

# **Obstetric anal sphincter injuries**

A population-based study of improvement of care

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## Scientific environment

This research project is a collaboration between the Department of Obstetrics and Gynecology and the Department of GI Surgery at Stavanger University Hospital in affiliation with the Department of Clinical Medicine K1, University of Bergen (UiB).

A collaboration partner has been the Faculty of Health Sciences, Department of Community Medicine, Research Group Epidemiology of Chronic Diseases, UiT The Arctic University of Norway, Tromsø.

I have been member of the Research Group for Women and Child Health of Stavanger University Hospital and The Postgraduate School of Clinical Medical Research, Department of Clinical Medicine K1, UiB, and I have followed the PhD program of the Faculty of Medicine and Odontology at the University of Bergen.



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midwifery research by Signe Egenberg will bring us further. I trust you and learn from you.

Thanks to the women of the randomised study for contributing to improved repairs of sphincter injuries during childbirth, and to the women whose data we have used aiming to reduce sphincter tears.

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Dear mother, thank you for always helping and supporting me, in my research project and every aspects of my life. Through generations the women of our families have gained higher levels of education. Thank you for telling me their stories. My late father always believed in me since I was little, encouraged me to use my potential and to not worry much about obstacles. Dear brother Einar, thank you for always being there!

## Abbreviations

AI	Anal incontinence
aOR	Adjusted odds ratio
BMI	Body mass index
CI	Confidence interval
EAS	External anal sphincter
EAUS	Endoanal ultrasonography
IAS	Internal anal sphincter
MHz	Mega Herz
OASIS	Obstetric anal sphincter injuries
OR	Odds ratio
TGCS	Ten Group Classification System
WHO	World Health Organization

## Abstract

**Background:** Obstetric anal sphincter injuries (OASIS) are tears of the anal sphincters, eventually also involving the rectum, sustained during vaginal birth, and 30% to 50% of women experience anal incontinence (AI) after OASIS, which is the main cause of AI in younger women. Furthermore, increasing OASIS rates were observed in Norway and other countries during the last decades. There was a strong need for improved sphincter repairs in order to reduce the morbidity after OASIS and for effective preventive measures. The Norwegian health authorities launched an action plan in 2006 aiming to reduce the OASIS rates. The plan included an interventional study of implementation of “hands-on” manual perineal support during the expulsive phase of labour, in which our department participated.

**Aims:** We aimed to compare the overlap technique and the traditional end-to-end approximation technique for the primary repair of OASIS with regard to faecal incontinence. Further, to investigate the association of oxytocin augmentation of labour with OASIS in a model of risk factors exerting their effect during the active, second stage of labour. Finally, to assess the impact of changes in clinical management on the prevalence of OASIS, and on risk factors associated with OASIS, from 2001 through 2012 in the unselected obstetric population of Stavanger University Hospital (SUS).

**Participants and methods:** We included 119 women who sustained OASIS at SUS between 2005 and 2007 in a randomised controlled trial (RCT) comparing the overlap technique with the traditional end-to-end repair for OASIS. After one year the participants were evaluated regarding anal incontinence, and endoanal ultrasonographic (EAUS) and anal manometry findings (*paper one*). We used consecutively registered, departemental data for the population-based studies of the associations between oxytocin augmentation and OASIS and for trends of OASIS and risk factors (*paper two and three*). The study populations comprised nulliparous women with a single, cephalic, term pregnancy and spontaneous labour, who delivered vaginally. We developed a dynamic, statistical model of risk factors on the

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causal pathway to OASIS for use in both studies. Based on the presence or absence of oxytocin augmentation, episiotomy, instrumental delivery and birthweight  $<4000$  g/ $\geq 4000$  g we modelled in logistic regression the best fit for the prediction of OASIS.

**Results:** The overlap and the end-to-end repair techniques were similar for all outcomes at the twelve month follow-up, which was attended by 101 out of the 119 participants. Overall, two women suffered from faecal incontinence, and 15% had AI as defined by Wexner score (*paper one*). Oxytocin augmentation was associated with aOR 1.8 (95%CI 1.5 – 2.2) for OASIS in spontaneous births of normal-sized infants among 15 476 nulliparous women between 1999 and 2012 (*paper two*). Episiotomy was associated with lower OASIS rates in instrumental, but not in spontaneous births. We found important effect modification between the predictors of OASIS. In the population of 14 479 nulliparous women of the overall OASIS rate declined from 9.8% to 2.9% between 2001 and 2012; from 6.5% to 2.2% in normal deliveries, and from 15.1% to 3.0% in instrumental deliveries when episiotomy was applied (*paper three*). The change was mainly explained by the implementation of the "hands-on" perineal support concept, and the recommendation of a routine, lateral episiotomy for instrumental deliveries from 2007. The distribution of the study population changed in line with our revised guidelines, which also included implementation of the WHO partogram and a restricted use of oxytocin augmentation.

**Conclusions:** The randomised study of repair techniques for OASIS did not support a recommendation of one repair method over the other. Better outcomes after OASIS than previously reported seem possible following training in anatomical sphincter repairs. We found an association of oxytocin augmentation with higher OASIS rates in the large population of nulliparous women having normal births. The "hands-on" management, and the routine use of a lateral episiotomy for instrumental births were associated with significantly lower OASIS rates. It is important to consider the interaction of factors associated with OASIS.

## List of publications

### Paper I

Rygh AB, Körner H. The overlap technique versus end-to-end approximation technique for primary repair of obstetric anal sphincter rupture: a randomized controlled study. *Acta Obstet Gynecol Scand* 2010;89:1256-62.

### Paper II

Rygh AB, Skjeldestad FE, Körner H, Eggebø TM. Assessing the association of oxytocin augmentation with obstetric anal sphincter injury in nulliparous women: a population-based, case-control study. *BMJ Open* 2014;4:e004592.

### Paper III

Rygh AB, Eggebø TM, Körner H, Skjeldestad FE. Manual perineal support and prevention of obstetric anal sphincter injuries; a population-based, cross-sectional study.

*Submitted*

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## 1. Introduction

My fascination and joy when a child is safely born and the mother is healthy, eager to take on the tasks of parenthood, has never faded. I usually reply to the outcry "It is over!" by saying "This is when it begins".

Women give birth under all kinds of circumstances, and the day of birth comes regardless of natural or man-made disasters or personal challenges. The mother should always receive the best support we can give. The resources may be limited; but we know that the presence of a trusted birth companion increases the odds of a safe birth.(1) On the other side, the most advanced technical equipment does not guarantee a good outcome. We need institutions that promote an evidence based practice and the sharing of knowledge, encourage transparent investigation of their outcomes interprofessionally, and acknowledge the woman's perspective in her treatment. We cannot achieve this unless we are willing to overcome communication barriers.

Anal sphincter injuries have been reported in between 0.1% and 19% of vaginal births in high resource settings (2-6) The etiology of anal incontinence (AI) is complex, however, obstetric anal sphincter injury (OASIS) is the main explanatory factor among healthy younger women.(7, 8) Between 30% and 50% of the women who sustain OASIS during childbirth report impaired control of the passage of gas, and less frequently, of faecal material.(9-12) This problem may have significant impact on her quality of life.(10-13)

Vaginal birth in humans is more complex than in other primates as the relatively large, egg-shaped fetal head passes through the tilted and curved female bony pelvis by a screwing motion, finally reaching the pelvic floor which is stretched as the fetal head is crowning. In the last minutes of labour the expulsive forces are directed through the slit-formed hiatus of the pelvic floor. The head rotates with the symphysis and neck as "the nave" and the back of the fetal head as "the hub of the wheel", when referring to a delivery from a normal (occiput anterior) position. The hiatus is further

widened to allow for the head to pass and the posterior perineum, with the anal sphincter apparatus, stretches as the fetal head rotates from the posterior fontanelle to the tip of the chin, and is delivered.

Factors characterising the woman in labour, the fetus and the birth attendants interact in a complex way on the occurrence of OASIS. These factors are in turn influenced by structural, external factors, such as the access to health care, maternal factors, e.g. child marriage and female genital mutilation, and trends among care providers and interest groups.(14-16)

From an evolutionary perspective there is a narrow balance between the limitations given by the birthing capacity of the pelvis of a female walking upright on two legs and the advantages of an increasingly larger fetal brain.(17, 18) The benefits of this evolutionary process must have trumped maternal mortality to some extent, and maternal morbidity to a larger extent. Sphincter tears were probably not associated with substantial *immediate* mortality in early human history, but rather reduced fertility and life expectancy due to loss of protection from their society, analogous to the destiny of women with obstetric fistulas in Africa in our time.(19) Thus, the capacity to give birth without tears has probably had an evolutionary advantage.

Despite highly developed health care systems in wealthy nations OASIS are still prevalent in the Western world. Thus, we still need to gain more knowledge on how to prevent, and deal with OASIS.

## 1.1 Historical and cultural aspects

The stigma associated with the sequelae of OASIS experienced by a woman of today was present long before our times, even back to ancient cultures. The oldest known religious scripts addressing personal hygiene appear to be the Hindu script "Laws of Manu" – Manusmriti – dated earlier than year 1000 BC.(20) Physical and spiritual cleanliness are linked in the rituals of the five great religions and were also prominent in the Roman culture.(21) The Finnish sauna was used for purification rituals of marriage and for childbirths. These associations add another dimension to the feeling

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of alienation and loss of dignity often expressed by women who have lost control of their natural functions.(13, 19)

Queen Henhenit, an Egyptian mummy of from year 2050 BC, is the first person known to display a vesicovaginal fistula, caused by obstructed labour which killed her.(22) Her lower bowel was protruding from the anus, which could indicate a laceration at the level of the cervical cuff together with a severe perineal laceration. Ibn Sina (980-1037) was an exceptional Persian scientist, philosopher and doctor of the golden age of Islam, and provided the first written text about the repair of perineal injuries. He was a doctor of medicine at 18 years of age, and among his many works, the canon of medicine, *al Qanun fi 'l-tibb*, was translated and widely used as a medical textbook until 1650.(23) Reality and reason were the key elements of his philosophy and science.

Before the 19th century childbirths occurred in people's homes and trusted women, in Norway called "hjelpkoner", cared for the mother during labour and the time after. A midwifery service was organized in Norway from 1810, and a formal education was established in 1815.(24) (Interestingly, royal childbirths were far from private. The court and noblesse were crowding the chambers of the Queen Marie Antoinette to witness her give birth and to prevent substitution of the newborn heir, according to the diaries of her servant Madame Campan).

From the middle of the 19th century medicine moved into hospitals, which before that were awful places for the sick and poor.(15) During the first decades of the 20th century safer anaesthesia, improved suture materials, aseptic principles, and later antibiotics, caused the progress of modern surgery, and more women gave birth in hospitals. An interventional attitude changed the management of labour.(15) Birth was considered a medical issue. Forceps deliveries, caesarean sections and episiotomy rates increased. Yet, by 1950 20%(the US) to 30%(Norway) of women still delivered at home.(24, 25) Reports on the occurrence of perineal tears before the 1960s vary widely and are uncertain. Episiotomy became a routine protective procedure after World War II. While mediolateral episiotomies remained the standard

in Europe, they were replaced by midline episiotomies in the US.(25) The feminist movement of the 1970s considered the medicalisation of birth as part of the suppression of women, particularly because many interventions lacked scientific support.(26) This influenced the use of manual perineal support or not, of episiotomy and other factors related to perineal tears.(16)

Giving birth is a profound experience shared by most women. Strangely, this experience is seldom dealt with in fictional literature. Three authors have written about childbirth in an interesting context. Through a long passage of "Kristin Lavransdatter" by Sigrid Undset we witness the protracted labour leading to the birth of Kristin's first son.(27) The text is remarkably explicit and radical for its time. The realism of the scenes are striking to birth attendants, however Kristin's pains also mirror her existential agony and struggles with remorse, a lead theme through the novel that earned Undset the Nobel prize of literature in 1928. "Vinterbørn" by Dea Trier Mørch is a vivid story from a maternity ward in the 1970s.(28) The context is women's empowerment and the recognition of social factors related to pregnancy and motherhood. This is displayed through the beautiful portraits of the mothers to be and their helpers. The story conveys ideas that for ever transformed the way obstetrics is conducted. Finally, in "The Handmaid's Tale", the Canadian author Margaret Atwood, often mentioned as a Nobel prize candidate, describes a dystopic future society where every aspect of female fertility and childbirth is controlled.(29) This science fiction story may be refused as irrelevant, but is a sad reflection of practices of the present and the past.

## 1.2 Functional anatomy of the pelvic floor in females

The pelvic floor comprises the muscular and fibrous structures closing the caudal opening of the bony pelvis, i.e. the levator ani muscle. The pelvic floor is traversed by the urethra, the vagina and the anal canal in females. Magnetic resonance imaging and translabial ultrasound has contributed to a better understanding of the pelvic floor and its function.(30-34) The muscular components are attached anteriorly to bone at the lower posterior surface of the symphysis, laterally to the ischial spines and

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posteriorly to the sacrum and coccyx. The lateral muscular attachments insert to the arcuate line which is a condensation of the connective tissue of the pelvic sidewalls. The muscles of the pelvic floor are the three parts of the levator ani muscle anteriorly and the coccygeal muscle posteriorly. Four tendinous structures connect the ischial spine with the coccyx and sacrum, constituting the posterior support of the pelvic floor.(35-38) (Figure 1)

The tone of the striated muscle fibers of the pelvic floor oppose the intraabdominal pressure. Infiltration of striated muscle fibers in the urethral and anal sphincters contribute to continence mechanisms and to anal continence and defecation through the puborectal sling. The levator muscle fibers can stretch up to three times their original length during vaginal birth according to a simulation study.(39) (Figure 2)

The other parts of the levator ani muscle act as slings around the urethra, vagina and anorectum, i.e. the pubovisceral muscle with its pubovaginal, puboperineal and puboanal parts, the puborectal muscle and the iliococcygeus muscle.(37)

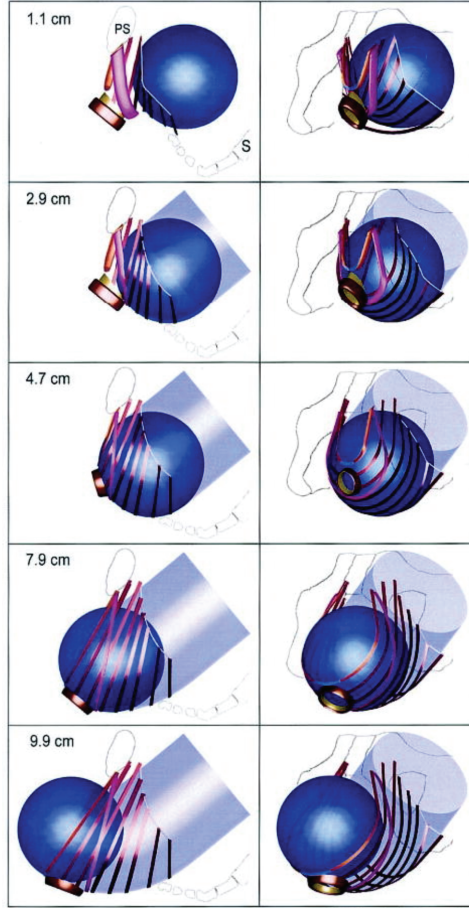
The urogenital triangle is a fibromuscular structure bounded anteriorly by the symphysis and laterally the ischiopubic rami, while the transverse perineal muscle represents the posterior border. The triangle is traversed by the urethra and the vagina. The superficial structures are the erectile tissues of the ischiocavernosus and bulbospongiosus muscles and the superficial transverse perineal muscle.(40)

The perineal body, or centrum tendineum perinei, is a tough fibrous structure connecting the urogenital and anal triangles of the perineum. Muscular fibers from the superficial perineal muscles, the external anal sphincter (EAS) as well as fibers from the fascia of the puborectal muscle and the rectovaginal fascia are interlaced in it.(41) (Figure 3) The tone and active contractions of the pelvic floor raise the perineal body cranially and close the vaginal opening; reduced tone is associated with a caudally bulging perineum and enlarged vaginal hiatus, characteristic of pelvic organ prolapse.(41)



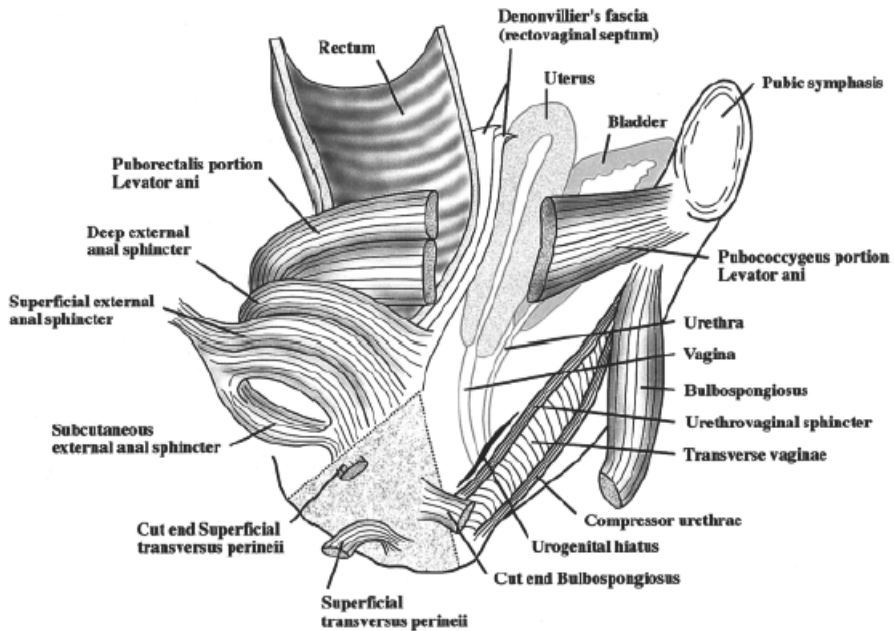
**Figure 1**

**Figure 1.** (Top) Inferior three-quarter view seen from the left, of the pelvic floor structures appearing behind the ischipubic rami (gray) (Bottom) The ileococcygeal, pubococcygeal, puborectalis muscles, urethra, vagina and rectum.



