

DISSERTATIONS IN  
**HEALTH  
SCIENCES**

**SARI RÄISÄNEN**

# *Obstetric Anal Sphincter Ruptures*

*Risk Factors, Trends and Differences Between  
Hospitals*

PUBLICATIONS OF THE UNIVERSITY OF EASTERN FINLAND  
*Dissertations in Health Sciences*



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EASTERN FINLAND

**SARI RÄISÄNEN**

*Obstetric Anal Sphincter Ruptures –  
Risk Factors, Trends and Differences Between Hospitals*

To be presented by permission of the Faculty of Health Sciences, University of Eastern Finland for public examination in Auditorium ML3, Medistudia building, University of Eastern Finland, on Friday, March 4<sup>th</sup> 2011, at 12 noon

Publications of the University of Eastern Finland

Dissertations in Health Sciences

42

Department of Nursing Science  
Faculty of Health Sciences  
University of Eastern Finland

Research Unit  
Department of Gynaecology and Obstetrics  
Kuopio University Hospital  
2011

Kopijyvä Oy

Kuopio, 2011

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Distribution:

Eastern Finland University Library  
P.O.Box 1627, 70211 KUOPIO  
FINLAND  
Tel.: +358 40 355 3430  
<http://www.uef.fi/kirjasto>

ISBN: 978-952-61-0360-0 (print)

ISBN: 978-952-61-0361-7 (pdf)

ISSN: 1798-5706 (print)

ISSN: 1798-5714 (pdf)

ISSN-L: 1798-5706

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Räisänen, Sari. *Obstetric Anal Sphincter Ruptures – Risk Factors, Trends and Differences Between Hospitals*. Publications of the University of Eastern Finland. Dissertations in Health Sciences 42. 2011. 69 p.

ISBN: 978-952-61-0360-0 (print)

ISBN: 978-952-61-0361-7 (pdf)

ISSN: 1798-5706 (print)

ISSN: 1798-5714 (pdf)

ISSN-L: 1798-5706

## ABSTRACT

Obstetric anal sphincter rupture (OASR) is a well-known complication of vaginal delivery; it can have serious implications for women's health since it results in anal incontinence in 20-60% of those affected. The incidence of OASR varies widely; in 2008 it was reported at a level of 0.9% in Finland but 2.6-5.6% in the other Nordic countries. The purpose of this study was to identify the risk factors for OASR, and to describe trends in the incidence of OASR and episiotomy between 1997 and 2007 in Finland. A population-based inventory of 514,741 women with singleton vaginal deliveries, including all presentations and assisted deliveries, recorded in the Finnish Medical Birth Register was analyzed. For the years 1997-2003, the information on OASR was taken from the Hospital Discharge Register (HDR). Primiparous (=first vaginal delivery) (n=2,315) and multiparous (n=534) women with OASR were compared in terms of possible risk factors to primiparous (n=215,463) and multiparous (n=296,429) women without OASR, respectively, using stepwise logistic regression analysis.

The risk factors for OASR included forceps delivery, a prolonged active second stage of birth, delivery of an infant weighing more than 4,000 grams, and vacuum assistance. Lateral episiotomy was associated with a 17% lower risk of OASR among primiparous women in spontaneous vaginal deliveries; however this approach was inefficient since more than 900 primiparous women must be exposed to an episiotomy to prevent a single OASR. In vacuum assisted deliveries among primiparous women the equivalent number was 66, which is clinically more acceptable. Correspondingly, among the multiparous women, episiotomy was associated with a doubling of the risk of OASR. Furthermore, pain management was associated with 13-52% lower risk of OASR among both groups of women except epidural analgesia among the multiparous women that increased the risk 1.5-fold.

In Finland, the incidence of OASR has increased, from 0.2% in 1997 to 0.9% in 2007. The likelihood of OASR increased 3.28-fold among primiparous and 2.83-fold among multiparous women during the study period, 1997-2007. Changes in population characteristics and in the use of interventions were small, and consequently did not cause the increased OASR rate. The only exception was vacuum assisted deliveries, which explained about 9% of the rising OASR risk, in line with the increased use of this technique. The results of this study suggest that time factors were of minor importance to the increasing rate of OASR, because the risk of it was shown to be 11% lower during the night than daytime and 15% lower in July (the most popular holiday month) than other months. In fact, ca. 3- to 8-fold inter-hospital differences in OASR risks in primiparous and multiparous women, respectively, were of greater importance. Hospitals with high rates of OASR for primiparous women also had high rates for multiparous women, implying that treatment differences might have played a crucial role in the variations or that there were differences in registration routines or in diagnosing OASR.

