivariate regression analysis (table 4), macrosomia and instrumental delivery significantly increased the OASIS risk for multiparous women 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 (table 4). However, multiparous women with episiotomy were very few in this study and interpretation of the results should be undertaken cautiously (tables 2 and 5).

DISCUSSION

In this study, comprising 31 709 vaginal deliveries, the OASIS incidence was reduced by 50% after introduction of a training programme on perineal protection during the second stage of delivery, aimed at reducing incidence of OASIS. The reduction in the OASIS incidence was similar in all subgroups defined by OASIS risk factors.

Similar reduction in OASIS following alteration in clinical routines and intervention programmes during the second stage of delivery have been presented

Table 3 Clinical characteristics and obstetric interventions among primiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). p Values from χ^2 test

Primiparous women	2003–2005		2008–2010	
	OASIS	Non-OASIS	OASIS	Non-OASIS
Deliveries	n=489	n=7562	n=263	n=8574
Incidence OASIS	6.1 (489/7562)		3 (263/8574)	
Risk factors (%)				
Age (years)	p=0.08		p=0.39	
15–29	43.4 (n=212)	48.6 (n=3673)	40.7 (n=107)	43.9 (n=3765)
30–34	43.4 (n=212)	39 (n=2952)	44.9 (n=118)	40.7 (n=3486)
35–51	13.3 (n=65)	12.4 (n=937)	14.4 (n=38)	15.4 (n=1323)
Birthweight (g)	p<0.001		p<0.001	
720–2999	8 (n=39)	17 (n=1282)	8.7 (n=23)	16.6 (n=1423)
3000–3499	27.6 (n=135)	38.5 (n=2915)	34.2 (n=90)	39.4 (n=3380)
3500–3999	39.3 (n=192)	32.8 (n=2478)	38.4 (n=101)	33.6 (n=2882)
4000–4499	20.2 (n=99)	10.4 (n=786)	14.8 (n=39)	9.1 (n=782)
4500–5850	4.9 (n=24)	1.3 (n=101)	3.8 (n=10)	1.2 (n=107)
Delivery method	p<0.001		p<0.001	
Spontaneous	65 (n=318)	82.5 (n=6240)	64.6 (n=170)	78.7 (n=6748)
Ventouse	29.4 (n=144)	15.7 (n=1187)	34.2 (n=90)	20 (n=1712)
Forceps	5.5 (n=27)	1.8 (n=135)	1.1 (n=3)	1.3 (n=114)
Episiotomy, all vaginal deliveries	p=0.21		p=0.93	
	33.9 (n=166)	31.2 (n=2362)	36.5 (n=96)	36.2 (n=3107)
Episiotomy, spontaneous deliveries	p=0.07		p=0.40	
	20.4 (n=65)	24.9 (n=1555)	20 (n=34)	22.7 (n=1535)
Episiotomy, instrumental deliveries	p<0.001	p<0.001		
	59.1 (n=101)	61 (n=807)	66.7 (n=62)	86.1 (n=1572)
Duration second stage (min)	p<0.001		p=0.07	
0–09	2.7 (n=13)	3.5 (n=268)	3.4 (n=9)	3.1 (n=264)
10–29	20.2 (n=99)	31.2 (n=2356)	28.1 (n=74)	29.4 (n=2517)
30–59	36.8 (n=180)	41.1 (n=3110)	35.4 (n=93)	41.8 (n=3580)
60–205	39.5 (n=193)	23.8 (n=1801)	33.1 (n=87)	25.7 (n=2201)
Missing data (n=4/n=27)	0.8 (n=4)	0.4 (n=27)	0 (n=0)	0.1 (n=12)
Epidural	p=0.14		p=0.90	
	46.6 (n=228)	43.2 (n=3266)	48.7 (n=128)	48.3 (n=4139)
Shoulder dystocia	p<0.001		p<0.001	
	2.5 (n=12)	0.8 (n=64)	3.4 (n=9)	0.6 (n=55)
Occiput posterior presentation	p=0.003		p<0.001	
	4.1 (n=20)	2.1 (n=156)	6.5 (n=17)	2.7 (n=228)
Induced labour	p=0.32		p=0.89	
	15.3 (n=75)	17.1 (n=1290)	19 (n=50)	18.7 (n=18.7)

OASIS, obstetric anal sphincter injuries.

previously, both in Norway,[17][18] and in the USA,[21] but we are not aware of other publications exploring the reduced incidence of OASIS in different subgroups defined by risk factors.