**Figure 2**

**Figure 2.** A simulation model of the stretching of the pelvic floor during delivery. Figures 1 and 2 are from Lien KC, Mooney B, DeLancey JO, Ashton-Miller JA. Levator ani muscle stretch induced by simulated vaginal birth. *Obstet Gynecol.* 2004;103(1):31-40. (With courtesy to JA Ashton-Miller) (With permission from Wolter Kluwers Health, inc.)



**Figure 3.** Female perineal body (shaded area) Note the cut-aways of the *pubococcygeus*, *bulbospongiosus* and *superficial transvers perinei* muscles. Ill. by Tom Pierce. By Woodman and Graney. (41) (With permission from John Wiley and sons)

### 1.3 The anal sphincter complex and anal continence in females

The striated muscle of the external anal sphincter (EAS) and the smooth muscle of the internal anal sphincter (IAS) constitute the anal sphincter complex, thus forming

the anal canal. The anal canal is divided into three levels: The upper anal canal (puborectal sling), the mid anal canal with the internal sphincter surrounded by the external sphincter, and the lower anal canal delineated solely by the external sphincter. This classification is the basis of modern assessment of sphincter injuries by EAS imaging.(42) The superficial EAS is attached posteriorly through the anococcygeal ligament to the coccyx and anteriorly to the perineal body. The superficial fibres mix with fibres from the superficial perineal structures. The deep part of the EAS is continuous with the puborectal muscles without anterior or posterior attachments.

During the second stage of labour the EAS is stretched being a part of the pelvic floor. The bottleneck structure of the EAS seen at rest will flatten out as a wide ring in the last minutes of labour.

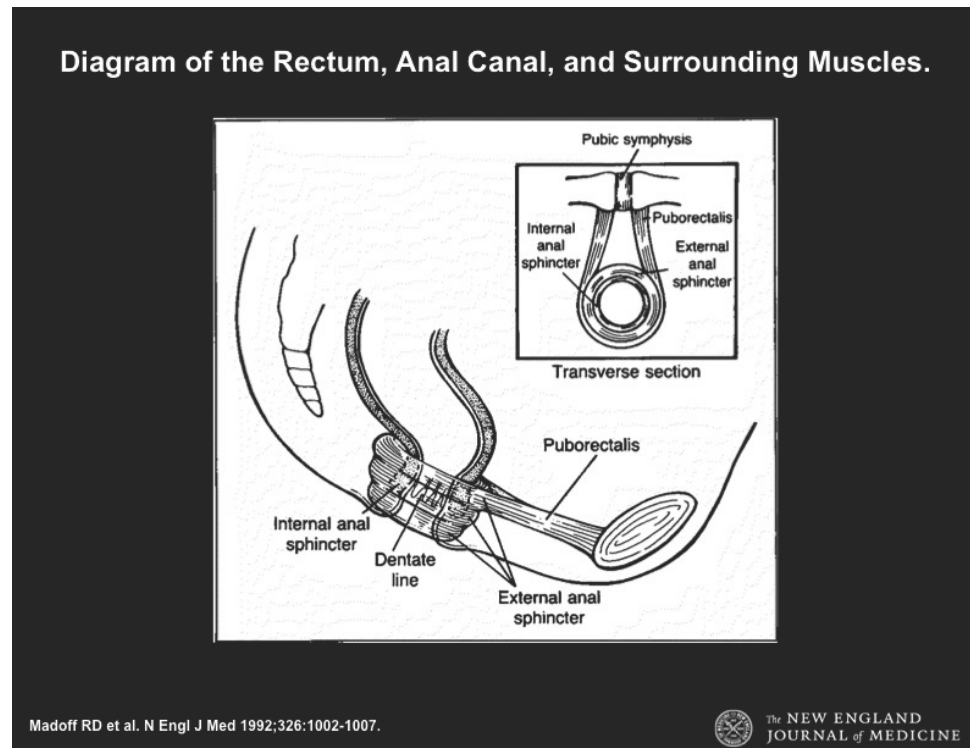
The IAS is a thickening of the distal part of the circular smooth muscle of the rectum, located 6-8 mm cranial to the anal border, characterised by its white colour. Between the IAS and the EAS the longitudinal muscle of the rectum continues as a fibromuscular layer containing some striated fibres from the puboanal muscle and smooth muscle fibres. Fibrous septa traverse the EAS and connect with the perianal skin. This layer is easily defined ultrasonographically. (Figures 4 and 5)

Anal continence is maintained by a complex neuromuscular interaction providing controlled passage of gas or faecal material. Faecal incontinence is defined as any involuntary or inappropriate loss of faecal material, anal incontinence also includes a bothering, involuntary loss of flatus.(43, 44)

The IAS, EAS and the puborectal muscle work synergistically to secure continence and to allow the voluntary passage of gas or stool. (Figure 4) During defecation the the puborectal sling and the IAS and EAS relax to release either gas or feces, as discriminated by the sensory nerve system, and coordinated with an increase of abdominal pressure and bowel movement. The sensation of pressure towards the pelvic floor initiates the process of defecation, which is controlled by conscious mechanisms, and can be postponed until the appropriate moment. Thus, the smooth



and striated musculature and all levels and branches of the nervous system are involved in maintaining anal continence.(44)



**Figure 4.** Diagram of the rectum, anal canal and surrounding muscles. (Reproduced with permission from Madoff RD, Williams JG, Caushaj PF. Fecal incontinence. *N Engl J Med.* 1992;326:1002-7. (With permission from NEJM).

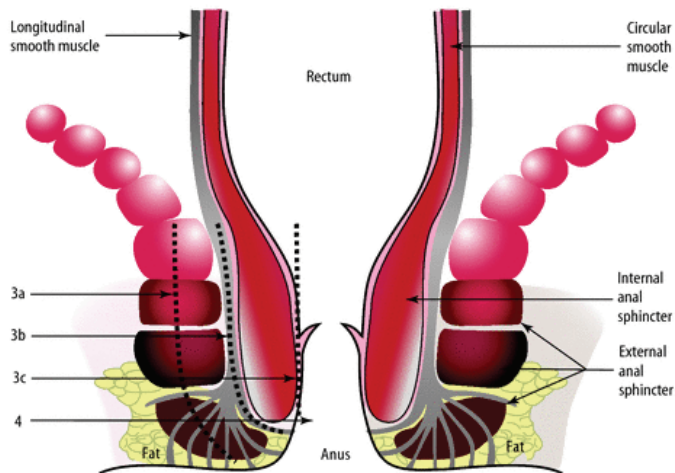
## 1.4 Obstetric anal sphincter injury – definition and diagnosis

As a response to a well-documented need for clarification Sultan proposed a new classification of perineal injuries during childbirth in 1999 which was adopted by the Royal College of Obstetricians 2001 and by the International Continence Society in 2005.(45-48)

- Grade 1: tears of the skin or mucosa.

- Grade 2: tears of the skin or mucosa and the perineal muscles, but not the anal sphincter.
- Grade 3: tears of the anal sphincter muscles subdivided into:
  - 3a: <50% of the external anal sphincter muscle thickness is torn.
  - 3b: >50% of the external anal sphincter muscle thickness is torn.
  - 3c: a combination of an external anal sphincter muscle tear and a tear of the internal anal sphincter.
- Grade 4: grade 3 injuries with disruption of the the anal epithelium as well.

OASIS comprise grade 3 and 4 perineal injuries. Before this definition was agreed upon perineal tears were classified as second degree when they involved the EAS and third degree if the tear extended into the rectum.(49)



**FIGURE 2.2.** Classification of perineal trauma depicted in a schematic representation of the anal sphincters.

*Figure 5. Classification of perineal trauma depicted in a schematic representation of anal sphincters by Sultan.(36) (reproduced with permission from Springer)*

A systematic clinical examination of the perineum including rectal exploration is

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required in order to assess perineal trauma and particularly to identify sphincter tears. Still, this is not always done. During the 1990s a series of papers documented that misclassification of perineal injuries, inadequate sphincter repairs and insufficient training in these repairs were common.(48, 50, 51) Many doctors and midwives were unaware of the risk of AI associated with sphincter injuries. In a prospective study 127 women underwent endoanal ultrasonographic examination (EAUS) before and 6-8 weeks after vaginal birth.(52) De novo anal sphincter injuries were revealed in 35% of the primiparous and 44% of the multiparous women, though only two tears were diagnosed at birth. Complaints of AI or were present in 13% and 23% of the women. Clinical re-examination and EAUS immediately after delivery increased the diagnosis from 11% to 24% in a prospective study of 254 women.(53) Among women with sphincter injuries revealed by EAUS flatus incontinence was a frequent symptom during the first year after delivery, but spontaneous recovery occurred in 25% during the first year.(54)

## 1.5 Anal sphincter repair in obstetrics

Traditionally obstetric sphincter repairs in Norway were performed by approximating the ends of the torn EAS with two sutures, without acknowledging IAS injuries, and in concert with international guidelines.(55, 56)

Colorectal surgeons on the other hand, preferred an overlap of the EAS ends for secondary repairs in patients suffering from faecal incontinence caused by a sphincter tear.(57) They reported restored continence in 74-100% of cases, in contrast to the disappointing 50% prevalence of AI observed in women after primary end-to-end repairs for OASIS.(8, 57)

In 1999 Sultan presented a series of 32 cases with an attempted primary overlap repair for OASIS, confirming the feasibility of the method.(58) The results were favourable as only eight percent of the women suffered from AI after three months. A Finnish series reported similar outcomes of overlap repairs.(59) The favorable results were, however, not confirmed by Fitzpatrick, who compared the end-to-end and overlap techniques in a randomised controlled trial (RCT) of 112 primiparous women

with OASIS in an everyday, clinical setting.(60) The methods were not significantly different regarding anal incontinence, endoanal ultrasonographic or anomanometric findings three months after delivery.

A Norwegian study of an anatomical sphincter repair, with emphasis on separate suturing for the torn EAS and IAS, showed favourable results compared to historical controls who had undergone conventional repairs.(61)

## 1.6 The burden of obstetric anal sphincter injuries

Anal sphincter tears during childbirth are the primary etiology of AI in young and healthy women.(8) Between 15% and 60% of women who sustain OASIS report AI, and 2-29% experience incontinence of faecal material.(9, 62-65) The broad range of prevalence of AI after childbirth is influenced by multiple factors, including differences in the recognition of OASIS, the grade of injury, the quality of repair, different methods of assessing AI, the time between injury and diagnosis.(42, 52, 64, 66, 67) Severe perineal injuries may disturb the postpartum period because of pain and emotional trauma, infection, or wound break down and compromise the bonding with the newborn.(13, 50, 60, 66, 68-70) From a long-time perspective OASIS may impair the the woman's quality of life, her sexual function, and the prospect of a recurrent injury may influence her plans for future pregnancies.(10, 68, 71-73) Moreover, the economic burdens of AI on society regarding health expences and social costs are considerable.(74)

## 1.7 Assessing anal function and the integrity of the anal sphincter apparatus

There are several *scoring systems* producing a numerical assessment of the severity and the components of anal incontinence. The widely used Wexner score covers both the nature and frequencies of incontinence episodes, the use of protective pads and lifestyle changes.(57) St. Marks score adds urgency, the use of anal plugs and constipating medication.(75) Other scoring instruments are the Pescatori index and the American System Score which all correlate well with clinical assessment.(75-77)

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*Digital rectal examination* provides important information about the length of the anal canal, scarring and assessment of the perineal body. The thickness of the EAS, resting tone of the IAS and the squeezing pressure of the EAS are important to assess. An older study found good agreement between digital examination by an experienced examiner and manometric findings.(78) Finally, it is also important to examine the ability of the puborectal muscle to contract and relax, and to find defects of the rectovaginal septum.

During a *routine gynecological exam* the gynaecologist may collect valuable information related to perineal injuries. The doctor should assess the height of the perineum (sagittal distance from the anus to the hymen).(79, 80) Further, take note of scars resulting from spontaneous tears or episiotomies, and look for any extensions of scars into the vagina or for abnormalities of the anal skin folds, that indicate sphincter injury, for descent of the perineum below the level of the ischial tuberosities during straining, and for signs and sites of bulging of the posterior vaginal wall.(52) Caudal retraction of any vaginal scars close to the hiatus should prompt a closer look for signs of EAS injury or rectovaginal fistula. During a rectovaginal examination the gynaecologist may address the anal canal and sphincters, and any defects of the rectovaginal fascia, especially discontinuation between the perineal body and the rectovaginal fascia, that are suggestive of considerable obstetric trauma to the posterior compartment. The anterior vulva and anterior- and mid-compartments of the vagina must also be examined with regard to injuries or prolapse.

*Endoanal ultrasonographic examination (EAUS)* is considered the cornerstone of assessment sphincter injury assessment. Since the 1980s ultrasound probes with rotating crystals have allowed depiction of defects of the sphincter muscles.(81) (Figure 6) The introduction of three-dimensional (3D) ultrasound in the early 2000s formed the basis for the development of a structured assessment of anal sphincter injuries. The Starck EAUS scoring system for sphincter defects from 0 (no defect) to 16 (>180 degrees, full length defect) had good reproducibility and corresponded well with Wexner scores.(82, 83) Scoring systems were gradually implemented in clinical practice.(42, 84)

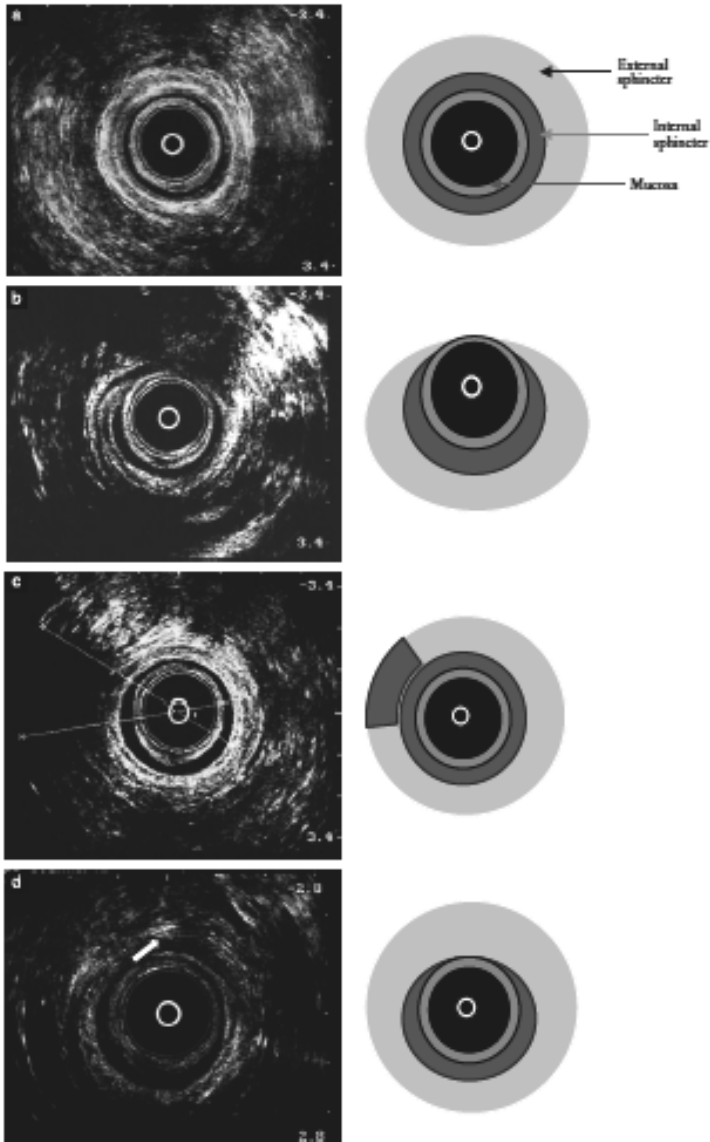


Figure 1 Endoscopic ultrasound images and schematic drawings of normal and defective anal sphincters. (a) Normal anal sphincter. The external sphincter is hypoechoic, the internal sphincter hyperechoic. (b) Combined total internal and external sphincter defect, the internal sphincter defect starting at 10 o'clock and extending 120° clockwise, the defect in the external sphincter starting at 11 o'clock and extending 100° clockwise. (c) Partial external sphincter defect starting at 9 o'clock and extending 40° clockwise. (d) Partial internal sphincter defect starting at 10 o'clock and extending 160° clockwise. A retraction and thickening of the internal sphincter is seen posteriorly caused by the partial sphincter defect. The arrow shows a hyperechoic scar in the external sphincter.

**Figure 6.** EAUS and schematic drawing of normal (a) and defect anal sphincters: EAS and IAS (b), partial EAS (c), partial IAS (d) From Starck M.(82) (With permission from Wiley and sons).