The results suggest that episiotomy provided protection from OASR in the first vaginal birth, but was a risk factor in multiparous women. Among the multiparous women, episiotomy was performed prophylactically more often in those who were at a high risk of OASR than in low risk women, consequently there might have been confounding by indication. The results indicate the value of selective use of lateral episiotomy, and its routine use might be advisable in vacuum assisted deliveries for primiparous women. Inter-hospital differences suggest that, between the hospitals, there may be an important healthcare quality issue or differences in recording or diagnosing OASR.

National Library of Medicine Classification: WQ415; WQ330; WP170

Medical Subject Headings (MeSH): Delivery, Obstetric; Obstetric Labor Complications; Anal Canal +injuries; Rupture +epidemiology; Episiotomy; Registries



Räisänen, Sari. Peräaukon sulkijalihasrepeämä synnytyksen komplikaationa – riskitekijät, ilmaantuvuus muutokset ja vaihtelu sairaaloiden välillä, Publications of the University of Eastern Finland. Dissertations in Health Sciences 42. 2011. 69 s.

ISBN: 978-952-61-0360-0 (print)

ISBN: 978-952-61-0361-7 (pdf)

ISSN: 1798-5706 (print)

ISSN: 1798-5714 (pdf)

ISSNL: 1798-5706

## TIIVISTELMÄ

Peräaukon sulkijalihasrepeämä on tunnettu alatiesynnytyksen komplikaatio, joka voi aiheuttaa vakavia ja pitkäaikaisia terveysongelmia, koska noin 20–60%:lle naisista jää jonkinasteinen ulosteinkontinenssi. Sulkijalihasrepeämien ilmaantuvuudessa on maiden välisiä eroja: vuonna 2008 se todettiin Suomessa 0,9 %:lla synnyttäjistä ja vastaavasti 2,6–5,6 %:lla muissa Pohjoismaissa. Tutkimuksen tarkoituksena oli nimetä peräaukon sulkijalihasrepeämän riskitekijöitä, tarkastella sen ilmaantuvuutta sekä tarkastella episiotomian eli välilihanleikkauksen käyttöä vuosien 1997 ja 2007 välisenä aikana Suomessa. Tutkimusaineisto muodostui Terveyden ja hyvinvoinninlaitoksen (THL) syntymärekisterin tiedoista vuosien 1997 ja 2007 väliseltä ajalta sisältäen tiedot kaikista yksisikiöisistä alatiesynnytyksistä (n=514 741). Tiedot peräaukon sulkijalihasrepeämistä saatiin vuosilta 1997–2003 Hoitoilmoitusrekisteristä (HILMO). Ensisyntyttäjästä (=ensimmäinen alatiesynnytys) (n=217 778) 2315:llä ja uudelleensynnyttäjistä (n=296 963) 534:llä todettiin sulkijalihasrepeämä. Peräaukon sulkijalihasrepeämän riskejä tarkasteltiin ensi- ja uudelleensynnyttäjien joukossa käyttäen analyysimenetelmänä askeltavaa logistista regressioanalyysiä.

Peräaukon sulkijalihasrepeämän riskitekijöitä olivat pihtisyntyminen, synnytyksen aktiivisen ponnistusvaiheen pitkittyminen, vastasyntyneen yli neljän kilogramman syntymäpaino ja imukuppiavusteinen synnytys. Ensisyntyttäjillä lateraalisen episiotomian vähensi peräaukon sulkijalihasrepeämän riskiä 17 %. Toimenpiteen tehokkuus peräaukon sulkijalihasrepeämien ehkäisyssä todettiin kuitenkin huonoksi, koska noin 900 episiotomiaa tehtiin yhden repeämän ehkäisemiseksi. Sen sijaan imukuppiavusteisissa synnytyksissä tehokkuus oli parempi, koska 66 episiotomian tekeminen ehkäisi yhden repeämän. Uudelleensynnyttäjillä episiotomia käyttö oli yhteydessä yli kaksinkertaiseen sulkijalihasrepeämän riskiin. Kivunlievitysmenetelmät olivat yhteydessä 13–52 % pienempää sulkijalihasrepeämän riskiin, mutta uudelleensynnyttäjillä epiduraalipuudutuksen käyttö lisäsi riskiä 50 %.