Strengths and limitations of the study

Strengths of this hospital-based large observational study includes a very low risk of diagnostic misclassification of the OASIS outcome as all OASIS diagnoses were validated for study purposes in addition to primarily being diagnosed by at least two accoucheurs, and always by an obstetrician or gynaecologist. This is in contrast to studies based on registries that are not primarily created for research, but are established for other purposes for the healthcare providers. In our study, the medical records of all patients registered with an OASIS were

carefully reviewed by one senior consultant (KL). In addition, diagnosis of OASIS cases were cross-checked between several available sources (individual patient records, delivery unit protocols and hospital discharge lists, including ICD-10 diagnose codes and surgical codes for OASIS repair) for the study years. Another strength is that the study was carried out at in a single large hospital focusing on improved quality of primary diagnosis and repair of OASIS, and this also reduces the risk of misclassification in registration. Strength of the study is also the unselected population of delivering women and a large number of deliveries.

A randomised controlled trial (RCT) would be the optimal design for evaluating an OASIS reducing effect of manual perineum protection, but carrying out such an RCT is challenging during delivery, due to

Table 4 Risk factors for OASIS in the multivariate regression model (adjusted OR(aOR) and 95% CI)

	Primiparous women		Multiparous women	
Time period	2003–05	2008–10	2003–05	2008–10
Vaginal deliveries	n=8051	n=8837	n=6736	n=8085
OASIS (n)	489	263	102	53
Incidence OASIS (%)	6	3	1.5	0.7
Risk factors	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Age (years)				
15–29	0.90 (0.72 to 1.08)	0.90 (0.67 to 1.15)	0.99 (0.60 to 1.64)	0.86 (0.40 to 1.90)
30–34	1	1	1	1
35–51	0.96 (0.71 to 1.28)	0.84 (0.58 to 1.22)	0.91 (0.57 to 1.44)	0.95 (0.52 to 1.75)
Birthweight (g)				
720–3499	0.70 (0.55 to 0.87)	0.80 (0.60 to 1.08)	0.46 (0.25 to 0.82)	0.93 (0.44 to 1.94)
3500–3999	1	1	1	1
4000–5850	1.50 (1.16 to 1.92)	1.26 (0.87 to 1.83)	2.81 (1.73 to 4.58)	1.19 (0.58 to 2.45)
Delivery method				
Spontaneous	1	1	1	1
Instrumental	2.10 (1.71 to 2.68)	2.46 (1.74 to 3.47)	2.19 (1.02 to 4.73)	1.72 (0.64 to 4.66)
Episiotomy				
No	1	1	1	1
Yes	0.72 (0.58 to 0.90)	0.52 (0.38 to 0.73)	0.92 (0.46 to 1.87)	1.57 (0.71 to 3.49)
Duration second stage (min)				
0–29	0.80 (0.62 to 1.02)	1.18 (0.87 to 1.60)	0.50 (0.31 to 0.82)	0.34 (0.18 to 0.64)
30–59	1	1	1	1
60–205	1.40 (1.15 to 1.79)	1.29 (0.95 to 1.75)	1.03 (0.41 to 2.58)	0.83 (0.28 to 2.48)
Epidural				
No	1	1	1	1
Yes	0.95 (0.78 to 1.15)	0.86 (0.67 to 1.12)	1.15 (0.69 to 1.93)	0.88 (0.44 to 1.76)
Shoulder dystocia				
No	1	1	1	1
Yes	1.58 (0.83 to 1.39)	3.73 (1.76 to 7.90)	1.58 (0.60 to 4.16)	2.25 (0.50 to 10.10)
Occiput posterior presentation				
No	1	1	1	1
Yes	1.72 (1.04 to 2.82)	2.40 (1.42 to 4.06)	0.24 (0.03 to 1.78)	1.95 (0.66 to 5.73)
Induced labour				
No	1	1	1	1
Yes	0.77 (0.60 to 1)	0.92 (0.66 to 1.27)	0.86 (0.46 to 1.60)	0.81 (0.37 to 1.77)

OASIS, obstetric anal sphincter injuries.

contamination of methods in different study arms and problems with blinding of patients or staff. We did not conduct an RCT because in Norway, several hospitals already had managed to reduce the incidence of OASIS with implementation of improved manual perineal protection, and we consider randomising women to hands-off delivering techniques as unethical in the light of these recent historical clinical results. Previous RCTs have not shown a beneficial effect on OASIS by hands-on perineal protection, but the published RCTs have not described a structured training of the staff, such as the intervention programme of our study.[22] These trials had problems with bias caused by contamination of compared methods and different use of medial episiotomy in the study arms,[23][24] were under-powered to explore OASIS, or were not designed to assess OASIS, but perineal pain or perineal injury in general (including first and second degree tears and episiotomy).[23–25] The marked 50% reduction in the OASIS incidence

obtained in our delivery unit appeared simultaneously with the introduction of a manual perineal protection during second stage of labour. The main difference for our study population between the two time periods was the perineum protection training programme, the patient characteristics remained almost unaltered between the time periods and could not explain the reduction of incidence of OASIS. Thus, our study indicates that such a perineal protection programme has a beneficial effect in reducing the incidence of OASIS, both for primiparous and multiparous women, despite the lack of an RCT supporting this conclusion.