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*Anal manometry* is used to assess the anal resting pressure conveyed by the IAS and the squeeze pressure generated by the EAS, the coordination between rectum and the anal canal (inhibitory reflex) and the length of the anal canal. A transducer within a catheter measure the pressures at different levels from the rectum through the anal canal. However, manometric findings do not, necessarily correspond to clinical continence, and are hampered by a low degree of reproducibility.(85)

Injury to the pudendal nerve may cause anal sphincter dysfunction. Pudendal nerve latency can be diagnosed using *electromyography*. However, several studies have shown that nerve injury is of less importance for AI after childbirth than expected.(52)

## 1.8 The prevalence of OASIS

Assessment of the true prevalence of OASIS based on older and more recent literature is difficult because of ambiguity in the classification of perineal injuries.(25, 48) There are substantial differences in the clinical routines, diagnostic methods and level of skills for ascertaining sphincter tears.(51, 86) Clinical and ultrasonographic re-examination immediately after delivery increased the diagnosis of OASIS from 11% to 24% in one study.(53) However, clinically unrecognised EAS defects diagnosed by EAUS are not necessarily clinically important, and may even be present in nulliparous women.(52, 60, 87) Moreover, AI is prevalent after childbirth, and not entirely prevented by caesarean section, and was associated with an EAS defect in only 45% in a prospective study.(88) The denominator must be carefully considered in reports of OASIS rates. The prevalence may be reported in all deliveries, restricted to vaginal deliveries or by parity. Moreover, it may be influenced by caesarean section rates and other obstetrical interventions and risk factors, and importantly, by the level of health care. (4, 5, 89)

Anal sphincter tears were reported in approximately 1% of vaginal births in the 1935-1965 period and increased to 17% from 1965 to 1985 in the US.(2) During the 1990s OASIS rates were reported to be 5.8% to 7.3% in large populations from the US,

5.8% in Japan, in contrast to 1.9% in the Netherlands.(3, 5, 90, 91) The Nordic countries showed striking differences in the prevalence of OASIS between Norway (4.1%), Denmark (3.6%), Sweden (4.2%) compared with Finland (0.6%).(92) An increase in the prevalence of OASIS emerged in the Nordic countries from the 1970s. Possible explanations were improved diagnosis and classification, changes in obstetrical practice and population changes.(92)

## 1.9 Risk factors for OASIS - investigating risks or associations in a clinical obstetric setting

A risk factor can only be truly estimated in a prospective randomised controlled study. However, well-designed observational studies may identify important associations, and the main findings of large observational studies have been shown to correlate well with RCTs, albeit with wider confidence intervals.(93, 94) Strong and consistent associations that can be explained by established patho-physiological mechanisms, a temporal sequence or a dose-response relationship to the outcome are more likely to represent causal pathways.(93) Ideally, associations should be further investigated in RCTs. However, conducting a RCT during labour may not be feasible or may be unethical. Prospective cohort studies may add valuable complementary information with good external validity, and the "bigger picture" from observational studies may sometimes be more informative than specific findings in RCTs with implications restricted to a strictly selected population.(95, 96)

The predictors of severe perineal tears are usually grouped into maternal, fetal and interventional ones, or into factors that are modifiable or not. They may also be categorized as links in a causal pathway to OASIS or not. We focused on this perspective in our work.

Primiparity, birthweight and operative vaginal delivery are consistently associated with higher prevalence of OASIS in population based studies and were significant risk factors in prospective studies.(3-5, 73, 97-99) The association between episiotomy and OASIS may be modified by a variety of factors, such as parity, mode



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of delivery, and type of episiotomy, and further by the rate of episiotomy.(4, 5, 90, 100-103)

Birthweight, episiotomy and operative vaginal delivery can be considered to be active factors on the causal pathway to OASIS. A sphincter injury will not occur unless forces are applied towards the sphincter complex. The trauma is related to the force that is applied, to the direction of the trauma, to the speed of stretching and the resilience of the maternal tissues. Episiotomy and operative vaginal delivery are modifiable interventions during labour, whereas birthweight is a given factor during labour, even if it is recognised prenatally.

### *Birthweight*

Birthweight was a significant risk factor for OASIS in the large, population based study by Baghestan(4) comprising 1 673 442 births in Norway between 1967 and 2004. Compared with normal birthweights, (3000 g – 3999 g), birthweights of 4000 – 4999 g were associated with an adjusted odds ratio (aOR) of 2.7 for OASIS, and the risk of injury was more than four-fold for birthweights 4500 g – 4999. These findings are in line with other large studies from Scandinavia, Europe, Israel and the US.(3, 5, 73, 104-107)

### *Operative vaginal delivery*

Operative vaginal deliveries are consistently associated with a two- to three-fold higher frequency of OASIS compared to spontaneous births in populations of mixed parity.(3-5) Forceps deliveries carry at least the double risk of vacuum extractions in most studies.(3, 52, 90, 107-109) The forceps add to the diameter of the fetal head and the birth attendant may apply more force than by the ventouse. The accoucheur controls the direction of traction during a forceps delivery, whereas the vacuum device will fall off when the angle of traction on the ventouse cup exceeds a critical point. Consequently, the potential for trauma to the birth canal is higher in forceps deliveries. Interestingly, the study from California reported a lower risk of OASIS in forceps assisted births than in vacuum deliveries following an increase in vacuum

deliveries and decline of forceps deliveries in California.(5) The preference of vacuum over forceps for deliveries with a high anticipated risk of OASIS was proposed as an explanation; that is, the association of forceps with OASIS was confounded by the indication for the intervention.

### *Episiotomy*

An episiotomy is a cut made to increase the diameter of the vaginal opening during the late second stage of labour in order to hasten the delivery, often in cases of fetal distress, or to protect the mother from perineal injuries.(15, 56) The first known reference to this procedure is from the book on midwifery by the man-midwife Sir Fielding Ould in 1741.(110) Episiotomy became a routine procedure during the 20th century, as hospital births became more prevalent.(15) Thacker and Banta(15) did not find evidence to support the routine use of episiotomy in their review of the English literature on episiotomy from 1860 to 1980, published in 1983. The role of episiotomy was further explored in several studies using different designs during the 1980s. In 2009 a meta-analysis of eight RCTs by the Cochrane Collaboration found a lower risk of severe perineal trauma (RR 0.67; 95% CI 0.49-0.91) for restrictive use compared to a routine use of episiotomy.(111) In the US a shift from mediolateral to routine midline episiotomies and a major increase in the use of episiotomy had occurred in the 1960s.(2, 15) Midline episiotomies were supposed to be associated with an easier repair than spontaneous tears, less discomfort and pain postpartum and a reduced risk of OASIS.(112, 113) Later studies did not confirm these assumptions.(114, 115) In contrast, midline episiotomies were associated with a three- to-five-fold higher prevalence of OASIS, which was modified by the mode of delivery.(6, 9, 90, 100, 115, 116) The combination of forceps delivery and episiotomy was associated with the highest risk of injury, whereas a modest protective association was found for spontaneous births.(90, 109, 117) Furthermore, prospective studies showed that mediolateral episiotomies which were angled closer towards the midline were associated with higher risk of OASIS, and episiotomies intended to be mediolateral were actually often midline.(97, 103) Lateral episiotomies, defined as an incision point 1-2 cm lateral to the midline (at "four o'clock" during crowning), and

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angled towards the ischial spine, were traditionally used in Finland.(118, 119) This practice, together with a consistent use of the "hands-on" perineal protection technique was proposed to explain the low OASIS rates (<1% in primiparous women) compared to other Scandinavian countries.(92, 120) This was in contrast to an increasing trend of a "hands-off" and no-episiotomy approach in many Scandinavian delivery units since the 1970s.(121) The Finnish population-based study by Räsänen(118) calculated that among primiparous women, 909 episiotomies would be needed to avoid one sphincter tear in spontaneous births, and 66 needed in vacuum deliveries, supporting a restrictive use of lateral episiotomy for spontaneous births and a routine use for vacuum deliveries.

#### *Other risk factors for OASIS*

Most fetal factors seem to correlate with the fetal size, proportions or to the fetal diameters which are critical for the passage through the pelvis. Fetal head circumference, occiput posterior position and post date pregnancy were significant associations in several studies.(3, 104, 109, 122) During delivery from a posterior occipital position the fetal head passes the vaginal hiatus with the broadest part of the head towards the perineum and the anal sphincter.

Among maternal factors Asian, South Islander, African and Hispanic origin, and gestational diabetes are associated with higher OASIS rates in several studies. (4, 5, 104) The results are inconsistent regarding the influence of maternal age. (4, 5, 104, 123-125) Finally, the associations of maternal obesity and body mass index with OASIS seem unclarified.(125-128)

Apart from the obstetric interventions with a consistent association with OASIS, induction of labour, epidural analgesia and application of fundal pressure have been discussed.(3-5, 9, 122, 123, 129-131) Shoulder dystocia is associated with increased risk of OASIS.(3, 5, 129)

A wide range of midwifery practices has been evaluated with regard to their impact on OASIS. In a Cochrane review of RCTs of perineal techniques and perineal injury,

perineal massage after pregnancy week 37 of pregnancy, and the application of warm compresses towards the perineum during the second stage of labour were associated with a significant reduction in the risk of OASIS.(132)

”Hands-on” perineal support compared to ”hands-off” management did not prevent perineal injuries in two RCTs; which, were not designed or powered to study OASIS as the primary outcome.(133, 134) Jönsson(135) evaluated ”hands-on”, defined as the Ritgen handgrip, versus routine perineal care, including manual perineal support, with regard to OASIS with no significant difference. The ”hands-off” approach was associated with fewer episiotomies.

On the other hand, the low OASIS rates in Finland, where ”hands-on” manual perineal support was still uniformly practiced, and the promising results following the implementation of the ”hands-on” technique in Norway supported this approach.(16, 120) The effects of birthing positions, the use of a birthing chair, water births and pushing techniques are not clear.(136, 137) However, some birthing positions prevent observation of the perineum and may hamper manual support.

Finally, OASIS rates have been shown to vary considerably between hospitals in Norway and Finland. (138, 139)

## 1.10 Reintroduction of manual perineal support in Norway

The Norwegian Directory of Health launched an action plan in 2006 with the aim to reduce the high OASIS rates revealed by a nationwide supervision of delivery units in 2004.(140) Implementation of the perineal support principles used in Finland was a part of the plan. The key point in the Finnish concept was to secure a slow and controlled delivery of the baby’s head, based on close communication with the mother during pushing to ensure that she did not push when the baby’s head was crowning.(16, 120) At the same time the midwife would apply ”hands-on” manual support to the perineum and, with the other hand, control the advancement of the fetal head and delivery of the chin. (Figure 6) “Hands-on” support was also recommended during instrumental deliveries. The delivery position must allow observation of the

perineum during the last minutes of labour. Episiotomy of the mediolateral or lateral type was recommended when indicated.(141) Halving of OASIS rates was attributed to the controlled delivery, which allowed the perineum to stretch slowly without tearing.



**Figure 6.** "Hands-on" perineal support. The midwife supports the perineum using her first and second fingers to protect the vaginal opening from tearing and the flexed third to fifth finger to ease the perineum over the baby's chin. The other hand slows down the advancement of the head. (photo A.Rygh).



*Figure 7. From "Vinterbørn" by Dea Trier Mørch, artwork by the author. (With permission from the publisher Cappelen Damm)*

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## 1.11 Implementation of the "hands-on" technique at Stavanger University Hospital

Our unit decided to implement the manual perineal support concept recommended by the The Norwegian Directory of Health, and participated in the study set up to evaluate the effect of implementing of "hands-on" perineal support.(141) During the fall 2006 Professor J. Pirhonen presented the concept for the entire staff in lectures. From 2007 onwards all midwives and doctors joined mandatory tutorials about the technique, including individual instruction and training on phantoms by Tiina Pirhonen, an experienced midwife. Individual supervised training was given by Tiina Pirhonen for the entire staff over several months. Moreover, local key resource midwives were educated, and training of new birth attendants and routines for individual follow-up after incidents were incorporated into the quality assurance system, and have been active since. OASIS rates were, and still are, on the agenda of the monthly joint meetings regarding quality assurance.

## 1.12 Oxytocin augmentation

An active management of labour was introduced by O'Driscoll(142) in Dublin in 1969 with the intention to reduce prolonged labours. Diagnosis of the onset of active labour and routines for assessing the progress of labour were essential. Amniotomy at admittance, frequent vaginal examinations, early stimulation with oxytocin for dystocia and the continuous support from a birth attendant were the central elements of active management. The total caesarean section rate in the study was 4.0%, but the primary aim of the concept was to improve the labour experience for the woman, not to reduce the caesarean section rate. In subsequent years active management of labour gained support, and oxytocin augmentation became a frequent intervention in obstetrics, and the concept was presented in a book as well.(143) O'Driscoll was very positive about the benefits of augmentation of labour, and did not express concerns about adverse effects such as fetal asphyxia or uterine rupture. At that time the methods of fetal surveillance and the understanding of the uteroplacental and fetal physiology were limited.

An interesting dispute about active management of labour occurred in Britain in 1994.(144, 145) The issues of audit in obstetrics, the need for relevant classification systems that allow comparison of results between institutions in observational studies, and the problems of conducting RCTs during active labour were put forward.(146)

At the beginning of the 21st century roughly 50% of nulliparous women in Scandinavia and in the UK received oxytocin augmentation.(147-150) Incautious use of oxytocin stimulation was linked to fetal asphyxia in 71% of litigation cases in Sweden.(151) Furthermore, stimulation failed to reduce caesarean section and operative vaginal delivery rates, though a modest shortening of labour was documented.(150) Several reports also confirmed a widespread, non-systematic use without proper indication, a lack of guidelines, and poor adherence to guidelines when they were present.(148, 149) In the US the problems associated with stimulated births were met with suggestions of check-lists for the use of oxytocin.(152)

### **1.13 The history of systematic quality improvement in an obstetric unit**

Ideas about a quality assurance system emerged in the early 1990s in the Department of Obstetrics and Gynecology at the Central Hospital of Rogaland (Stavanger University Hospital since 2004 ) which had at that time around 4000 births annually. Sissel Moe Lichtenberg MD, who held leading positions from 1990 until she retired in 2013 met with ideas about systematic quality management during her studies of health management and through the Quality Assurance Committee of the Norwegian Medical Association. She experienced a need for shared clinical procedures, coherent patient information and the systematic review of clinical outcomes and adverse events in the department. She considered interprofessional development of guidelines and transparency about procedures and outcomes to be important. Dr Leif K. Gjessing became an important coworker. In addition to being a specialist in obstetrics and gynaecology, he was a skilled computer programmer with statistical competence, and together they established a departmental website and a structured obstetrical



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record with precise variables to be used for quality assurance. Consecutive plotting of data from all deliveries and a system of continuous quality control in close cooperation with doctors and midwives provided a dataset accepted for quality assurance by the Norwegian Data Protection Authority. The Gjessing® system was running from 1 September 1996, and was systematically updated with new variables, and provided the compulsory transfer of data to the National Birth Registry of Norway (MBRN).

The Quality Council was established in 1990 and doctors, nurses and midwives worked together in order to develop clinical guidelines shared by all professions. The clinical guidelines would include the preventive measures, laboratory tests, dosage schemes and treatment algorithms relevant for both midwives and doctors. Involvement by all professions added aspects of comprehension, clarity and practical implementation to the evidence-based routines and was assumed to enhance the adherence to the guidelines. All members of the staff were given access to the routines through folders in the wards, as pocket manuals and on the internet to ensure active use.

The Quality Council evaluated outcomes and addressed adverse events and considered the revision of guidelines and organisational or individual measures of improvement.

The idea of transparency resulted in a departmental website in 1998 <http://kvinneklonikken-sus.com> - that provided public access to the departmental guidelines and an enhanced version of the key results, the first department to do that. Dr. Gjessing presented the quality assurance concept for the first time at the annual meeting of The Norwegian Association of Gynecology and Obstetrics in 1998. (Figure 8)

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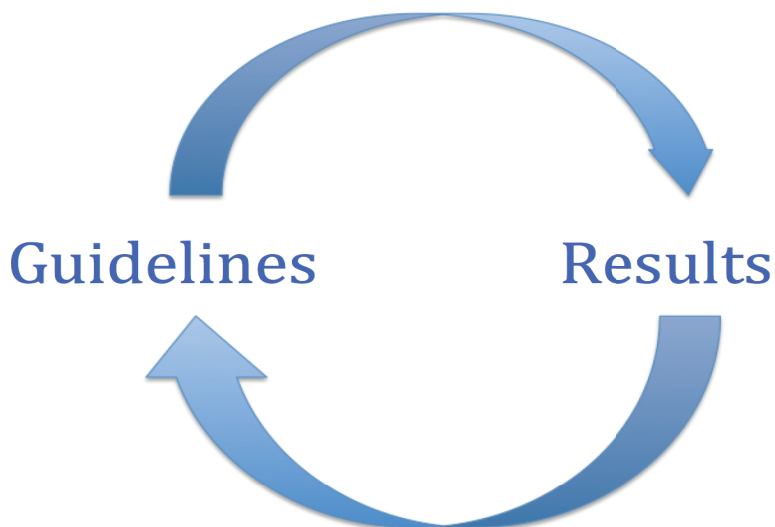
Avd. overlege: [Sissel Moe Lichtenberg](#)

Stedf. avd. overlege: [Stein Tore Nilsen](#)

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<a href="#">Ledige stillinger</a>	<a href="#">KK SiR's leger</a>	<a href="#">Resultater</a>	<a href="#">Linker</a>

Web sidene fungerer best med [Microsoft Explorer 4.0](#). ([klikk for download](#))

WEBmaster [Leif K. Gjessing](#) sist oppdatert 18.08.98



**Figure 8.** Slide from the presentation of the quality assurance system in 1998, including the website, and the "quality circle". With courtesy from dr. Leif K. Gjessing.

## 2. Hypothesis and aims of the study

### *Null hypothesis*

The morbidity and incidence of obstetric anal sphincter injuries are not amenable to changes in clinical practice.

### *Aims*

The main aims of this study were to compare two methods of primary repair with regard to outcomes after OASIS, and to investigate how changes in clinical practice influenced OASIS rates in the population served by the Obstetric Department of Stavanger University Hospital.