Suomessa sulkijalihasrepeämien ilmaantuvuus nousi 0,2 %:sta 0,9 %:iin vuosien 1997 ja 2007 välisenä aikana. Ensisyntyttäjillä peräaukon sulkijalihasrepeämän riski nousi 3,28-kertaiseksi ja uudelleensynnyttäjillä 2,83-kertaiseksi. Sulkijalihasrepeämän riskin noususta noin 9 % selittyi imukuppiavusteisten synnytysten lisääntymisellä, mikä todennäköisesti johtuu toimenpiteen lisääntyneestä käytöstä. Synnyttävässä populaatiossa ja toimenpiteiden käytössä tapahtuneet muut muutokset olivat vähäisiä ja ne eivät selittäneet sulkijalihasrepeämien lisääntymistä. Tutkimustulosten perusteella voidaan todeta, että synnytyksen ajankohdalla ei ollut peräaukon sulkijalihasrepeämän riskitekijä, koska riski oli yöaikaan (00.00–07.59) 11 % pienempi kuin päiväaikaan ja vastaavasti heinäkuussa (tavallisin lomakuukausi Suomessa) 15 % pienempi kuin muina kuukausina. Sairaaloiden välillä sulkijalihasrepeämän riski vaihteli ensisyntyttäjillä jopa kolminkertaisesti ja uudelleensynnyttäjillä kahdeksankertaisesti. Korkeimmat peräaukon sulkijalihasrepeämien ilmaantuvuudet kummassakin synnyttäjien ryhmässä todettiin samoissa sairaaloissa, mikä viittaa siihen, että sairaaloiden hoitokäytäntöjen yhteys sulkijalihasrepeämän riskiin saattoi olla merkittävä. Ero saattaa selittyä myös sairaaloiden välisistä eroista tilastoinnissa tai sulkijalihasrepeämän diagnosoinnissa.

Episiotomia suojasi peräaukon sulkijalihasrepeämältä ensimmäisessä alatiesynnytyksessä, mutta oli riskitekijä uudelleensynnyttäjillä. Uudelleensynnyttäjillä episiotomia oli kuitenkin tehty useammin suuressa peräaukon sulkijalihasrepeämän riskissä oleville ja siksi ryhmät eivät ole vertailukelpoisia. Tutkimustulosten perusteella voidaan suositella lateraalisen episiotomian selektiivistä käyttöä, mutta ensisyntyttäjillä imukuppiavusteissa synnytyksissä episiotomian käyttö vaikuttaa perustellulta. Sairaaloiden väliset erot sulkijalihasrepeämien ilmaantuvuudessa voivat kertoa hoidon laatueroista tai eroista repeämien tilastoinnissa ja diagnosoinnissa.

Yleinen suomalainen asiasanasto (YSA): synnytys; komplikaatiot; peräaukko; vammat; riskit; esiintyvyys; rekisterit



# Acknowledgements

The present study was carried out in the Department of Nursing Science, University of Eastern Finland, and in the Department of Obstetrics and Gynaecology, Kuopio University Hospital during the years 2007-2010. I owe my deepest gratitude to everyone who has contributed to this study, and especially, I would like to thank the following persons.

I am grateful to the National Research and Development Centre for Welfare and Health (Stakes) currently the National Institute for Health and Welfare (THL) for providing me the possibility to use the Medical Birth Register in this scientific work.

I am indebted to Professor Katri Vehviläinen-Julkunen (PhD), the supervisor of my thesis for her great support and guidance.

I owe my deepest gratitude to Professor Seppo Heinonen (MD, PhD, Head of Department of Obstetrics and Gynaecology), the supervisor of my thesis. His encouraging support and guidance has been crucial for completing this thesis.