A weakness of our study is that the use of perineum support method, if used during second stage of delivery, was not registered in the medical records, and therefore, use of perineum support could not be assessed directly in our retrospective study. However, if this method was not used in some deliveries during the second time period or was used in some deliveries during the first

Table 5 Clinical characteristics and obstetric interventions among multiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). p-Values from χ^2 test

Multiparous women	2003–2005		2008–2010	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
Deliveries	n=102	n=6634	n=53	n=8032
Incidence OASIS	1.5 (102/6634)		0.7 (53/8032)	
Risk factors	%		%	
Age (years)	p=0.79		p=0.71	
15–29	24.5 (n=25)	27.5 (n=1824)	17 (n=9)	21.4 (n=1721)
30–34	44.1 (n=45)	41.9 (n=2778)	41.5 (n=22)	40.6 (n=3265)
35–51	31.4 (n=32)	30.6 (n=2032)	41.5 (n=22)	37.9 (n=3046)
Birthweight (g)	p<0.001		p<0.001	
720–2999	2.9 (n=3)	11.9 (n=791)	9.4 (n=5)	11.6 (n=933)
3000–3499	17.6 (n=18)	32.8 (n=2173)	18.9 (n=10)	32.1 (n=2581)
3500–3999	32.4 (n=33)	36.4 (n=2414)	35.8 (n=19)	37.5 (n=3010)
4000–4499	33.3 (n=34)	15.3 (n=1015)	17 (n=9)	15.4 (n=1238)
4500–5850	13.7 (n=14)	3.6 (n=241)	18.9 (n=10)	3.4 (n=270)
Delivery method	p<0.001		p<0.001	
Spontaneous	89.2 (n=91)	96.3 (n=6388)	84.9 (n=45)	96.5 (n=7748)
Ventouse	7.8 (n=8)	3.4 (n=226)	15.1 (n=8)	3.3 (n=265)
Forceps	2.9 (n=3)	0.3 (n=20)	0 (n=0)	0.2 (n=19)
Episiotomy, all vaginal deliveries	p=0.33		p<0.001	
	9.8 (n=10)	7.3 (n=482)	22.6 (n=12)	8 (n=644)
Episiotomy, spontaneous deliveries	p=0.80		p=0.43	
	5.5 (n=5)	6.1 (n=391)	13.3 (n=6)	6.1 (n=471)
Episiotomy, instrumental deliveries	p=0.57		p=0.42	
	45.5 (n=5)	37 (n=91)	75 (n=6)	60.9 (n=173)
Duration second stage (min)	p<0.001		p < 0.001	
0–09	19.6 (n=20)	34.9 (n=2315)	18.9 (n=10)	29.6 (n=2380)
10–29	49 (n=50)	49.9 (n=3311)	39.6 (n=21)	55.8 (n=4484)
30–59	23.5 (n=24)	12.3 (n=815)	30.2 (n=16)	11.7 (n=941)
60–205	6.9 (n=7)	2.5 (n=167)	9.4 (n=5)	2.7 (n=214)
Missing data (n=4/n=27)	1 (n=1)	0.4 (n=26)	1.9 (n=1)	0.2 (n=13)
Epidural	p=0.21		p=0.36	
	19.6 (n=20)	14.9 (n=988)	22.6 (n=12)	17.5 (n=1407)
Shoulder dystocia	p=0.001		p<0.001	
	4.9 (n=5)	1.2 (n=82)	5.7 (n=3)	0.9 (n=70)
Occiput posterior presentation	p=0.39		p=0.046	
	1 (n=1)	2.2 (n=149)	7.5 (n=4)	2.9 (n=233)
Induced labour	p=0.62		p=0.80	
	11.8 (n=12)	13.4 (n=891)	17 (n=9)	15.7 (n=1260)

OASIS, obstetric anal sphincter injuries.

time period, our study would tend to underestimate the OASIS incidence reducing effect of the perineum protection intervention programme, and hence, our efficacy estimates on reduction of OASIS from the intervention are minimum estimates.

Meaning of the study

The observed reduction of incidence of OASIS came rapidly after the introduction of the perineal protection programme and the low incidence of OASIS has lasted over the last years. The changes in clinical characteristics of the study population were very modest between the two time periods, and cannot explain the rapid reduction of the incidence of OASIS. Without the intervention programme, we could have expected an increase of the

incidence of OASIS in the second time period, as one of the most important OASIS risk factors, instrumental delivery, became more frequent in the study population (table 1) over the study years. In our study the reduction of incidence of OASIS was surprisingly consistent in all subgroups defined by OASIS risk factors (table 2). The decrease of the incidence of OASIS was similar in spontaneous and operative deliveries and in parity groups (primiparous and multiparous), again surprising, as primiparity is one of the most important risk factors for OASIS, as is operative delivery.[5] [10] [15] Interestingly, as shown in figure 1, the 2010 incidence of OASIS in women delivered by ventouse delivery is of similar magnitude as the incidence of OASIS in the spontaneous deliveries was back in 2005 (3.6% and 3.8%, respectively).