We have addressed these aims in three papers:

*Paper one* compared the overlap technique and the end-to-end approximation technique for the primary repair of obstetric anal sphincter injuries grade 3b, 3c and 4 with regard to faecal incontinence.

*Paper two* investigated the association of oxytocin augmentation of labour with OASIS in a model of risk factors exerting their effect during the active, second stage of labour.

*Paper three* assessed the impact of changes in clinical management on the prevalence of OASIS and on risk factors associated with OASIS over four time-periods from 2001 through 2012.

### 3. Ethical considerations

The randomised, controlled trial (*paper one*) was approved by The Regional Committee for Medical Ethics of Western Norway (REK\_V 123.04 June 2004) and by Norwegian Social Science Data Services 11481, and registered at ClinicalTrials.gov (July 2005, SF2005-07). All participants provided informed, written consent shortly after delivery, when a grade 3 or 4 injury was suspected. In this trial no immediate, additional procedures were associated with participation, and the REK-V considered the possible advances in knowledge to outweigh the ethical dilemmas.

The studies in *paper two and three* were based on deidentified obstetric data from the structured obstetric records of Stavanger University Hospital. The Regional Committee for Medical Ethics of Western Norway approved the protocol as a quality assurance study in obstetric care, fulfilling the requirements for data protection procedures (REK 2011-1247) and the Data Protection Officer of Stavanger University Hospital approved the study (Eph. 2011/44) and an extension of the study population through 2012 (Eph. 2011/382). Our research was conducted in compliance with the Helsinki Declaration.

## **4. Participants and methods**

### **4.1 The obstetric population served by Stavanger University Hospital**

The source population of this thesis comprised all women giving birth at Stavanger University Hospital, which serves a population of 340 000 people in the Rogaland County. The Department of Obstetrics and Gynecology had approximately 4500 deliveries annually during between 1999 and 2012, and received all women in labour, except the very few in need of nationally centralised obstetric services and those giving birth elsewhere by choice or circumstance. Between 20 and 40 unplanned home births occurred annually and no private maternity units existed. The three studies were conducted in the everyday clinical setting of the obstetric department. All tasks were performed by the personnel who normally carry out these responsibilities.

### **4.2 Data sources and the quality assurance system**

We used the departmental structured medical record containing demographic and obstetric data for the studies. This system was formally approved as a local quality register in obstetrics by the Norwegian Data Protection Authority. The data were plotted into the structured, electronic obstetrical record of the woman immediately after delivery by the attending midwife. On 15 May 2008 the Gjessing® system was replaced by the Imatus Natus® system of obstetrical records. The variables in both systems are well-defined, compatible and provide consecutively registered data from all births at Stavanger University Hospital from 1996 and onwards and provided information from 15 May 1999 through 15 May 2012 for the three studies. We used the quality assurance system of the department for information and for implementing of the routines related to the studies. All routines with revisions were dated precisely.

## 4.3 Study populations

### *Paper one*

All women who gave birth at Stavanger University Hospital with a suspected anal sphincter injury from 1 February 2005 through 28 February 2007, and could give their informed consent, were eligible for the study. Inclusions occurred around the clock, and randomisation was done before surgery. During surgery the perineal tear was graded by the surgeon, and patients with an injury less severe than 3b were excluded from the study. From the population of 167 eligible women, 128 (77%) were randomised. Eight patients were excluded because of perineal injuries less severe than 3b at surgery, and one patient did not receive the allocated treatment, 119 patients were treated according to the protocol, and 101 women (85%) of those were evaluated for the primary outcome after 12 months.

### *Paper two and three*

The structured medical records provided the information for these population-based studies from 15 May 1999 through 31 December 2012. The study populations comprised nulliparous women with spontaneous start of labour at gestational week  $\geq 37$ , and a single fetus in cephalic presentation (Group one in the Robson Ten Group Classification System, TGCS) who delivered vaginally (Appendix, table S2). After excluding 52 women with no estimated date of delivery and 17 with missing information of fetal presentation at delivery 15 476 were left for analyses in *paper two*. A total of 14 479 women were included in the study in *paper three*.

## 4.4 Settings

All three studies were conducted in the Department of Obstetrics and Gynecology at Stavanger University Hospital, Norway. The endoanal examinations were carried out in the out-patient clinic of the of the hospital's Department of Gastrointestinal Surgery.

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## 4.5 Obstetric anal sphincter injuries – classification, diagnosis and inclusion

From 15 May 1999 onwards, perineal injuries were categorized according to Sultan in the structured medical records.(45) We included women with grade 3b or greater perineal injuries for the RCT in *paper one*, and women with grade 3 and 4 perineal injuries in *papers two and three*.

The midwife attending the birth called the obstetrician when she suspected an anal sphincter tear. The final grading of the injury was done during surgical repair, and the result was entered into the electronic obstetric record by the midwife in charge of the birth.

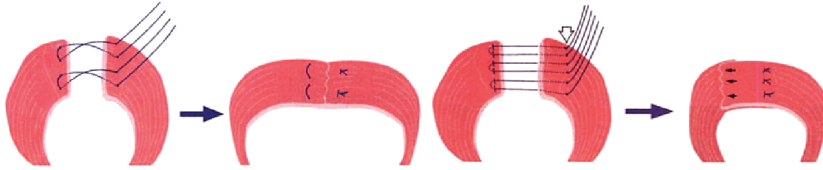
In a workshop in 2004, upfront the RCT in *paper one*, all doctors received instructions on identifying the EAS and IAS and training in overlap- and end-to-end repairs. No more local workshops were arranged, but continuous training and supervision of junior midwives and doctors went on as part of their local and national educational programmes.

## 4.6 The surgical repair of obstetric anal sphincter injuries

### *Paper one*

Surgical repair was performed in the operating theatre immediately after delivery, regardless of the hour, by the consultant or a trained resident on call, or by a resident receiving hands-on supervision by a senior. The woman received either general or regional anaesthesia. Diagnosis and repair of internal sphincter injury were intended. External sphincter tears were repaired using the end-to-end or overlap technique as described in the protocol, without division of any remaining sphincter fibres, and interrupted sutures were used to repair the IAS and the anal mucosa. The superficial tissues of the perineum and vaginal tears were sutured, and the skin was closed with an intracutaneous running suture. We used 3-0 polydioxanone sutures for the IAS and EAS repair, and 2-0 and 3-0 polyglactin sutures for further perineal repair. Women

with grade 4 injuries received intraoperative antibiotic prophylaxis (cephalotin 2.0 g intravenously). The postoperative regimen was according to the general routines and included softening laxatives during the hospital stay; instructions in individual pelvic floor exercises by a hospital physiotherapist, and a scheduled appointment in the gynaecological outpatient clinic after 6 months, or earlier if needed.



**Figure 9.** Diagrammatic representation of the end-to-end repair and the overlap repair by Sultan.(36) (Reproduced with permission from Springer)

#### *Paper two and three*

The procedures for the diagnosis, repair and follow-up were the same as in *paper one*; except no specific recommendation was given regarding the end-to-end versus the overlap technique for repair of the EAS after 2010. Before 2005 our guidelines did not specifically state that sphincter repair should be performed in the operating theatre, and we performed end-to-end repairs.

## 4.7 Assessment of anal function

### *Anal incontinence score*

The Wexner questionnaire scoring system for assessing of anal incontinence is a retrospective scoring system from 0-20 that records the frequencies of faecal and gas leakage together with the need for life style adjustments and the use of pads.(57) In this retrospective scoring system from 0-20 the frequencies of faecal and gas leakage is recorded together with the need for life style adjustments and the use of pads. A Wexner score of 20 indicates complete anal incontinence, a score of  $\geq 10$  severe incontinence, and score of 0 complete continence as defined by the International



Continence Society.(44) The women filled in the questionnaire before their 12-month visit.

Type of incontinence	Frequencies				
	Never	Rarely	Sometimes	Usually	Always
<b>Solid</b>	0	1	2	3	4
<b>Liquid</b>	0	1	2	3	4
<b>Gas</b>	0	1	2	3	4
<b>Wears pad</b>	0	1	2	3	4
<b>Lifestyle alterations</b>	0	1	2	3	4

Never: 0    Rarely: <1/month    Sometimes: <1/week

Usually: <1/day,  $\geq$ 1/week    Always:  $\geq$ 1/day.

0 perfect continence, 20 complete incontinence

**Table 1** Wexner scoring system of anal incontinence.(57)

#### *Endoanal ultrasonography*

All endoanal ultrasound examinations were performed by an experienced examiner and colorectal surgeon (H.Körner (HK)), who was blinded to the treatment allocation and clinical outcomes of the patients, using a 3D, 10 MHz endoanal ultrasound probe (Brüel&Kjær, Denmark; Hawk 2102 EXL, 2050) in a standardized way to obtain the image file. HK used the image file to evaluate the anatomy of the upper, middle and lower anal canal and the EAS and IAS, to diagnose EAS defects (dehiscence of >90 degrees of the EAS below the upper anal canal) and IAS defect (loss of continuity of the hypochoic IAS ring), and to measure anterior EAS lengths in the sagittal plane.

#### *Anal manometry*

The examinations were done by HK, with the assistance of a trained endoscopy nurse, by applying the stationary pull-through technique to assess the median, minimum and maximum values for resting and squeeze pressure. The procedure was performed by introducing a balloon catheter through the anus and measuring the intraluminal pressures in the pressure zone as the catheter was pulled from the rectum to the anal verge.

## 4.8 Data collection

### *Paper one*

The doctor who performed the sphincter repair filled in a case report form immediately after surgery. The forms and the informed consent were collected by the study leader and entered into a study database that was later linked with the departmental register to obtain the other parameters. We used the electronic delivery protocol continuously to track any missing case report forms.

The women brought the completed study questionnaire to their 12-months follow-up visit. If the time was inconvenient the woman was telephoned by Astrid Rygh (AR) and offered another appointment or motivated to send the questionnaire using a prepaid envelope.

HK entered the results from the anal manometric and endoanal sonographic examination into a password secured database that was later combined with the study database. AR checked the information in the study database against the medical record for quality control, and an anonymous file was used for the statistical analyses.

### *Papers two and three*

We established a research dataset by linking the relevant variables from the Gjessing® system from 15 May 1999 through 14 May 2008 and the Imatus Natus® system from 15 May 2008 through 31 december 2012 after necessary recoding. Missing variables, which were few, were recoded as the mean value of the variable. We reported according to the STROBE statement.

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## 4.9 Statistics

We used the Students t-test for continuous data with a normal distribution and Mann-Whitney U test when the data were not normally distributed. Categorical data were analysed using chi-square test and by Fischer's exact test when appropriate. Logistic regression was used to calculate of odds ratios (ORs) and 95% confidence intervals (CIs) and we used chi-square test for linear trends. Statistical modelling was used for the studies of *papers two and three*. Data are presented with 95% CIs and  $p < 0.05$  was considered significant. Our analyses were performed using SPSS for Macintosh v.17.0 (SPSS Inc., Chicago, IL, USA) or IBM SPSS Statistics for Windows, v.19.0 Armonk, NY: IBM Corp.

The power calculation for the RCT of paper one was based on the study by Sultan.(58) However, we assumed that 16% would experience faecal incontinence instead of 8% because the repair was performed in an everyday clinical setting. Using 1:1 randomisation we would need 50 patients in each group in order to demonstrate a difference in faecal incontinence of 16% vs. 41% with 80% power,  $\alpha 0.05$ , and a two-sided test of significance. We extended the randomisation to 128 women to compensate for exclusions and loss to follow-up. The study was planned according to the CONSORT guidelines.(153)

### *The statistical model of paper two and three*

In *paper two* we developed a statistical model in order to assess the associations of risk factors with OASIS. We built a model based on our understanding of the dynamic factors that are active during the expulsive phase of labour: oxytocin augmentation, episiotomy, operative vaginal delivery, and birthweight ( $< 4000$  g/  $\geq 4000$  g). We explored the interactions between the effect variables as we built the model, that is, whether the association of one effect variable (i.e. episiotomy) with the outcome variable (OASIS) is the same for different levels of another effect variable (i.e. operative vaginal delivery) or not. The best fit of the model resulted in twelve strata of combinations of the targeted factors. We simplified this model by collapsing insignificant strata that reflected clinically meaningful scenarios. For example, we

collapsed the two strata of episiotomy in spontaneous births of infants weighing <4000 g, as the estimates for OASIS were similar. Furthermore, we collapsed the four strata of spontaneous births of infants weighing  $\geq 4000$  g, independent of episiotomy and oxytocin augmentation, as the estimates for OASIS were very similar. Thus our final model comprised eight strata. We used the final model in order to analyse trends in the prevalence of anal sphincter injuries in the study population in *paper three*. We used chi-squared to test for linear trends and for changes in factors associated with OASIS, stratified by four time-periods between 2001 and 2012. Changes in risk factors were investigated using multivariable logistic regression. Possible and clinically relevant confounders other than the targeted risk factors were tested one by one to the stratified model. Confounders that changed any estimate of the combinations of risk factors by 10% or more were included in our model as confounders. Interactions were considered significant at  $p < 0.05$ .

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## 5. Results

### *Paper one*

We randomised 128 of the 167 eligible women to this comparison of the end-to-end and the overlap repair techniques. A total of 119 of the women received the allocated treatment and 101 women were evaluated for the primary endpoint: 99 by a complete Wexner score, 87 by EAUS and 85 by anal manometry. Eight women were excluded because of injuries less severe than grade 3b; one woman with a grade 4 injury was excluded because of the surgeon's decision to perform an end-to-end repair instead of the allocated treatment. Nine patients in each group did not attend the follow-up at twelve months, eight in each group were impossible to reach or declined to participate, one woman in the overlap group had undergone a colostomy because of inflammatory bowel disease, and one woman in the end-to-end group was pregnant at term.

The end-to-end and overlap groups were statistically similar with regard to clinical and demographic characteristics: two-thirds were primiparous in both groups, and two thirds delivered spontaneously. Among the multiparous women six in the end-to-end group and three in the overlap group had sustained OASIS in a previous delivery, and eight and three had no previous vaginally birth respectively. We detected internal sphincter injuries in 35% of cases in the end-to-end group and in 46% of cases in the overlap group.

The following outcomes were similar in the two treatment groups: solid stool incontinence weekly or more often was reported by one out of 51 women in the end-to-end group and by none out of 50 in the overlap group; flatus incontinence weekly or more was present in 14 out of 51 women in the overlap group and in 10 out of 50 in the overlap group. The mean Wexner score was 2.4 in the 49 women in the overlap group versus 2.2 in the 50 women in the end-to-end group. One woman in the end-to-end group had a Wexner score  $\geq 10$ , reflecting severe anal incontinence. Endoanal ultrasonography revealed two cases with a  $>90$  degree defect of the EAS out of 46

cases in the end-to-end group and no such defects among the 41 cases in the overlap group. The manometric findings were similar in the two groups. Finally, the prevalence of urinary incontinence (37%) and dyspareunia (39%) was the same in both groups.

The primary and secondary outcomes of the two repair techniques were not statistically different, and the overlap repair method was not superior to the end-to-end method in our study population.

### *Paper two*

We investigated of the association between oxytocin augmentation and OASIS in 15 476 women in TGCS group one who delivered vaginally between 15 May 1999 and 15 May 2012. Among these women 1013 (6.5%) had sustained OASIS, and 6976 women (45%) had their labours augmented. The TGCS group one comprised 27% of the birthing population during the study period.

Oxytocin augmentation, operative vaginal delivery, birthweight, time-periods, maternal age and the duration of the active second stage of labour were significantly associated with the OASIS in the univariate analysis. Origin, epidural analgesia, episiotomy and occiput posterior position were not significant factors. In the univariate analyses we observed a significant association between oxytocin augmentation and OASIS in normal births. In the modified model oxytocin augmentation was associated with an 80% higher OR for OASIS in spontaneous births of infants weighing <4000 g (aOR 1.8, 95%CI 1.5 to 2.2). However, oxytocin augmentation was not associated with OASIS in spontaneous births of large infants or in operative vaginal deliveries. Episiotomy was strongly associated with lower OASIS rates in instrumental deliveries, particularly for high birthweights, but not in spontaneous births. High birthweight was associated with threefold higher OASIS rates in spontaneous births and an even stronger association in operative vaginal deliveries. Finally, epidural analgesia was associated with 30% lower OR for OASIS.

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Oxytocin augmentation of labour was associated with an 80% increased OR of OASIS in spontaneous births of infants with normal birthweight.

*Paper three*

We investigated the trends for the prevalence of OASIS in a population of 14 479 women in TGCS group one who delivered vaginally between 1 January 2001 and 31 December 2012. The overall OASIS rates declined from 9.8% to 2.9% over the four time-periods, from 6.5% to 2.2% among normal births and from 15.1% to 3.0% among instrumental deliveries assisted by episiotomy. From the second to the third time-period the prevalence of OASIS decreased by 65%. Finally, we found a 62% reduction in the adjusted odds ratio (aOR 0.38, 95% CI 0.30 to 0.48) for OASIS from the first to the last time-period after adjusting for risk group. Among obstetrical interventions we found a significant increase in episiotomies and operative vaginal deliveries, and a decline in augmented births. The use of epidural analgesia remained stable at around 42%. The proportion of newborns weighing  $\geq 4000$  g declined gradually. (Appendix Table S1)

We observed a significant decline in the prevalence of OASIS in all except one of the groups displayed in the modified model. The decline was gradual for all spontaneous deliveries, whereas the main change in OASIS rates in instrumental deliveries occurred between the second and third time-period when the perineal protection program was introduced. During the study period the prevalence of OASIS decreased to one-third in spontaneous deliveries and to less than one-fourth among instrumental deliveries assisted by episiotomy.