I owe my sincere thanks to the co-author Professor Mika Gissler (Dr.Phil, M.Soc.Sc.) for his kind and careful guidance in statistical and data management methods.

I express my sincere thanks for official reviewers of my thesis, Professor Elina Hemminki (MD, PhD) as her contribution to the completion of this dissertation has been indispensable, and Professor Sanna Salanterä (PhD), for her valuable and constructive comments for this thesis.

I also owe my thanks to Marja-Leena Hannila (MSc) for the skilled assistance in statistical analyses, Petri Kainulainen (MSc) for his kind assistance in drawing the figures, and Sees-editing Ltd., United Kingdom for revising the language of the articles and this thesis. I owe my deepest gratitude to the whole staff of the Department of Nursing Science of University of Eastern Finland, and particularly Secretary Maija Pellikka for her assistance concerning the final version of this thesis.

I owe my sincere thanks to my colleagues in Savonia University of Applied Sciences in Iisalmi for understanding and encouragement at the end of this process.

I owe my warmest gratitude to my family, especially my mother, Raili Räisänen, for being a great support during these years. I am grateful to visual artist, Päivi Tuovinen for drawing the pictures, and also for her friendship. My special thanks go to my dear friends Maija-Riitta Jouhki, Tuula Paldanius, Arja Halkoaho, Pirjo Rytönen, Maija Harju, Sari Hättinen, Ritva Litmanen, Mirja Löytömäki, and Ulla Väisänen of the moments of relaxation, laughter and supporting discussions.

This study was financially supported by University of Eastern Finland, the Northern-Savo Hospital District (EVO-funding), the Finnish Cultural Foundation, the Foundation of Nurse Education, the Research Foundation of Kuopio University Hospital, the Federation of Finnish Midwives, and the Finnish Association of Nursing Research. I owe my deepest gratitude to all of them for their support.

Kuopio  
February, 2011

Sari Räisänen



## List of original publications

The dissertation is based on the following original articles, which are referred to in the text by their Roman numerals.

- I Räsänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. Lateral episiotomy protects primiparous but not multiparous women from obstetric anal sphincter rupture. *Acta Obstetrica et Gynecologica Scandinavica* 2009; 88(12):1365-72.
- II Räsänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. 1 The increased incidence of obstetric anal sphincter rupture – An emerging trend in Finland. *Preventive Medicine* 2009; 49(6):535-40.
- III Räsänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. Up to seven-fold inter-hospital differences in obstetric anal sphincter injury rates– A birth register-based study in Finland. *BMC Research Notes* 2010: 3:345.
- IV Räsänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. The role of nocturnal delivery and delivery during the holiday period in Finland on obstetric anal sphincter rupture rates – a population based observational study. *BMC Research Notes* 2010: 3:32.
- V Räsänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. High episiotomy rate protects primiparous women from anal sphincter ruptures with poor efficiency - A birth register-study on delivery intervention policies in Finland. *Scandinavian Journal of Public Health* (Submitted).

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## Abbreviations

BMI	body mass index
CI	confidence interval
HDR	Hospital Discharge Register
MBR	Medical Birth Register
NNT	number needed to be treated
OASR	obstetric anal sphincter rupture
OECD	Organisation for Economic Cooperation and Development
OA	occiput anterior
OP	occiput posterior
OR	odds ratio
RCOG	Royal College of Obstetricians and Gynaecologists
SD	standard deviation
STAKES	The National Research and Development Centre for Welfare and Health
THL	The National Institute for Health and Welfare
WHO	World Health Organization



# 1 Introduction

Promoting healthy and safe pregnancy and childbirth is the goal of maternity care. Despite significant improvements in recent decades, women and newborn babies are still at risk during the perinatal period (Ministry of Social Affairs and Health 2006, World Health Organization 2004). Birth injuries have been chosen as one of the 21 indicators of patient safety by the Organisation for Economic Cooperation and Development (OECD) countries (OECD, 2004). Further, they are one of the 36 quality indicators in Nordic countries, and are one of the potentially important perinatal health indicators in the EURO-PERISTAT project, although this project requires further work before implementation (Nordisk Ministerråd 2010, EURO-PERISTAT Project 2008).