Under-reporting OASIS cases in the second time period is an unlikely cause for the registered reduction of the incidence of OASIS, as the procedure emphasising more than one accoucheur present at all deliveries was introduced before the second study period in form of a written procedure. Caesarean rate was unaltered between the two study periods and cannot explain the reduction of the incidence of OASIS.

Comparison with other studies

Traditionally, there has been a focus on OASIS risk factors with high OR. However, such risk factors may not necessarily represent the most frequent events in a delivery unit. Shoulder dystocia and occiput posterior presentation are examples of risk factors with high OR and a very low incidence.[5] [15] In numbers, most of the OASIS occurs during deliveries with low risk; during spontaneous deliveries with an infant of normal size. In our study, the number of women with OASIS illustrates the major groups of women that will suffer this obstetric complication; of the 752 primiparous women with OASIS in our study, 488 delivered spontaneously, only 21 after shoulder dystocia, 39 from an infant in occiput posterior presentation. In total 77% (580/752) of the primiparous women with OASIS delivered an infant that was not macrosomic (>4000 g). Actually, 38% of the women with OASIS delivered an infant smaller than the mean infant birth weight (3500 g) in our study population.

Medial and close to medial episiotomies have a higher risk for OASIS.[20] Large register studies show that mediolateral and lateral episiotomies have a protecting effect against OASIS, particularly among primiparous women and in instrumental deliveries.[9] [10] [26–28] Use of episiotomy was registered in our study, but type of episiotomy was not registered, and improvement of performed episiotomy technique in order to avoid median cuts was a part of the training package at our delivery unit.

During the study period, the use of episiotomy in our hospital decreased slightly in spontaneous deliveries in primiparous women (from 24.7% to 22.7%), but increased in instrumental deliveries in primiparous women (from 60.8% to 85.1%; table 1), and was shown to be a protective factor against OASIS for primiparous women in both time periods (table 4). Differences in effect of episiotomy between different parity groups on OASIS occurrence can be explained by indication bias, a mix between cause and effect, as episiotomy is used in deliveries with high OASIS risk. Multiparous women needing episiotomy may represent a group of women with difficult delivery with many risk factors.

Research and policy implications

We expected a more notable reduction of the incidences of OASIS in the subgroups with lower risk (low or normal infant birth weight), as compared with women with higher risk (large infant), if the perineal support programme had been followed consistently in all deliveries. We believe that a non-consistent use of perineum support in deliveries with lower risk for OASIS could account for the results; the main clinical focus was on women with high risk for OASIS, based on publications focusing on such risk factors. Previous studies have shown that antenatal scoring systems based on patient risk factors could not predict OASIS,[29–31] therefore methods that reduce risk for OASIS should be offered to all delivering women, not only for women in high risk for OASIS.

The training programme for perineal protection is a low-cost intervention requiring no extra resources or equipment, only training of the existing staff. Such perineum protection programmes were previously successfully implemented in five hospitals in Norway,[17] [18] therefore we can conclude that the programme is easily generalisable and applicable to other settings than ours.

CONCLUSIONS

Our study shows a large and rapid reduction of the incidence of OASIS following an introduction of a perineum support programme, across all risk groups of OASIS. We suggest that future OASIS research should focus more on variables connected to delivery procedures, including perineal protection procedures during delivery and not restricting risk analyses to demographic and individual obstetric data of the delivering woman or the infant. Using manual perineal protection is a low-cost intervention and requires no extra resources or equipment, except for training of the existing personnel. The reduction of incidence of OASIS in the last time period of our study could not be explained by the differences in patient characteristics or risk factors across the study period, because the incidence of these risk factors in the two time periods were either the same or increased in the second time period. Our study indicates that training programme for improved perineal protection can reduce the risk of OASIS across all groups of delivering women, not only in high-risk groups.

Author affiliations
[1]Department of Obstetrics, Oslo University Hospital, Ullevål, Oslo, Norway
[2]Faculty of Medicine, University of Oslo, Oslo, Norway
[3]Women's Health and Perinatology Research Group, Department of Clinical Medicine, University of Tromsø, Tromsø, Norway
[4]Unit of Biostatistics and Epidemiology, Oslo University Hospital, Oslo, Norway
[5]Department of Gynaecology, Oslo University Hospital, Ullevål, Oslo, Norway

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