Before 2007 the use of episiotomy was not associated with lower OASIS rates in instrumental deliveries. After 2007 the aORs for sphincter injuries were halved among women in this group, but remained unchanged among women who had instrumentally deliveries without episiotomy. The association of instrumental deliveries without episiotomy with OASIS remained at least four-fold higher than the reference across the study. The strong association between high birthweight and OASIS remained unchanged through the study period. Oxytocin augmentation was

significantly associated with a doubled risk of OASIS only in the second time-period in which 56% of the births were stimulated.

We observed major changes in the distribution of the study population during the study period, reflecting our revised guidelines, and more women received care associated with a lower risk of OASIS. Though the majority of instrumental deliveries were not assisted by episiotomy during the first two time-periods, we observed an increase in line with the new guidelines during the following periods. The 67% decrease in oxytocin stimulation of was most noticeable from 2010 onwards and increased the number of women with normal births and low risk of OASIS. The entire decline in high birthweights was reflected in a relative increase of spontaneous deliveries of normal-sized infants.

Finally, we estimated the contribution of these changes to the reduced OASIS rates. We estimated that, at most, 87% of the improvement we observed between the second and the last time-periods could be attributed to the perineal protection concept, and 13% to improved episiotomy technique and fewer newborns weighing  $\geq 4000$  g.



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## 6. Discussion

This thesis investigated areas of potential improvements in the treatment and prevention of obstetric anal sphincter injuries in an unselected obstetric population in the southern Rogaland County.

*Paper one* showed that the overlap repair was not significantly better than the end-to-end approximation repair for grade 3b, 3c and 4 perineal injuries in regards to leakage of solid stool every week or more often twelve months after delivery. The results were similar regarding flatal incontinence and Wexner score. Overall, anal incontinence measured by Wexner score was present in 15% of the study population. The EAUS findings and anal manometric results were not significantly different for the two methods.

The primary clinical endpoint of the Sultan(58) study was anal incontinence, also referred to as "bowel symptoms". The sample size of our study was based on the incidence of flatal incontinence in that study. We may have arrived at a larger sample size by using the prevalence of flatal incontinence after OASIS in our own population. By including multiparous women the possibility of blunting of our findings with injuries sustained in a previous delivery was introduced. We primarily aimed to identify EAS defects during our endoanal ultrasound, without applying more advanced scoring methods that not were fully implemented at that time.(42, 82) Use of the Faecal Incontinence Quality of Life Questionnaire, registration of wound-related morbidity and evaluation at multiple time points would have added value to our study.(154)

Three RCTs were included in a 2006 Cochrane review(155) addressing the overlap and end-to-end repair techniques for OASIS.(60, 156, 157) The heterogeneity of these studies with regard to parity, surgery, and outcomes and other factors complicated their comparison. Fitzpatrick(60) found no difference in incontinence scores in primiparous women three months postpartum, Williams(157), who primarily compared suture materials, found similar results for the two techniques

regarding anal incontinence after three months, and only half of the patients attended later controls. Fernando(156) found better results for the overlap repair regarding faecal incontinence episodes and faecal urgency in 52 primiparous women after twelve months. The Cochrane review based on these trials concluded that no recommendation was appropriate.(158)

The 2013 update of the Cochrane review(159), included 588 women, adding results from our study(160), the large trial by Farrell(161), and the study by Garcia (162). The Garcia study of 41 women had limitations, including issues regarding allocation concealment in 9/51 cases.(162) Potential sources of bias included not clearly defining the primary outcome, the inclusion of women with prior AI, and different suture material for the two repair techniques. Finally, the treatment groups had different sizes (23 versus 18), and 37% of women were lost to follow up at three months. Garcia reported similar outcomes for the two groups. Anorectal complaints were more prevalent (42%) than in our study (15%), but this difference could be influenced by the shorter observation period and the loss to follow-up in the Garcia study.

The Farrell study included 149 primiparous women with complete third-degree (no fibres left) and fourth-degree tears, and the primary endpoint was flatal incontinence.(161) In contrast to our findings and the conclusion from the 2006 Cochrane review, Farrell found a significantly higher incidence of flatal incontinence in the overlap group at six months (61% versus 39%) and at twelve months (56% versus 31%). Faecal incontinence rates were in the same direction however, not significant. The superiority of the end-to-end technique had disappeared at the two- and three-year follow-ups.(163, 164)

Compared to the previous RCTs, including ours, the Farrell study had more statistical power due to the large sample size and the high prevalence of flatal incontinence after severe sphincter injuries. On the other side, their findings are not necessarily generalizable to women with less severe injuries. The inferior results after an overlap repair could be associated with a more traumatic preparation of the EAS ends in order to achieve an overlap. The pelvic floor muscles are not fully recovered until one year after delivery, and may explain the transience of the symptoms after overlap

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repairs.(165) We experienced that, in contrast to the opinion of Fernando and Farrell, an overlap is possible when some fibres are intact due to their elasticity. The overall flatal incontinence rate of 24% in this study was lower than in older studies and in the Farrell study, but higher than for expert repairs, and comparable to those achieved after anatomical repairs, and following structured training.(8, 58, 61, 156, 161, 166, 167) We observed only 2/87 cases with EAS defects of >90 degrees during endoanal sonography. This finding should be interpreted with caution, however corresponds with the clinical outcomes and the emphasis that put on an anatomic repair of the sphincters.

Our staff adhered to our guidelines as all repairs took place in the operating theatre, in contrast to in the Farrell(50%) and Fitzpatrick(20%) studies. Further, supervised training was prioritised as a specialist was present during 84% and supervised a junior during 45% of the repairs. Our overall outcomes of 15% anal incontinence among women after OASIS are in accordance with a prospective study of longterm outcomes following structured training and supervision on sphincter repairs.(168) The 2013 Cochrane update, which was based mainly on the addition of the Farrell study and our study, recommended that the surgeon should choose the method for repairing OASIS based on his clinical evaluation

*Paper two* confirmed that oxytocin augmentation of labour is associated with higher ORs for OASIS during the spontaneous births of a normal-sized baby (aOR 1.8, 95%CI 1.5 to 2.2) in our study population of women in TGCS group one who delivered vaginally. Episiotomy appeared to be protective in operative vaginal deliveries, but not in spontaneous births, and high birthweights were associated with higher OASIS rates, and epidural analgesia with reduced OASIS rates. We found considerable risk modification between the predictors for OASIS in the active second stage of labour, implying that the associations with OASIS varied for different combinations of the effect variables.

*Papers two and three* have the inherent limitations of observational studies with regard to causality.(93) Furthermore, a number of relevant variables were not available in our databases; i.e. delivery positions, the use of manual perineal

protection and episiotomy techniques, and birth attendant experience and skills. Finally, we cannot exclude detection bias resulting from the increased focus on sphincter injuries. However, the diagnostic procedures were unchanged throughout the study years.

We are not aware of other studies primarily designed to investigate the association of oxytocin augmentation with OASIS. However, recent national birth registry studies from Finland and Denmark confirmed 14% higher OASIS rates in augmented births among primiparous women, whereas an Australian study did not.(118, 169, 170) Other large studies from Norway, Sweden, the US and England did not include this factor.(4, 5, 104, 171)

We chose nulliparous women for our studies because they are at high risk of OASIS and parity is known to modify the associations between major obstetrical interventions and OASIS.(3, 4, 73) Their labours are frequently augmented, and the association of oxytocin augmentation with OASIS was significantly modified by parity in our initial multivariable regression analyses.(150) In our experience the TGCS categories are useful with regard to outcomes other than caesarean section rates, and facilitates comparisons with other populations.(172) By restricting our study population to TGCS group one we excluded induced labours (TGCS group 2a), which have different obstetric characteristics and weak or no association with OASIS.(4, 5, 102, 169) (Appendix table S2)

*The strength of the dynamic statistical model.* The groups in our statistical model corresponds to relevant clinical situations in contrast to lists of associations from multivariable regression analyses. We are not aware of other studies that have applied a comparable model in their studies of OASIS. However, the value of analyzing combinations of risk factors has been acknowledged in recent publications.(4, 169, 171)

The building of the dynamic, statistical model was based on our understanding of the dynamic interplay of the factors leading to OASIS. First we included the three interventions, oxytocin augmentation (the variable of interest in *paper two*), episiotomy, instrumental delivery, and birthweight (<4000 g/≤4000 g), which are risk

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factors on the causal pathway to OASIS. We considered these factors before other risk factors. These factors often correlate in clinical scenarios; i.e. an episiotomy is often applied during an instrumental delivery of a large baby, prolonged labours are often stimulated, and women failing to progress in labour are more often delivered instrumentally. Based on our understanding of the dynamics of the first and second stages of labour we consider that risk factors may have a direct or indirect influence on the occurrence of OASIS. Further, the effect on the outcome of one factor varies for different categories of another. We built the modified statistical model of clinically meaningful combinations as described in the *Statistics* part of this thesis and tested for confounding effects of the risk factors *considered not to be on the causal pathway to OASIS* to this model. Finally, we assessed the associations with OASIS for each clinical risk group.

Among the potential confounders from the univariate analyses epidural analgesia was associated with 30% lower odds of OASIS in the adjusted analyses of *paper two and three*, which corresponds to recent studies of nulliparous women, but is in contrast to the no association or higher OASIS rates in older studies.(118, 123, 130, 169, 171, 173) The absence of a confounding effect of the occiput posterior position on OASIS rates in this study contradicts the findings of other reports.(102, 122, 169) This factor was probably captured within the variable operative vaginal delivery (53% of occiput posterior cases in our population were delivered instrumentally). The association of maternal age with OASIS is discussed, but was not a confounder in our study.(4, 5, 104, 123, 124) The association between non-Western, particularly Asian, origin and OASIS in several studies has been explained by possible anatomical differences or by communication barriers.(4, 5, 104, 170, 174, 175) Non-Western origin was not a confounder in our studies, suggesting that the majority of these women were of an origin without a high susceptibility to OASIS. Despite conflicting reports regarding the duration of the second stage of labour as a predictor of OASIS, we did not adjust for this factor because a prolonged labour is the indication for our variable of interest, oxytocin augmentation.(176) In addition, because of collinearity the duration of the second stage was measured through operative vaginal delivery and oxytocin augmentation (*paper two*). Furthermore, it appears unlikely that the duration of the

active second stage of labour is on the causal pathway to OASIS within the usual time frames in our setting. During a prolonged second stage the leading part is usually located above the level of the anal sphincter, without direct contact, most of the time.

We find it likely that the association of oxytocin stimulation with OASIS is explained by strong contractions leading to impaired control of the perineum during the expulsive phase of labour.(141) Oxytocin augmentation was not associated with OASIS in spontaneous deliveries of large sized infants, but this may be related to the sample size and may be explored using birthweight as a continuous variable. The lack of association between oxytocin augmentation and OASIS in instrumental deliveries may be explained by a dominant effect of an instrumental delivery.

Episiotomy did not appear to protect against OASIS in spontaneous births, regardless of oxytocin augmentation or birthweight, which is in agreement with RCTs and some observational studies.(4, 111, 169) Conflicting results in other reports may be explained by modification of the association with OASIS by the type of episiotomy, episiotomy rates, and by caesarean section rates.(5, 89, 177, 178) The protective association of episiotomy we observed in operative vaginal deliveries corresponds well with previous studies on mediolateral and lateral episiotomies, which were recommended in our unit. The protective effect appears to be related to the characteristics of the cut. (97, 103)

*Paper three* demonstrated a decreasing trend in the overall prevalence of OASIS in TGCS group one from 9.8% to 2.9% across the study period. The main change appeared following the implementation of the "hands-on" perineal protection concept in 2007, and was present in both spontaneous births and operative vaginal deliveries assisted by episiotomy. Our estimates attribute up to 87% of the improvement after 2007 to the "hands-on" perineal protection concept. A considerable redistribution of the study population occurred across the study as more women received care associated with lower risk.

We lacked individual-level data on an on whether the manual perineal protection was used or not and the type of episiotomy applied. However, the systematic, individual

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training of every birth attendants during the intervention and afterwards, and the follow-up of incidents support the likelihood of a good adherence with the routines. The process of quality improvement was continuous, and included improvements regarding fetal surveillance and systematic risk differentiation of women in labour, resulting in a higher proportion of births occurring in the low-risk, low interventional, midwife-led delivery unit. These factors may have had unaccounted confounding effects.

The overall declining trend of OASIS corresponds with the decline in Norway after 2004. Trends of increasing OASIS in Norway before this time, and the increase in other Scandinavian countries, UK, Canada and Australia, are mainly explained by increased recognition of tears rather than changes in risk factors and in the quality of care. (4, 92, 171, 179-181) However, the contribution of changes in the management of the perineum is discussed. (92, 132, 182) The declining OASIS rates in the US are attributed to increasing caesarean section rates, and a large study concluded that OASIS rates would be of limited utility as a quality indicator because it would probably enhance this undesired trend. (89, 183) The overall caesarean section rate in our unit was 12.5% during the study (*paper three*), and the acute caesarean rate in TGCS group one increased from 5.0% in 1999 to 7.5% in 2012 which we consider to have had minor influence on the trends for OASIS.

Midwives attend the majority of births in many countries. Measures intended to prevent OASIS need to be integrated with the elements of good midwifery practices in order to ensure an overall high quality of care. (1) The "hands-on" perineal protection technique appeared feasible and highly protective in this study. However, the effect of this approach is discussed, as the results from four RCT have been interpreted in favour of the "hands-off" technique with regard to OASIS and used as an argument against crediting "the hands-on" intervention for the decline in Norwegian OASIS rates. (133-135, 184, 185) However, three of these studies did not have OASIS as the primary outcome, did not compare "hands-on" with a "hands-off" management, and all were insufficiently powered to detect a difference with regard to OASIS. The influence these studies have had on midwifery practise is discussed. (182, 186, 187)

The optimal rate for lateral episiotomies used restrictively in normal deliveries is still unclear, and varied among the interventional hospitals in Norway.(141) Moreover, the advantage of an intact perineum or a minor tear must be balanced against the high number of episiotomies needed in order to avoid one sphincter tear.(115, 188)

In line with the national results high birthweight remained associated with two- to three-fold higher OASIS rates throughout the study, and the reduced proportion of large infants was confined to spontaneous births. High birthweight may be expected and prepared for in operative deliveries, but they are rather unpredictable in spontaneous births. Consequently, effective protective measures against tears need to be part of the general midwifery practice.

Doctors attend births carrying a higher risk of OASIS, and effective preventive measures are characterized by a lower number needed to treat.(118) The change to routine lateral episiotomy for operative vaginal deliveries and improved perineal support was associated with perineal outcomes comparable to those of spontaneous deliveries. Episiotomy appeared to be used restrictively for instrumental births during the first two time-periods of our study, and was not associated with a protective effect during these years, in contrast to national findings.(4) Correctly performed operative vaginal deliveries reduce the trauma to the pelvic floor. Our low caesarean section rate, systematic training and supervision of juniors in the performance of instrumental births and the recommendation of vacuum extractions before forceps use most likely contributed to the good outcome.(189, 190) Moreover, the increase in instrumental deliveries, however with a lower risk of OASIS, indicates a possible confounding effect by indication.

Previous studies of the "hands-on" intervention in Norway with a before-and-after design concluded that the intervention was effective in the presence of various risk factors, both in instrumental and non-instrumental births, whereas other risk factors remained stable.(16, 141, 191) The intervention was associated with reduced OASIS rates, but with a smaller effect estimate in the times-series analysis than claimed in the previous papers.(184) Furthermore, appeared to be most effective in low-risk births in a model of risk groups defined by the presence of one to four risk factors.(191) This design prevents a reasonable comparison with our results because



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the effect of parity, and interactions are not dealt with in their model.

## 6.1 Validity of the studies

### *Internal validity*

RCTs range close to the top of the evidence pyramid. The RCT in *paper one* was conducted according to the CONSORT statement and was evaluated as being high quality in a Cochrane review. The cross-sectional studies (*papers two and three*) based on consecutive data range in the middle of the pyramid and followed STROBE guidelines for reporting of observational studies. *Selection bias* was unlikely in *paper one* because of the high inclusion and evaluation rates and the randomization and clear assignment to treatment and evaluation. The unselected source population reduced *selection bias*, and the precisely defined variables and the systematic procedures for data collection and quality control and dating of recommendations reduced *information bias* in *paper two and three*. The quality assurance system also contributed to reduced *information bias* in all the studies, though we cannot exclude that increased focus on OASIS may have influenced the recognition of injuries.

*Confounding* from OASIS sustained in a previous delivery was relevant in *paper one*, but considered to have a minor influence based on the information from the medical notes for the parous women. The study database included important possible confounders (*papers two and three*), which were tested in the model. However, we lacked specific variables regarding manual perineal support and type of episiotomy between other, and cannot exclude the presence of unknown confounders.

*Interaction, or effect modification*, (i.e., the effect of an exposure on the outcome varies for different levels of another variable) was thoroughly analysed and accounted for in the stratified model of *paper two and three*.

### *External validity*

The unselected, heterogenous source population, including both high- and low-risk pregnancies from a well-defined Norwegian region, and the high data quality contribute to the external validity of the studies. The findings should apply to

populations with similar characteristics. Furthermore, the results are supported by other studies.(16, 118, 141, 159, 169, 191)

### *Precision*

The RCT in *paper one* may be criticised for having a too small sample size because the outcomes for both repair techniques were better than estimated in the power analysis. A few subgroups in *papers two and three* had wide 95% CIs explained by small samples, with results that were not significant, or should be interpreted with caution.