Obstetric anal sphincter rupture (OASR) is a serious complication of vaginal delivery; it was first described by Sir Fielding Ould in 1742 in the first English language textbook of obstetrics, *Treatise of Midwifery* (Carroli & Mignini 2009, Graham 1997). The current classification of perineal ruptures was provided by Sultan (1999), and previously there might have been differences in classification of the third degree ruptures (Sultan & Thakar, 2002, Sultan 1999). In the Nordic countries, OASR has been classified by Sultan's classification (third degree ruptures are pooled) and registered by ICD-10 codes since 1996. Surgical correction of the complication results in anal incontinence in 20-60% of those affected, and consequently it has serious long-term implications for women's health and quality of life (Molander et al. 2007, Williams et al. 2005a, Kairaluoma et al. 2004, Pinta et al. 2004a).

The incidence of OASR varies with time and between countries; for example, in the Nordic countries incidences of OASR have increased over recent decades and in 2008 ranged from 0.9% in Finland to 5.6% in Iceland (The National Institute for Health and Welfare 2010b, Laine et al. 2009). These data originated from national birth registers, and their quality has been confirmed by validity declarations and in several independent studies (Baghestan et al. 2010, Laine et al. 2009, Gissler et al. 1997). It is, however, of note that there might have been differences in registration and diagnosing OASR. In the USA, frequencies of 3.5% for vaginal deliveries and 15.3% for assisted deliveries have been reported (Frankman, et al, 2009). In Finland, the frequency of OASR has increased from 0.2% in 1997 to 1.0% in 2009. At the same time, there have been changes in the use of obstetric interventions such as increased use of epidural analgesia and vacuum assistance, while the use of episiotomy has decreased. However, substantial inter-hospital differences in the use of episiotomy have been reported, and, for example, in 2006-2007 it ranged from 18.4% to 86.4% among primiparous women (The National Institute for Health and Welfare 2010a).

There have been many epidemiological studies aimed at identifying risk factors for OASR from populations derived from a single hospital, while national population-based studies covering the entire population of a country have been rare or lacking. Previous studies have shown an increased risk of OASR associated with primiparity (Eskandar and Shet 2009), infant birth weight over 4,000 g (Eskandar & Shet 2009, Hudelist et al, 2005), a prolonged active second stage of birth (Samarasekera, et al. 2009), and obstetric interventions such as vacuum assistance (Prager et al. 2008), forceps (Samarasekera et al. 2009), mediolateral episiotomy (Andrews et al. 2006b) and midline episiotomy (Fitzgerald et al. 2007). The results concerning mediolateral episiotomy have been ambiguous since it has also been identified as having a protective function (Samarasekera et al. 2009) or having no effect (Prager et al., 2008). Furthermore, data pertaining to lateral episiotomy, the only technique that is used in Finland are rare. However, the type and the technique of episiotomy have been poorly defined or not defined at all in most studies, which is noteworthy when evaluating results.

Overall, it seems that attributable risks of OASR have been established, but most studies have been performed outside Finland and the Nordic countries, and there are some particular concerns. For example, the studies performed in countries with a prominent private healthcare sector, such as the USA, are probably less applicable to Finland, which provides free access to antenatal and obstetric services covering almost all deliveries. Furthermore, the type of episiotomy used, differences in use of interventions such as higher episiotomy rate compared to other Nordic countries, may also affect outcomes considerably. The risk profile of OASR may be very different in countries with markedly lower or higher OASR rates. Consequently, despite the existing international research, there is a need to study the topic in the context of Finnish healthcare; this is in line with the National Development Programme for Social Welfare and Health Care (Kaste), which highlights the quality and effectiveness of healthcare services (Ministry of Social Affairs and Health 2008). For the present study, a systematic literature review of the incidence, trends and risk factors of OASR was rejected. The incidence and trends are discussed only for the Nordic countries.

The purpose of this retrospective register-based cohort study was to identify the risk factors for OASR, to discover how they interact with each other, and to describe the trends in OASR and episiotomy between 1997 and 2007 in Finland among vaginally delivered women, including all presentations and assisted deliveries. The aim of this study was to produce evidence that could be used to aid in the prevention of obstetric anal sphincter ruptures and to audit midwifery and obstetric care practices and education in order to contribute to their development.