## 7. Conclusions

In the randomised control trial in *paper one* the comparison of the overlap method and the end-to-end approximation technique for primary repairs of grade 3b, 3c or 4 OASIS revealed no significant difference in faecal or flatal incontinence or Wexner incontinence scores twelve months after the repair. In addition, endoanal ultrasonographic and anal manometric findings were similar. Our findings did not support a recommendation of one technique over the other. Our findings suggest improved outcomes after systematic training in primary sphincter repairs, and that correct anatomical diagnosis of the injury followed by a specific repair of the external and the internal anal sphincter muscles after OASIS is important.

*Paper two* showed that oxytocin augmentation of labour in women with spontaneous birth of a normal-sized infant was associated with 80% higher odds of OASIS in our study population. Women in TGCS group one with the prospects of a normal delivery of a normal-sized baby represent a large and very important subgroup because an uncomplicated, vaginal first birth has positive bearings on future births. Oxytocin augmentation is a modifiable risk factor with limited positive effects, and a more cautious use is recommended. *Paper two* also demonstrated that the interaction of the main factors on the causal pathway to OASIS must be accounted for in studies aimed to reduce severe perineal trauma during the first birth. Episiotomy appeared to be protective in operative vaginal deliveries, but was not associated with lower OASIS rates in spontaneous deliveries.

From 2001 through 2012, we showed a significant decline from 9.8% to 2.9% in OASIS rates in women in TGCS group one in our study population (*paper three*). The improvement appeared to be associated mainly with the implementation of the "hands-on" manual perineal support, and the recommendation of a systematic use of lateral episiotomy for instrumental births from 2007 onwards, and appeared in nearly all risk groups of our model. The distribution of the population changed as more

women received care associated with a lower risk of OASIS. This finding was in line with our revised recommendations for the management of the perineum, a restricted use of oxytocin augmentation, and with the decline in the proportion of newborns weighing  $\geq 4000$  g.

*Null hypothesis*

Based on the findings from these three studies we reject our null hypothesis. The morbidity and incidence of obstetric anal sphincter injuries appeared amenable to changes in clinical practice in our population.

## 8. Future perspectives

In line with other studies *paper one* confirm that women today may expect better outcomes after OASIS compared to two decades ago.(61, 168) Based on the current evidence a primary recognition of injuries and a high quality anatomical reconstruction of the perineum and the anal sphincter apparatus immediately after the injury improves the woman's prospects of a normal life after OASIS.(159, 192) This must be reflected in structured training programmes.(168) Simulation models may be valuable supplements to supervised training, and birth attendants, regardless of profession or experience, should systematically use the learning potential of real situations.(193)

Innovations in translabial 3D ultrasound of the pelvic floor, transvaginal ultrasonographic assessment of the anal sphincter apparatus and functional magnetic resonance imaging may improve our understanding of pelvic floor trauma during childbirth and of the treatment options in women suffering from anal incontinence.(31, 194-196) Moreover, the feasibility of ultrasound examination in the delivery room may contribute to a timely diagnosis and better treatment of pelvic floor injuries in the future.(65)

The history of interventions in obstetrics is paved with good intentions, but oxytocin augmentation of labour, routine episiotomy, midline episiotomy and manual perineal support or not all had unexpected outcomes. *Paper two* exemplifies an adverse outcome of an intervention based on insufficient knowledge. The physiological progress of labour in nulliparous women is not fully understood. An ongoing Norwegian RCT, the LAPS study (ClinicalTrials.gov NCT02221427), may contribute to a clarification, and to better partograms and guidelines for prolonged labour.(197) Future studies of OASIS and obstetrical interventions should take their strong interaction into account in order to arrive at valid conclusions (*paper two*).

The associations of clinical interventions and improved OASIS rates in *paper three* emphasise the importance of prospective registration of perineal support techniques

and other interventions in future studies. The international collaboration on the standardisation of variables will make international multicenter studies of OASIS possible.(119) The optimal episiotomy rates, the indications for episiotomy during spontaneous delivery, and adverse outcomes of lateral episiotomy, such as pelvic floor dysfunction or Bartholini gland problems should be investigated.

Caesarean section is the main alternative to a complicated vaginal birth in many countries because of a lack of operative vaginal delivery skills and fear of perineal tears.(89, 198) WHO still state that caesarean section rates above 15% are unjustified.(198) Effective training programmes and the implementation of quality assurance systems are suggested to achieve safe instrumental deliveries.


Midwives' views on the processes interacting during the second stage of labour should be reflected in research. Successful integration of safety measures with attention to the needs of the woman has professional and organisational aspects. The clinical guidelines and the interprofessional cooperation in the delivery units would benefit from midwifery research on these issues.

The women's perspectives on the management of her pregnancy and labour must be acknowledged.(199) This should be reflected by use of validated questionnaires regarding outcomes in future studies. The womens views on important areas of investigation and relevant outcomes would enhance obstetrical research. Furthermore, we should gain more knowledge about how we can discuss her views on equal terms without running away from our medical responsibility.



*Figure 10. From "Vinterbørn" by Dea Trier Mørch, artwork by the author. (With permission from the publisher Cappelen Damm)*

## 9. Appendix


 Pasient ID \_\_\_\_\_  
 fjernes etter at data er lagt inn i databasen

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### Suturerings skjema av rifter grad IIIb og IV

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**Diagnose**

Rift grad III b (Eksterne sfinkter rupturert, men <50% fibre intakt )  
 Rift grad III b (Eksterne sfinkter fullstendig [=KOMPLETT] rupturert)  
 Rift grad IIIc (Intern sfinkter ruptur)  
 Rift grad IV (Analslimhinne ruptur)

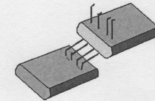
**Behandlingssted**

Suturert på operasjonsstuen  
 Suturert på fødestue

Sfinkter e.. **End-to-End metode**
 Sfinkter e.. **Overlappende metode**




1, 2 eller 3 silke suturer




1 2 eller 3 suturer

**Sfinkter INTERNUS** suturert i tillegg
  **Rectumslimhinne** suturert



Reapproximation of internal anal sphincter muscle



Gjennom submucosa, IKKE i Lumen

Operasjonsvarighet \_\_\_\_\_ min  
 Antall sfinkter-suturer \_\_\_\_\_  
 Ja, komplikasjon \_\_\_\_\_ beskriv

**Operatør** \_\_\_\_\_  
 Ass.lege alene  
 Asslege med Overlege  
 Overlege

**VÆR SNILL Å LEGG DET UTFYLTE SKJEMAET I MIN HYLLE. TAKK. Eli**

Figure S1. The case report form filled in by the doctor immediately after surgery (paper one)



Pasient \_\_\_\_\_  
 Navn \_\_\_\_\_  
 Fødselsdato \_\_\_\_\_  
 Dato besvært \_\_\_\_\_

— PASIENT SPØRRESKJEMA

vennligst sett kryss	Aldri	Sjeldent mindre enn 1 gang per måned	Av og til	Vanligvis	Alltid
			mindre enn 1 gang per uke <small>men oftere enn 1 gang per måned</small>	mindre enn 1 gang per dag <small>men oftere enn 1 gang per uke</small>	minst 1 gang per dag
Har du ufrivillig avgang av <u>fast</u> avføring ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Har du ufrivillig avgang av <u>løs</u> avføring ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Har du ufrivillig avgang av <u>luft</u> ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Må du bruke <u>bind</u> eller <u>bleie</u> pga avføringslekkasje?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Har du endret <u>levemåte</u> / <u>daglige rutiner</u> pga avførings- eller luftlekkasje	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Har du <u>urinlekkasje</u> ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Har du smerte ved <u>samleie</u> ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ammer du?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**Figure S2.** The questionnaire filled in by the woman before attending the twelve month follow-up visit (paper one).

		2001-03 N=3169 %	2004-06 N=3611 %	2007-09 N=3826 %	2010-12 N=3873 %	X <sup>2</sup>	P-trend
Maternal age (years)						0.11	=0.74
	<25	27.0	26.0	26.1	24.2		
	25-29	34.2	33.7	32.3	36.5		
	30-34	17.5	17.6	18.6	20.3		
	>35	21.3	22.8	23.1	18.9		
Origin Non Western		6.9	9.1	11.7	15.3	140.1	<0.001
Episiotomy	Yes	25.8	21.2	45.1	38.4	311.4	<0.001
Epidural analgesia	Yes	42.1	43.7	41.1	41.1	2.7	=0.10
Oxytocin augmentation	Yes	49.1	56.3	46.9	31.2	313.6	<0.001
Instrumental delivery	Yes	19.6	24.1	26.5	25.8	40.0	<0.001
Birthweight ≥4000 g	Yes	14.1	14.2	11.8	9.9	37.3	<0.001
Occiput posterior position	Yes	3.5	4.0	6.1	6.5	45.2	<0.001

**Table S1.** Trends for risk factors for OASIS through four time-periods from 2001 through 2012 (paper three).

<i>Group</i>	<i>Characteristics</i>
<b>1</b>	P0, single cephalic, $\geq 37$ GA, in spontaneous labour
<b>2</b>	P0, single cephalic, $\geq 37$ GA, induced or CS before labour
<b>3</b>	P1+, single cephalic, $\geq 37$ GA, in spontaneous labour
<b>4</b>	P1+, single cephalic, $\geq 37$ GA, induced or CS before labour
<b>5</b>	Previous CS, single cephalic, $\geq 37$ GA
<b>6</b>	P0, breeches
<b>7</b>	P1+, breeches (including previous CS)
<b>8</b>	All multiple pregnancies, (including previous CS)
<b>9</b>	All abnormal lies (including previous CS)
<b>10</b>	All single cephalic, $< 36$ GA (including previous CS)

CS (caesarean section) GA (gestional age) P0 (nulliparous) P1+(parous)

**Table S2.** *The Robson Ten Group Classification System (TGCS).*(172) *The classification is prospective, woman based, with mutually exclusive and totally inclusive categories. Group 2 and 4 are frequently divided into a (induced labours) and b (caesarean section before labour).*



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# Paper I

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RANDOMIZED CONTROLLED TRIAL

## The overlap technique versus end-to-end approximation technique for primary repair of obstetric anal sphincter rupture: a randomized controlled study

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### Abstract

**Objective.** To compare the outcome of end-to-end approximation versus the overlap technique for primary repair of obstetric anal sphincter rupture (OASR) at 12 month follow-up. **Design.** Prospective, randomized controlled study. **Setting.** University hospital. **Sample.** One hundred and twenty-eight patients with grade 3b, 3c or 4 OASR were randomized; 119 (end-to-end 60, overlap 59) received the allocated treatment. We obtained information concerning fecal incontinence from 101 (85%) patients. **Methods.** The obstetric team on call performed the repairs. Wexner score, endoanal ultrasound (EAUS), and manometry were used to evaluate anal sphincter function at 12 months post-surgery. **Main outcome measures.** Primary outcome was incidence of solid stool leakage at least once a week. Secondary outcomes were flatus incontinence, Wexner score, external anal muscle defect examined by EAUS, and anal manometry results. **Results.** One patient in the end-to-end group and none in the overlap group reported leakage of solid stool once a week or more. Fourteen patients in the end-to-end group and 10 in the overlap group reported flatus incontinence ( $p = 0.48$ ). Mean Wexner score was similar in both groups, 2.4 versus 2.2. One patient in the end-to-end group and none in the overlap group had a Wexner score  $>10$  (severe anal incontinence) (NS). External sphincter defect was found in 2/46 in the end-to-end group compared to 0/41 in the overlap group (NS). Anal manometry findings were similar in both groups. **Conclusion.** The overlap repair was not superior to the approximation technique with regard to fecal incontinence at 12 months.

**Key words:** Obstetric anal sphincter rupture, repair, overlap technique, fecal incontinence, surgical techniques

### Introduction

Obstetric anal sphincter rupture (OASR) is a well-known complication of vaginal deliveries, with a frequency of 0.5–5% reported in the literature (1). Between 20 and 67% of these patients develop fecal incontinence, which has great impact on quality of life as well as subsequent pregnancies (2). OASR related morbidity might be reduced by focusing on delivery technique, correct diagnosis of perineal injury, improving methods of repair, and maintaining optimal perioperative conditions (3,4). Sultan et al. (1) reported that the overlap technique, the preferred

method for secondary anal sphincter repair among colorectal surgeons, was feasible also for primary repairs, and superior to the end-to-end approximation method, which is traditionally used by obstetricians. However, reports in the literature show conflicting results. A Cochrane review from 2006 of three randomized controlled trials (RCTs) concluded that there is insufficient scientific basis to recommend one method in favor of the other (5).

In the current RCT, we compared the overlap technique and end-to-end approximation technique for primary repair of grade 3b, 3c, and 4 OASR with regard to fecal incontinence.

## Material and methods

The study was conducted in the Department of Obstetrics and Gynecology at the University Hospital of Stavanger, Norway, a university hospital that is the only obstetric unit in the region (population 320,000) with approximately 4,200 deliveries a year. Since 1996, detailed obstetric data have been registered consecutively in a departmental database. The incidence of OASR grade 3 and 4 was 5.6% in 2004.

Prior to the study, all doctors within the department were trained to diagnose and classify OASR according to the International Consultation on Incontinence (6). They received training in both the end-to-end approximation technique and the overlap technique on porcine anal sphincters. The gynecologists performing the repairs were experienced trainees, medium experienced trainees assisted by a senior, or senior consultants.

During the study period, all women diagnosed by the obstetrician on call with a perineal rupture grade 3b, 3c, or 4 immediately after delivery were eligible for inclusion. Participants were allocated 1:1 to either overlap or end-to-end repair. The obstetrician picked a sealed, numbered, opaque envelope containing the information of the method of repair. Information about the method to be used had been put into envelopes; equal numbers for each method; and the envelopes were sealed, numbered and mixed by an independent person. Participating patients were blinded with regard to the type of repair.

Eligible women were offered participation in the trial. Informed consent was obtained in the delivery room, and randomization took place before transfer to the operating theater. The obstetric team on call performed the repair, and the level of experience of the operating team was registered.

The operation was performed under general or regional anesthesia and the perineal injury was diagnosed in detail. If the initial diagnosis was proven incorrect, the patient was excluded from the study.

The external anal sphincter was identified and sutured with 3-0 polydioxanone either by end-to-end approximation or overlap technique as described by Sultan et al. (1). Remaining continuous external sphincter fibers in 3b ruptures were not divided. Identification of injury to the internal anal sphincter was intended, and rupture was repaired with interrupted 3-0 polydioxanone sutures. In grade 4 ruptures, the anal mucosa was adapted with interrupted 3-0 polyglactin sutures. The muscles of the perineum and vaginal tears were sutured using 2-0 polyglactin sutures, and the skin was closed by continuous intracutaneous 3-0 polyglactin sutures. Postoperative routines were identical in both treatment groups. Intraoperative intravenous antibiotics were given in

grade 4 OASR. During the hospital stay paracetamol, nonsteroidal anti-inflammatory drugs, and lactulose were administered, and all women received individual counseling and instruction in pelvic floor exercises by a specialized physiotherapist. A gynecological examination was scheduled 6 months postpartum according to departmental routine.

Evaluation of the patients was performed at a study visit 12 months after sphincter repair. All patients were contacted by telephone to make a suitable appointment in order to minimize loss to follow-up. All patients were asked to answer a Wexner incontinence score questionnaire prior to the visit (7). Participants who did not want to attend the visit were asked to answer the incontinence score questionnaire and return it by mail. During the study visit, information on anal continence, sexual function, pain, and future deliveries was recorded by the gynecologist (ABR) prior to anal examination. The patient remained blinded to the method of repair. The patient was examined by endoanal ultrasound (EAUS) and anal manometry by the colorectal surgeon (HK) who was blinded to the treatment allocation and unaware of clinical outcome of the individual patient.

Examination during the study visit included three-dimensional EAUS (Bruel & Kjaer, Denmark; Hawk 2102 EXL, 2050 endoanal ultrasound probe). The image file was acquired in a standardized way, and evaluated with regard to anatomy of the internal and external sphincter, that is, the upper, middle, and lower anal canal. Defect of the external anal sphincter below the upper anal canal was defined as a dehiscence of the external anal sphincter of >90 degrees (8). Furthermore, length of the anterior aspect of the external sphincter was measured.

Anal manometry was performed in cooperation with a trained endoscopy nurse. The stationary pull through method was applied using Polygraf ID 8 channel manometry system with Polygram NET software. Median, minimum, and maximum values of resting pressure and squeeze pressure were recorded. Data from the trial were recorded in a password-protected database, which was later combined with individual obstetric data from the departmental database.

The trial was approved by the regional research ethics committee of Western Norway (June 2004 REK-V 123.04) and registered at ClinicalTrials.gov (July 2005, SF2005-07) and reporting is in conformity with the CONSORT Statement (9).

## Statistics

The study was designed to test the hypothesis that overlap repair was superior to the approximation



method. Primary outcome measure of the study was leakage of solid stool once a week or more at 12 months, and a difference in outcome with a  $p$ -value  $<0.05$  was considered significant. Secondary outcome measures were anal incontinence assessed by Wexner incontinence score, EAUS evaluation of the integrity of the external and internal anal sphincter, and anal manometry measurements.

Power calculations were performed based on the assumption that 8% of patients operated with the overlap technique suffered anal incontinence compared to 41% of historical controls treated by the end-to-end method (1). As the obstetricians on call would operate on the patients, we expected the results to be somewhat inferior. Assuming that 16% of patients treated by the overlap technique suffered anal incontinence compared to 41% in the end-to-end group, 50 patients were needed in each group to demonstrate such a difference with 80% power and an  $\alpha$  value of 0.05 with a two-sided test of significance. Data were analyzed on an intention to treat base using SPSS statistical software v. 17 for Macintosh (SPSS Inc., Chicago, IL, USA). Category variables were analyzed using the  $\chi^2$  test or the Fischer's exact test when appropriate. Continuous variables with a normal distribution were compared using the  $t$ -test, and variables with non-normal distribution were compared by Mann-Whitney  $U$  test.