## 2 General background

### 2.1 ORGANIZATION AND CONTENT OF OBSTETRIC SERVICES

Maternity care can be divided into three parts: antenatal care, intrapartum care, and postnatal care. Finnish antenatal care was initially established by Arvo Ylppö, who had a lifelong professional involvement with mothers and children (Forsius 2001). Since 1944 all women have had free access to antenatal care, which is currently provided by regionalized healthcare centers run by local municipalities (Finlex 1972). Almost all pregnant women in Finland attend such centers (Hakulinen-Viitanen et al. 2005). Antenatal care, which consists of health education, screening, support and parentcraft advice, is delivered by public health nurses and physicians, usually general practitioners in Finland. On average, women visit maternity care units in Finland sixteen times during each pregnancy (The National Institute for Health and Welfare 2010a). Women with pre-existing medical conditions, social needs or complicated pregnancies are sent for specialist consultation in hospital antenatal clinics (The National Research and Development Centre for Welfare and Health 1999).

Intrapartum care, covering almost all deliveries, is provided at publicly financed hospitals, which have geographical catchment areas for low risk births; women at high risk are referred to hospitals that can give an appropriate level of care (Finlex 1989). The focus of postpartum care in hospital is on infant surveillance, rooming-in, infants' feeding practices, fathers' overnight presence at the maternity hospital, and social support from personnel (Ministry of Social Affairs and Health 2006). The mean length of hospital stay after delivery decreased from 4 days in 1997 to 3.0 days in 2009 (The National Institute for Health and Welfare 2010a).

### 2.2 HOSPITALS

Almost all women (99.4%, in 2008) give birth in hospital; annually, very few babies are born as planned home births (0.01%, in 2008) (Gissler, 2009). In 2007, there were 33 delivery care units in Finland of which five were university teaching hospitals, with the highest number of deliveries annually (range ca. 2,300-5,100) and the most complicated deliveries. Most women give birth in one of five university teaching hospitals; this amounted, for example, to 46% of births in 2009. In addition, there are ten hospitals annually with more than 1,500 deliveries, nine hospitals with 750-1499 deliveries and eight hospitals with less than 750 deliveries (The National Institute for Health and

Welfare 2010a). There is an ongoing debate about hospital size and quality of care, and during the last decade several smaller units have been closed and births have been concentrated into larger units. It has been suggested that the low volume of deliveries in smaller units may lead to suboptimal care for women with complications (Ministry of Social Affairs and Health 2010), although larger units may be impersonal.

Finland lacks a standard relating to staffing in maternity care units and obstetric management, so these can vary substantially between hospitals. The obstetric care is lead by obstetricians, and provided equally by trainees and senior doctors, with trainees being on call at the hospital and senior doctors at home in most of the hospitals. Midwives are independent practitioners who attend uncomplicated vaginal births, and call an obstetrician when they consider this to be necessary. Currently, the midwifery education includes registered nurse education and lasts 4.5 years (Opetusministeriö 2006). Within the European Union member countries, the specific standards for education and training are described in the directive 80/155/EEC (WHO Regional Office for Europe 2009).

### **2.3 POPULATION SERVED AND OUTCOMES**

During the last decade the number of deliveries in Finland has increased by 5%. In 2009, there were 59,921 deliveries, and the total fertility rate was 1.86, which is one of the highest in Europe. The mean maternal ages of primiparous fluctuated from 27.6 to 28.1 and of all women from 29.8 to 30.1 between 1997 and 2009. In 2009, the mean maternal age of primiparous women was 28.1 and of all women was 30.1. (The National Institute for Health and Welfare 2010a).

The age at which women bear children varies widely between the European countries, but generally, throughout Europe, bearing children late in life has increased. The proportion of teenaged mothers (younger than 20) varied from 1.3% in Denmark to 9.3% in Latvia in 2004, while the mean proportion was less than 3% in the European Union. The proportion of older mothers (35 years or older) ranged from 7.5% in Slovenia to 24.3% in Ireland. (EURO-PERISTAT Project, 2008.) In Finland, the number of teenaged mothers has been quite constant during the last two decades, and accounted for 2.4% in 2007 (range 2.4-3.2%), whereas almost one in five births were to women of at least 35 years old in 2007, with a constantly increasing trend, from 13.3% in 1987 to 18.7% in 2009 (The National Institute for Health and Welfare 2010a).