## Results

Between February 2005 and February 2007, 167 women sustained a grade 3b or more perineal rupture. Of these, 128 women (77%) gave informed consent to participate in the study and were included by random allocation as described (Figure 1). Eight women were excluded before operation because the injury was reclassified in the operating theater as less than 3b, and one was excluded because she was not treated according to the randomization allocation.

One hundred and nineteen patients were treated according to the protocol, comprising the study population, with 59 patients assigned to overlap repair and 60 to end-to-end repair. Clinical characteristics were similar in both groups (Table 1).

Eighteen patients were lost to follow-up or declined further participation. Accordingly, information about fecal incontinence was obtained from 101 participants (85%), of whom 99 reported a complete Wexner score (Table 2) at the 12-month study evaluation. Of those, 88 patients (74%) were examined by EAUS and anal manometry, and complete data were obtained from 87 (73%) for EAUS and from 85 (71%) for anal

manometry. The last evaluation took place in March 2008.

There were no differences between treatment groups with regard to fecal incontinence (Table 2). One patient in the end-to-end group and none in the overlap group reported leakage of solid stool once a week or more frequently. Flatus incontinence was reported by 14 patients (27%) in the end-to-end group and 10 (20%) in the overlap group,  $p = 0.48$ . Mean Wexner score was 2.4 in the end-to-end group versus 2.2 in the overlap group,  $p = 0.73$ . Severe anal incontinence, defined as a Wexner score  $>10$ , was registered in only one patient, treated by end-to-end repair. Teaching, that is, procedures performed by a trainee supervised by a senior, was more frequent in the end-to-end repairs, but the results were not different (Table 1).

The EAUS examination of 87 patients revealed an external sphincter defect (i.e. dehiscence of  $>90$  degrees) in two of 46 in the end-to-end group as compared to none of 41 in the overlap group ( $p = 0.5$ ). These two patients suffered from anal incontinence (Table 3).

To analyze a possible effect of previous deliveries, we performed a review of the medical records of the 42 multiparous women (Table 1). Analysis with regard to previous OASR, or previous vaginal deliveries, did not reveal differences in outcome.

Dyspareunia and experience of urinary leakage were frequent symptoms, reported by 39 and 37% of the patients, respectively; there were no differences between the groups. Operating time was similar in both groups.

## Discussion

This study was a large RCT comparing primary end-to-end repair versus overlap repair for OASR with regard to fecal incontinence after 12 months. The study was carried out in a typical daily clinical setting of a university hospital with participating doctors trained in both repair techniques. We did not find any significant differences between the two methods, neither with regard to the primary endpoint, that is, leakage of solid stool once a week or more at 12 months, nor secondary endpoints of Wexner incontinence score, flatus incontinence, or external anal sphincter defects evaluated by EAUS or anal manometry.

A 2006 Cochrane review reported that overlap repair may be associated with lower incontinence scores. However, sound conclusions concerning outcomes were difficult because of the possibility of skewed data. Furthermore, there was considerable

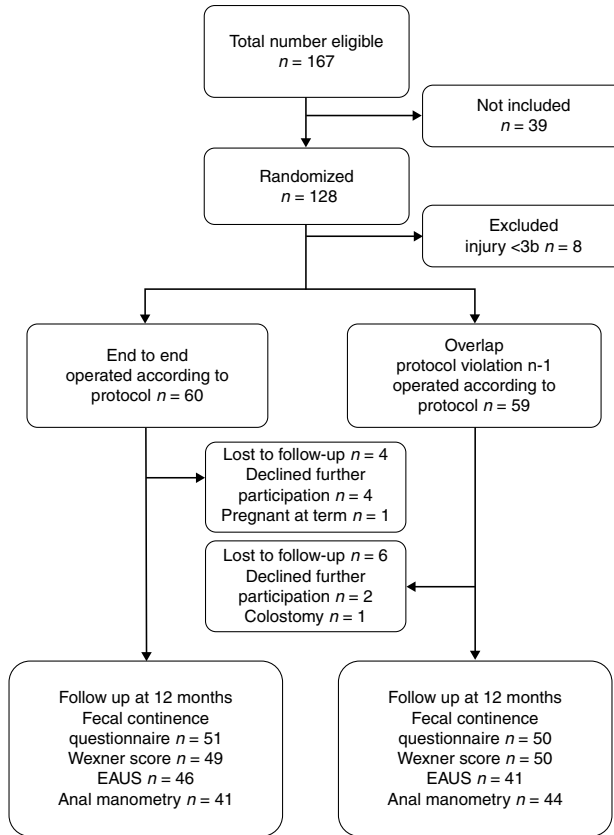


Figure 1. Flow chart of 167 patients eligible for randomization to either end-to-end approximation or overlap repair of grade 3b, 3c or 4 obstetric anal sphincter rupture (OASR). Of those, 128 patients (77%) were allocated to one of the two techniques according to the randomization procedure. After exclusion of eight patients with injuries grade <3b, 60 patients were treated with overlap repair and 59 with end-to-end approximation technique (one patient excluded due to protocol violation).

heterogeneity between the various RCTs with regard to endpoints, patient populations, type of rupture, surgical experience, and postoperative care. The meta-analysis failed to show significant differences in anal incontinence scores >10 (i.e. severe incontinence) (5).

The three former trials differ considerably with regard to the types of injury included and the repair procedures (5). Our study included 3b, 3c, or 4 injuries similar to the Fernando trial (10); by contrast, Fitzpatrick et al. (11) and Williams et al. (2) included all partial ruptures. In the Fernando trial (10), two expert gynecologists performed the repairs, while in the other studies, as in the present analysis, trained obstetricians on call performed the repairs (2,11). We report on the surgical experience of the participating

doctors. Teaching was reported significantly more frequently in the end-to-end group. Training is part of an everyday clinical setting, and we believe that the results reflect that measures were taken both to secure adequate competence in the team as well as to undertake teaching. The operating time was same in both groups and the outcome was similar, indicating that teaching did not affect the quality of the procedures.

In the present study, we aimed to identify and repair internal sphincter injury, which may have contributed to the overall results (12). This was also done by Sultan et al. and Fernando et al. (1,10), but not by Williams et al. or Fitzpatrick et al. (2,11). Fernando divided remaining external sphincter fibers in some cases of 3b injuries to allow a complete overlap. We avoided, like Williams et al., division of undamaged

Table 1. Clinical and demographic characteristics of 119 patients randomized to end-to-end approximation versus overlap repair for grade 3b, 3c, and 4 obstetric and sphincter rupture (OASR).

	End-to-end group (N = 60)	Overlap group (N = 59)	p-Value
Median maternal age, years (range)	29 (18–36)	29 (21–40)	1
Parity, n (%)			1
Primiparous	39 (65)	38 (64)	
Multiparous	21 (35)	21 (36)	
Previous OASR	6	3	0.11 <sup>a</sup>
Vaginal, no OASR	7	15	
No previous vaginal	8	3	
Mode of delivery, n (%)			0.26
Spontaneous delivery	40 (66)	37 (63)	
Ventouse	19 (32)	17 (29)	
Forceps	1 (2)	5 (8)	
Episiotomy, n (%)	11 (18)	13 (22)	0.65
Duration stage 2 of delivery (minute)	39	38	0.83
Degree of anal sphincter injury, n (%)			0.41
3b	39 (65)	32 (54)	
3c	13 (22)	19 (32)	
4	8 (13)	8 (14)	
Birth weight (mean), g (range)	3,976 (3,016–5,260)	3,880 (2,528–4,900)	0.19
Head circumference, cm (mean)	36	36	1
Operation time (minute)	39	41	0.5
Operator experience			0.01
Experienced trainee	4	15	
Trainee assisted by a senior consultant	28	17	
Senior consultant	28	27	

<sup>a</sup>p-Value with regard to OASR and previous deliveries.

muscle fibers (2). Fitzpatrick and Sultan do not state this aspect explicitly (1,2).

We did not exclude patients with previous OASR, which may be a weakness of our trial. While Fitzpatrick included only primiparous women (11), Fernando excluded patients with previous OASR (10), and Williams included multiparous women without addressing this topic (2). However, this aspect did not influence our results.

According to the Cochrane review the overlap repair appeared to be associated with a lower risk

of fecal urgency and less risk of deterioration of symptoms over time, while quality of life was the same (5). We did not address these aspects in our study. However, we would expect that a tendency toward better long-term results for the overlap technique would result in significant differences between the groups after 12 months.

Our study was designed to show the superiority of the overlap technique. We were able to achieve a high degree of follow-up, as 101 of the 128 included patients (85%) were evaluated after 12 months, and

Table 2. Functional outcomes in 101 patients randomized to end-to-end approximation versus overlap repair for grade 3b, 3c, and 4 obstetric anal sphincter rupture (OASR) at 12 months with regard to anal incontinence, dyspareunia, and urinary incontinence.

	End-to-end group (N = 51)	Overlap group (N = 50)	p-Value
Fecal incontinence $\geq 1$ /week, solid stool	1/51	0/50	1
Fecal incontinence $\geq 1$ /week, liquid stool <sup>a</sup>	2/50	0/50	0.5
Flatus incontinence $\geq 1$ /week	14/51	10/50	0.48
Dyspareunia $\geq 1$ /month <sup>b</sup>	22/50	17/49	0.41
Urinary incontinence <sup>d</sup>	20/51	17/50	0.68
Wexner score (mean) <sup>c</sup>	2.35 (n = 49)	2.18 (n = 50)	0.73
Continence status			0.48
Continent <sup>c</sup> (Wx $\leq 5$ )	40/49	44/50	
Anal incontinence <sup>c</sup> (Wx 6–9)	8/49	6/50	
Severe AI <sup>c</sup> (Wx $\geq 10$ )	1/49	0/50	

<sup>a</sup>Missing data for one patient in the end-to-end group.

<sup>b</sup>Missing data for two patients, one in each group.

<sup>c</sup>Missing data for two patients in the end-to-end group.

<sup>d</sup>Patients experiencing urinary leakage episodes at all.

Table 3. Endoanal ultrasonographic (EAUS) and anal manometric findings in 87 patients randomized to end-to-end versus overlap repair for grade 3b, 3c, and 4 OASR at 12 months.

	End-to-end group (N = 46)		Overlap group (N = 41)		p
EAUS					
External sphincter defect >90°, axial plane	2		0		0.5
Anterior external sphincter length* (mm)	14 (1–22)		13 (5–26)		0.9
Anal manometry <sup>b</sup> (mmHg)	Mean	SD	Mean	SD	
Resting, mean	15	6.3	13	5.5	0.07
Squeeze, mean	81	32.2	85	25.2	0.48

\*Results from 81 patients, 37 in overlap group, 44 in end-to-end group.

<sup>b</sup>Results from 85 patients, 44 in overlap group, 41 in end-to-end group.

thus reached the necessary number of participants according to power calculations. Fernando (10) obtained data from 81% of the 64 patients, and Williams et al. (2) from 54% of the 112 included patients at 12 months. Fitzpatrick et al. (11) examined the 112 (100%) patients 3 months postpartum.

Our RCT did not reveal any differences in outcome between repair techniques at 12 month follow-up. The overall results were good with regard to fecal continence, regardless of method of repair. Ultrasound examination revealed only two patients with external sphincter defects >90 degree, both in the end-to-end group. These findings correlated with inferior clinical results. While ultrasound assessment in our study focused on external sphincter defects in the transversal plane and length of the anterior aspect of the external sphincter, more sophisticated scoring systems are now available (8,13). However, our ultrasound assessment, even if less advanced in comparison to the present standard, did not reveal any differences between the two study groups, and was in agreement with the primary outcome measure of this study. Long-term follow-up including EAUS assessment according to validated scoring systems is warranted.

Our study does not support the hypothesis that the overlap repair is superior to the end-to-end repair. We believe that a focus on precision of diagnosis and repair technique combined with optimal perioperative conditions and postoperative routines is important to achieve acceptable clinical results for primary repair of OASR. Good results can also be obtained in the setting of surgical teaching. We believe that our results contribute to the core knowledge of primary repair of OASR grade 3b, 3c, and 4 and effects on fecal incontinence. Follow-up studies are needed to evaluate primary repair of OASR for long-term outcomes.

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**Declaration of interest:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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**Supplementary material available online**

CONSORT 2010 checklist

Patient Questionnaire

Translated Patient Questionnaire



## Paper II

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# BMJ Open Assessing the association of oxytocin augmentation with obstetric anal sphincter injury in nulliparous women: a population-based, case-control study

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## ABSTRACT

**Objective:** To assess the association of oxytocin augmentation with obstetric anal sphincter injury among nulliparous women.

**Design:** Population-based, case-control study.

**Setting:** Primary and secondary teaching hospital serving a Norwegian region.

**Population:** 15 476 nulliparous women with spontaneous start of labour, single cephalic presentation and gestation  $\geq 37$  weeks delivering vaginally between 1999 and 2012.

**Methods:** Based on the presence or absence of oxytocin augmentation, episiotomy, operative vaginal delivery and birth weight ( $< 4000$  vs  $\geq 4000$  g), we modelled in logistic regression the best fit for prediction of anal sphincter injury. Within the modified model of main exposures, we tested for possible confounding, and interactions between maternal age, ethnicity, occiput posterior position and epidural analgesia.

**Main outcome measure:** Obstetric anal sphincter injury.

**Results:** Oxytocin augmentation was associated with a higher OR of obstetric anal sphincter injuries in women giving spontaneous birth to infants weighing  $< 4000$  g (OR 1.8; 95% CI 1.5 to 2.2). Episiotomy was not associated with sphincter injuries in spontaneous births, but with a lower OR in operative vaginal deliveries. Spontaneous delivery of infants weighing  $\geq 4000$  g was associated with a threefold higher OR, and epidural analgesia was associated with a 30% lower OR in comparison to no epidural analgesia.

**Conclusions:** Oxytocin augmentation was associated with a higher OR of obstetric anal sphincter injuries during spontaneous deliveries of normal-size infants. We observed a considerable effect modification between the most important factors predicting anal sphincter injuries in the active second stage of labour.

## INTRODUCTION

Obstetric anal sphincter injuries occur in 0.5–5.0% of vaginal deliveries<sup>1</sup> with a subsequently increased risk of faecal incontinence.<sup>2–4</sup> Nulliparity,<sup>1 3 5</sup> high birth weight

## Strengths and limitations of this study

- Stratifying by the main risk factors that are active during the expulsive phase of labour and testing for confounders are strengths of the study.
- We reveal how oxytocin augmentation interacts with the major factors active in the expulsive phase of labour.
- The study is based on prospectively collected data from a large, unselected population, which makes bias unlikely.
- The study design is a limitation, as we cannot prove causality between oxytocin augmentation and obstetric anal sphincter injuries in an observational study.

(BW),<sup>1 3 5 6</sup> operative vaginal delivery,<sup>1 3 5</sup> advanced maternal age,<sup>1 5 6</sup> Asian or African ethnicity,<sup>1 7</sup> and prolonged second stage of labour<sup>3 7 8</sup> are consistently reported as risk factors for obstetric anal sphincter injuries, whereas the effect of epidural analgesia<sup>9 10</sup> and episiotomy<sup>1 11–13</sup> is debated. However, only a few authors have evaluated oxytocin augmentation as a possible risk factor for obstetric anal sphincter injuries.<sup>5 14 15</sup> Further, the current literature dealing with risk factors for obstetric anal sphincter injuries has not sufficiently addressed their possible interactions. Studies usually present a summary of associations between risk factors and obstetric anal sphincter injuries adjusted for confounders without investigating effect modification, that is, exploring whether the effects are uniform across various levels of the studied risk factors.

In many delivery units, oxytocin augmentation is used during more than half of births.<sup>16 17</sup> Oxytocin augmentation has been shown to shorten the duration of labour, but not to decrease the need for operative deliveries.<sup>18</sup> We hypothesise that oxytocin augmentation may reduce control over



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contractions and impair perineal support by causing the delivery to progress too quickly, and thereby increase the risk of perineal injury. Thus, the widespread use of oxytocin in daily obstetric practice calls for an exploration of its possible harmful effects. The aim of our study was to assess the association between oxytocin augmentation and obstetric anal sphincter injuries in a dynamic model related to the active second stage of labour.

## MATERIALS AND METHODS

The Department of Obstetrics and Gynecology of Stavanger University Hospital serves as the only delivery unit for a population of 320 000 people, and approximately 4500 deliveries occur there annually. From 1996 onward, all obstetric data have been consecutively recorded. The electronic database consists of clearly defined variables, and is continuously maintained using standardised procedures for data entry and quality control. During the study period, 15 May 1999 to 15 May 2012, 56 517 women with a pregnancy duration of  $\geq 23$  weeks of gestation delivered infants with a BW of  $>300$  g in the department. Estimated day of delivery was determined by second trimester ultrasound scan or from menstrual data when no ultrasound examination was performed. We restricted the study population to nulliparous women whose labour started spontaneously, with single cephalic presentation, pregnancies of  $\geq 37$  weeks of gestation (Group 1 in Robson's Ten Group Classification System; TGCS<sup>19</sup>) and who delivered vaginally. After excluding 69 women with missing data (52 without an estimated day of delivery, 17 with missing information of fetal presentation at delivery), this case-control study comprised 15 476 women.

The main outcome measure was obstetric anal sphincter injuries as defined by the International Continence Society, that is, partial or complete tears of the anal sphincter muscles, with or without disruption of the anal mucosa (grades 3–4 perineal tears).<sup>20</sup> When an obstetric anal sphincter injury was suspected, the obstetrician on call diagnosed the grade of the tear during surgical repair.