Finnish maternity care is aimed at producing healthier mothers and newborn babies (The National Research and Development Centre for Welfare and Health 1999). Nowadays Finland has one of the lowest perinatal mortality rates in the world, with 5.0 per 1000 live births in 2009. Maternal mortality was 8.4 per 100,000 live births in 2008 in Finland. (The National Institute for Health and Welfare 2010a.) The equivalent figure for the whole of the European Union was 6.6 in 2003-2004 (EURO-PERISTAT Project 2008).

To provide a uniform basis for comparisons of perinatal health, THL gathers a range of information on maternity care in Finland. The data on deliveries and births have been collected since 1987, and are obtained from hospitals and clinics, and are complemented with data from Statistics Finland and the Population Register Centre. (The National Institute for Health and Welfare 2010c.) Projects using register data, for example, the Nordic Collaborative project on Health and Social Inequality in Early Life (NorCHASE) and the EURO-PERISTAT project have developed valid and reliable indicators that can be used for monitoring and evaluating perinatal health and health services (EURO-PERISTAT Project 2008, The National Institute of Public Health 2008). The EURO-PERISTAT project has defined ten core indicators, which are considered desirable for a more complete picture of perinatal health in the EU member states. These are grouped into four themes: fetal, neonatal and child health; maternal health; population characteristics; and risk factors and health services. The project makes it possible to benchmark performance in providing effective health services and promoting the health of women and newborns. In the future, the aim is to develop research capacity to support development of evidence-based practices. (EURO-PERISTAT Project 2008.)

Pregnancy outcomes vary substantially between social and demographic groups within populations and between countries (EURO-PERISTAT Project 2008). The impact of socioeconomic factors, such as poverty and low social status, on perinatal outcomes presents a new research avenue aimed at improving perinatal health (Gissler et al. 2009, Raatikainen et al. 2006a). Furthermore, factors such as giving birth at an advanced age, alcohol and other intoxicant use, and mothers' obesity have been identified as new health challenges for childbearing women. In addition, medical innovations and increased use of health technology have raised concerns and may create new risks. (Hemminki 2009, EURO-PERISTAT Project 2008.) Thus, there is a clear need to develop benchmarks and valid and reliable indicators that can be used for monitoring and evaluating perinatal health.

### **2.3.1 Maternal overweight and high birth weight**

Being overweight during pregnancy is an increasing public health problem, which increases pregnancy risks and complications such as diabetes, hypertension and perinatal death, and is an issue in ca. 20-30% of all pregnancies in Finland (Raatikainen et al. 2006b, Vehkaoja et al. 2006). In Finland,

the average body mass index (BMI) of parturients before pregnancy was 24.3 in 2009. One in three was overweight (BMI  $\geq 25$ ), and 12% were obese (BMI  $\geq 30$ ) (The National Institute for Health and Welfare 2010a).

The management of fetal macrosomia has been the subject of much clinical concern and scientific investigation for several years since macrosomic infants are at elevated risk of shoulder dystocia, brachial plexus injury, skeletal injuries, meconium aspiration, perinatal asphyxia, hypoglycemia and fetal death. There is no universally accepted definition of fetal or neonatal macrosomia or high birth weight. An absolute weight, usually  $>4000$ ,  $>4500$  or  $>5000$  grams, is frequently used to identify the macrosomic neonate. (Ju et al. 2009, Zhang et al. 2008, Boulet et al. 2003, Sacks and Chen 2000.) However, it has been suggested that defining macrosomia as  $>4000$  grams may be useful for the identification of increased risks of birth complications, a definition of  $>4500$  grams may be more predictive of neonatal morbidity, and  $>5000$  grams may be a better indicator of infant death risk. Generally, the birth weight over time, and also the proportion of macrosomic infants, has been increasing; for example, in the USA as a consequence of rising rates of maternal diabetes mellitus and obesity. (Boulet et al. 2003.) The complications of macrosomia indicate the need to identify macrosomic fetuses prior to birth, but only 68% of instances are detected clinically and 58% by ultrasound, levels that need to be increased to improve clinical care (Weiner et al. 2002).