Oxytocin augmentation was defined as oxytocin used to stimulate contractions during established labour. An intravenous infusion of 5 international units (0.01 mg) of oxytocin in 500 mL saline was administered, starting with 30 mL/h and a dose increment of 15 mL/h every 15 min to a maximum of 180 mL/h, guided by the response. Normal births were taken care of by midwives, while doctors performed the operative deliveries. Throughout the study period, episiotomy was performed either mediolaterally or laterally. According to our routines and national guidelines, operative vaginal delivery was indicated if delivery had not taken place after 60 min of bearing down. We used vacuum extraction with a Malmström metal cup as the preferred procedure for operative vaginal delivery. Vacuum extraction was applied for mid-cavity and outlet release. A combination

of low-dose ropivacaine/fentanyl was used for epidural analgesia. Ethnicity was classified as Western, that is, originating from Europe or North America, or non-Western.

The intention of this study was to explore the effect of three obstetric practices (oxytocin augmentation (O), episiotomy (E) and vacuum/forceps (VF)) and BW on obstetric anal sphincter injuries before other risk factors were considered. These main risk factors correlate as episiotomy is often used for instrumental deliveries and when large babies are expected. Furthermore, oxytocin augmentation is provided for failure to progress because of dystocia. Women with dystocia are more often delivered instrumentally than women without dystocia. This basic understanding of the birth dynamics of the first and second stages of labour indicates that the main risk factors may have a direct or indirect effect on obstetric anal sphincter injuries, and that the effects of categories across different explanatory variables are not constant on the outcome.

We analysed our dataset using the  $\chi^2$  test and backward manual stepwise logistic regression analyses with  $p < 0.05$  as significance level. We built and checked the fit of our regression model as proposed by Agresti.<sup>21</sup> Step one compares the model including the highest order four-way interaction with a model without the four-way interaction. If the highest order product is not significant, Agresti proposes continuing by removing the highest order term with the highest non-significant  $p$  value until all remaining terms have statistically significant  $p$  values. Four main predictors (O, E, VF and BW) are used to predict the proportions of women with sphincter injuries. Confounders, possible risk factors in addition to the main factors of interest, were tested one by one and set to at least 10% change in any estimate in the model of best fit. Interaction terms were significant at  $p < 0.05$ . Statistical analyses were performed with IBM SPSS Statistics for Windows, V.19.0, IBM Corp, Armonk, New York, USA.

The Regional Committee for Medical and Health Research Ethics, Western Norway, approved the protocol as a quality assurance study in obstetric care, and fulfilling the requirements for data protection procedures (REK 2011-1247).

## RESULTS

The study population comprised 15 476 (27%) of the 56 517 women giving birth during the study period, including 1013 (53%) of a total of 1894 women diagnosed with obstetric anal sphincter injuries.

The overall prevalence of obstetric anal sphincter injuries was 6.5%. The rate declined from 9.6% in 1999–2000 to 2.8% in 2010–2012. The characteristics of the study population and the prevalence of obstetric anal sphincter injuries are displayed in [table 1](#).

The prevalence was higher in women who received oxytocin augmentation (8.0% vs 5.3%), those who were delivered

**Table 1** Characteristics of the study population and the prevalence of obstetric anal sphincter injury

Factor	Obstetric anal sphincter injury		In total N=15 476	Prevalence Per cent	p Value
	No N=14 463 Per cent	Yes N=1013 Per cent			
Time period					<0.001
1999–2000	11.1	16.9	1781	9.6	
2001–2003	19.8	30.7	3169	9.8	
2004–2006	22.9	29.6	3611	8.3	
2007–2009	25.5	14.3	3826	3.8	
2010–2012	20.8	8.6	3089	2.8	
<i>Maternal factors</i>					
Age (years)					<0.001
<25	26.6	19.3	4040	4.9	
25–29	33.5	37.6	5233	7.3	
30–34	17.8	20.8	2785	7.6	
≥35	22.1	22.2	3418	6.6	
Origin					NS*
Western	90.5	92.0	14 025	6.6	
Non-Western	9.5	8.0	1451	5.6	
<i>Obstetric factors</i>					
Epidural analgesia					NS
No	58.1	57.7	8992	6.5	
Yes	41.9	42.3	6484	6.6	
Oxytocin augmentation					<0.001
No	55.6	44.7	8500	5.3	
Yes	44.4	55.3	6976	8.0	
Active 2nd stage of labour (min)					<0.001
Missing information	0.6	0.3	92	3.3	
0–14	10.8	6.8	1627	4.2	
15–29	26.8	18.5	4063	4.6	
30–59	40.1	37.8	6181	6.2	
≥60	21.7	36.6	3513	10.6	
Episiotomy					NS
No	67.1	65.4	10 372	6.4	
Yes	32.9	34.6	5104	6.9	
Operative vaginal delivery					<0.001
No	77.5	60.3	11 817	5.2	
Yes	22.5	39.7	3659	11.0	
<i>Fetal factors</i>					
Birth weight (g)					<0.001
<4000	87.8	74.2	13 454	5.6	
≥4000	12.2	25.8	2022	12.9	
Occiput posterior position					NS
No	95.4	94.8	14 771	6.5	
Yes	4.5	5.2	705	7.4	

p Values from  $\chi^2$  tests.

\*Non-significant.

instrumentally (11.0% vs 5.2%) and in those who gave birth to an infant weighing  $\geq 4000$  g (12.9% vs 5.6%). Furthermore, the prevalence increased with longer durations of the active part of the second stage of labour.

After adopting the strategy of Agresti by deleting the highest statistically non-significant terms in the model until all remaining terms are statistically significant, we ended up with a best fitting model involving the three-way interaction of oxytocin augmentation, episiotomy

and vacuum/forceps (O×E×VF) and the two two-way interactions episiotomy/birth weight (E×BW) and vacuum/forceps (VF×BW) (model A). We could resolve interaction terms into stratified analysis of eight strata of combinations of oxytocin augmentation, episiotomy and instrumental delivery for BW <4000 g, and four strata of combinations of episiotomy, instrumental delivery and BW  $\geq 4000$  g, independent of oxytocin augmentation. The results are displayed in [table 2](#).

**Table 2** Model A: Stratified analyses of eight strata of combinations of oxytocin augmentation, episiotomy, instrumental delivery and birth weights <4000 g, and four strata of episiotomy, instrumental delivery and birth weights ≥4000 g, independent of oxytocin augmentation

Group	Oxytocin augmentation*	Episiotomy*	Operative vaginal delivery*	Birth weight†	Women N	OASI‡ N (%)	OR	95% CI
1	–	–	–	–	5328	198 (3.7)	1.0	
2	–	+	–	–	1434	60 (4.2)	1.1	0.8 to 1.5
3	–	+	+	–	537	43 (8.0)	2.3	1.6 to 3.2
4	–	–	+	–	316	47 (14.9)	4.5	3.2 to 6.4
5	+	+	+	–	1283	92 (7.2)	2.0	1.6 to 2.6
6	+	–	+	–	896	103 (11.5)	3.4	2.6 to 4.3
7	+	–	–	–	2621	148 (5.6)	1.6	1.3 to 1.9
8	+	+	–	–	1039	61 (5.9)	1.6	1.2 to 2.2
9	+/-	+	–	+	418	40 (9.6)	2.7	1.9 to 3.9
10	+/-	–	–	+	977	104 (10.6)	3.1	2.4 to 4.0
11	+/-	+	+	+	393	55 (14.0)	4.2	3.1 to 5.8
12	+/-	–	+	+	234	62 (26.5)	9.3	6.8 to 12.9

Crude OR and 95% CIs.

\*Used (+)/unused (–).

†≥4000 g (+)/&lt;4000 g (–).

‡Obstetric anal sphincter injury.

From a clinical perspective we can simplify model A into model B by collapsing groups that comprise similar risks for sphincter injury by obstetric interventions despite overlapping CIs. Spontaneous delivery of an infant weighing <4000 g without oxytocin augmentation and episiotomy was chosen as the reference group (group 1). We collapsed groups 1 and 2 as the OR for sphincter injury was similar with and without episiotomy in unstimulated, spontaneous births of normal-size infants. Groups 3 to 6 displayed the OR for sphincter injury in instrumental deliveries of normal-size infants with and without oxytocin augmentation and episiotomy. A marked difference in the OR for sphincter injury was observed between women delivered instrumentally with (groups 3 and 5) and without (groups 4 and 6) episiotomy, despite the fact that those stimulated with oxytocin had a non-significant lower OR for sphincter injury. It was, therefore, reasonable to collapse groups 3 and 5 and groups 4 and 6. Furthermore, we collapsed groups 7

and 8 as the OR for sphincter injury was similar with and without episiotomy during spontaneous deliveries of infants <4000 g, regardless of oxytocin augmentation. Finally, the use of episiotomy appeared to be strongly associated with lower OR for sphincter injury in instrumental deliveries of infants ≥4000 g (groups 11 and 12). The modified model B (table 3) comprises a clinically relevant risk estimation of anal sphincter injury among the main modified risk factors for sphincter injury.

Age, origin of the mother and occiput posterior position had no confounding effect on ORs for obstetric anal sphincter injury across combinations of episiotomy, oxytocin augmentation, operative vaginal delivery and BW (groups A to G in table 3).

The unadjusted OR for the presence or absence of epidural analgesia was 1.02; however, the adjusted OR for epidural analgesia was 0.73, (95% CI 0.63 to 0.84), that is, epidural analgesia was associated with a 30% lower OR of anal sphincter injury.

**Table 3** Modified model displaying the collapsed non-significant strata (1–12) from table 2 into new strata (A–G)

Group (group in table 2)	Oxytocin augmentation*	Episiotomy*	Operative vaginal delivery*	Birth weight†	Women N	OASI‡ N (%)	OR	aOR (95% CI)
A (1,2)	–	+/-	–	–	6762	258 (3.8)	1.0	1.0
B (7,8)	+	+/-	–	–	3660	209 (5.7)	1.5	1.8 (1.5 to 2.2)
C (3,5)	+/-	+	+	–	1820	135 (7.4)	2.0	2.3 (1.8 to 2.8)
D (4,6)	+/-	–	+	–	1212	150 (12.4)	3.6	4.1 (3.3 to 5.1)
E (9–10)	+/-	+/-	–	+	1395	144 (10.3)	2.9	3.1 (2.5 to 3.9)
F (11)	+/-	+	+	+	393	55 (14.0)	4.1	4.7 (3.4 to 6.5)
G (12)	+/-	–	+	+	234	62 (26.5)	9.1	10.5 (7.6 to 14.4)

Unadjusted OR, adjusted (aOR) and 95% CIs after adjusting for epidural analgesia.

\*Used (+)/unused (–).

†≥4000 g (+)/&lt;4000 g (–).

‡Obstetric anal sphincter injury.

The use of oxytocin augmentation increased with the duration of the second stage of labour over all the time periods from an average of 32% in the <30 min group, 46% in the 30–59 min group, and 65% (range 49–76%) in the ≥60 min group during the active second stage of labour. The prevalence of operative deliveries across all study periods was consistently between 45% and 49% when the active part of the second stage of labour lasted ≥60 min versus 12–21% for durations of the second stage of labour of <60 min. We found strong associations between oxytocin augmentation and the duration of the second stage, and between operative delivery and the duration of the second stage (collinearity), which means that the duration of the second stage is measured through operative delivery and oxytocin augmentation.

## DISCUSSION

We found that oxytocin augmentation during active labour was associated with a 80% increased OR of obstetric anal sphincter injury in women in TGCS group 1 giving spontaneous birth to an infant weighing <4000 g. We did not find an association between episiotomy and tears during spontaneous deliveries, but a significantly reduced association in all operative vaginal deliveries.

Oxytocin augmentation is widely used in delayed labour to prevent operative delivery. However, a Cochrane review concluded that a reduction of labour by 2 h was the only proven effect, and there was no effect on operative deliveries.<sup>18</sup> Another recent review found the entire concept of active management of labour to be associated with a slightly reduced risk of caesarean delivery.<sup>22</sup> As in other studies, we found that approximately 50% of nulliparous women received oxytocin augmentation.<sup>16 17 23</sup> There is reason to believe that guidelines for the diagnosis and treatment of protracted labour are unclear or inconsistently applied in daily practice.<sup>17</sup> We hypothesise that stimulation with oxytocin may speed up the progress of the expulsive phase of labour leading to rushed situations, impaired communication with the mother, less focus on protection of the perineum and a controlled delivery of the head. Recent studies from Norway indicate that focus on these elements is important in preventing perineal injuries.<sup>24 25</sup>

Many authors have used logistic regression analysis to identify risk factors for obstetric anal sphincter injuries, but only a few have included oxytocin augmentation. Samuelsson *et al*,<sup>14</sup> Prager *et al*,<sup>15</sup> and Jander and Lyrenas<sup>5</sup> found oxytocin augmentation to be predictive of obstetric anal sphincter injuries in univariate analysis, but only Jander and Lyrenas confirmed this finding in multivariable analyses. Samuelsson *et al*<sup>14</sup> did not stratify by parity, which is a methodological weakness since the true effect of other factors is concealed by the strong impact of parity. Prager *et al*<sup>15</sup> studied obstetric anal sphincter injuries in nulliparous women, entering

oxytocin augmentation, duration of active second stage of labour and instrumental delivery into the same model.

Our study shows strong collinearity between a prolonged active second stage of labour and both oxytocin augmentation and instrumental delivery. We consider the duration of the active second stage of labour to be a 'proxy' for oxytocin augmentation and instrumental delivery, and not a risk factor for obstetric anal sphincter injury in itself. Long duration of the second stage is a time-related event before the expulsion of the head. During this latency the active forces do not inflict injury on the sphincter apparatus, the sphincter injury occurs during the expulsive phase. Consequently, we do not consider the duration of the active second stage as a risk factor for anal sphincter injuries.

Jander and Lyrenas<sup>5</sup> conducted a single institution, retrospective, case-control study of 214 cases to explore 44 possible risk factors, and found that oxytocin augmentation was a significant risk factor for obstetric anal sphincter injuries in multivariable analyses (OR 2.00; 95% CI 1.13 to 3.53). However, these researchers did not stratify by parity or state whether or not interactions were tested for. Furthermore, three older studies on the risk of obstetric anal sphincter injury included oxytocin use without differentiating whether oxytocin was provided for induction or augmentation purposes.<sup>26–28</sup> Three large population-based studies on the risk of obstetric anal sphincter injuries did not include oxytocin augmentation in their analyses.<sup>1 7 8</sup>

The influence of epidural analgesia on anal sphincter injuries is unclear. Eskandar and Shet<sup>9</sup> found a reduced risk, but did not stratify by parity. Dahl and Kjølhed<sup>10</sup> found epidural analgesia to be an independent protective factor in nulliparous women. Poen *et al*<sup>29</sup> stratified by parity and found a significantly increased OR associated with epidural analgesia in nulliparous women. In our study, epidural analgesia was associated with a significantly reduced OR for sphincter tears.

Our study takes into account four factors that exert their effect on the anal sphincter during the final minutes of delivery. As in previous studies,<sup>1 3 5</sup> we found both operative vaginal delivery and high BW to be strongly associated with obstetric anal sphincter injuries. We found episiotomy to be associated with a lower prevalence of sphincter tears in operative vaginal deliveries, but not in spontaneous births. This is consistent with a large national registry study from Norway,<sup>1</sup> but differs from other studies.<sup>8 11 13 30 31</sup> In our study, neither oxytocin augmentation nor episiotomy were associated with obstetric anal sphincter injury during spontaneous delivery of an infant weighing ≥4000 g.

Our methodological approach, stratifying by the factors that are active during the expulsive phase of labour and testing for confounders, is considered the strength of the study. This approach leads to a more detailed understanding of how oxytocin augmentation



interacts with these major risk factors. Logistic regression analyses, without testing for possible interactions, would fail to reveal this information. This case-control study is based on prospectively collected data from a large unselected population, and represents all deliveries meeting the inclusion criteria that occurred during the study period, which make bias unlikely. Our department has a high proportion of vaginal deliveries. The overall caesarean delivery rate in our institution was 12.5% over the study period. For women in TGCS group 1 the acute caesarean section rate increased from 5.0% in 1999 to 7.5% in 2012. Accordingly, the study population includes both high-risk and low-risk pregnancies, which adds to the external validity of our results.

However, some limitations apply. We cannot prove causality between oxytocin augmentation and obstetric anal sphincter injuries in an observational study. Furthermore, socioeconomic status, smoking, body mass index, maternal delivery positions, perineal support technique and the birth attendant's experience level may be possible risk modifiers not included in our database. Finally, single institution studies, also when based on unselected populations, should be interpreted with caution.

Our findings have some important implications. Birth attendants should be aware of the association between oxytocin augmentation and obstetric anal sphincter injuries in the large subgroup of nulliparous women giving spontaneous birth to a normal-size infant. More restrictive use of oxytocin may help prevent obstetric anal sphincter injuries. Implementation of evidence-based guidelines for using oxytocin augmentation should be encouraged. The WHO recommends the use of a partogram with an action line defining failure to progress. However, a recent Cochrane review could not confirm that such a partogram was beneficial in high resource settings.<sup>32</sup> Given the doubtful benefits from augmentation of labour, randomised controlled trials are strongly needed, and we propose anal sphincter injury as one of the most important endpoints.

Moreover, our study supports restricted use of episiotomy during normal births and as a recommendation for operative vaginal deliveries. BW is an important, albeit unpredictable risk factor as weight estimation of a large fetus is unreliable.<sup>33</sup>

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# Assessing the association of oxytocin augmentation with obstetric anal sphincter injury in nulliparous women: a population-based, case-control study

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