In Finland, the mean birth weight was quite constant between 1997 and 2009 (3520 and 3483 g, respectively), and the proportion of infants weighing more than 4000 grams decreased from 18.7% in 1997 to 16.8% in 2008 (The National Institute for Health and Welfare 2010a).

## **2.4 STANDARDS OF CARE**

Some international guidelines covering the pathway of care from pregnancy through to the transition to parenthood have been developed (National Centre for Women's and Children's Health 2008), but Finland lacks a system of standard care other than prenatal screening, which was harmonized by 2010 (Finlex 2006). However, The National Research and Development Centre for Welfare and Health (STAKES), currently known as The National Institute for Health and Welfare (THL), have produced recommendations for antenatal services and collaboration, and the Ministry of Social Affairs and Health has compiled the first national action program in Finland for the promotion of sexual and reproductive health; both are implemented locally. Overall, it seems that there have been attempts to standardize less technologically oriented evidence-based practices and to increase options for childbearing women. (Ministry of Social Affairs and Health 2006.) Thus, a high priority is been placed

on good communication between the woman and her partner and the autonomy of women is enshrined in law (Finlex 1992).

#### **2.4.1 Operative vaginal deliveries**

Operative vaginal delivery refers to a delivery during which forceps or a vacuum device is used. The instrument is applied to the fetus' head and then the operator uses traction to extract the fetus, typically during a contraction while the woman is pushing. The goal of operative vaginal delivery with adequate technique is to assist spontaneous vaginal birth, minimizing maternal and neonatal morbidity. (Vacca 2007.)

Operative vaginal delivery is a frequently and widely used obstetric intervention, accounting for 6.5-8.4% of deliveries in the Nordic countries, and ca.11% in the UK in 2004 (EURO-PERISTAT Project,2008). There are variations in and between obstetric and midwifery practices worldwide, thus influencing the rate of operative vaginal deliveries. Historically, the obstetric forceps has been the primary instrument used, and in many countries it still is, but has been superseded by vacuum extractors in some countries. Forceps are classified according to whether traction alone or rotation of the fetal head is required. (Bofill et al. 1996.) Forceps extractions have been preferred in the United States, Canada, South America and Eastern Europe, while vacuum extractors made of metal, plastic or silicone have been the instrument of choice in Western Europe, Asia and the Middle East (Learman 1998).

In Finland, vacuum assistance has been favored over the use of forceps, which have been used rarely during the last two decades. The use of forceps decreased from 0.3% in 1987 and to 0.0...% in 2009, while the use of vacuum extractors has increased from 3.5% to 8.4% during the same period (The National Institute for Health and Welfare 2010a).

## **2.5 PERINEUM PROTECTION TECHNIQUES**

Risk factors that contribute to OASR have been identified; however, awareness of these does not always help to predict which women will be affected. Even an attempt to devise a predictive scoring system to identify women at risk, based upon the calculated risks from a meta-analysis, and to test the ability to predict cases performed badly when used to discriminate between cases of women with sphincter injury and controls. (Williams et al 2005b.) Suggested perineum protection methods in obstetrics include avoiding episiotomy or favoring mediolateral episiotomy over the midline type, and preferring spontaneous or vacuum-assisted deliveries over forceps delivery (Power et al. 2006, Eason

et al. 2000). In addition to these modifiable obstetric practices several preventive techniques to reduce the risk of OASR have been established, including hand maneuver and pushing techniques.

### 2.5.1 Episiotomy

Episiotomy, one of the most common surgical procedures on women, is a surgical incision in the perineum using a pair of scissors, performed to enlarge the vaginal opening for birth. The operation was first described by Sir Fielding Ould in 1742, and was initially performed to shorten the second stage of birth for reasons of maternal or fetal distress during difficult births, and to reduce severe perineal tears. (Carroli & Mignini 2009, Graham 1997.) Moreover, a straight incision was considered to be easier to repair and to heal better than a natural injury (Carroli & Mignini 2009, ClearyGoldman & Robinson 2003, Lede et al. 1996).

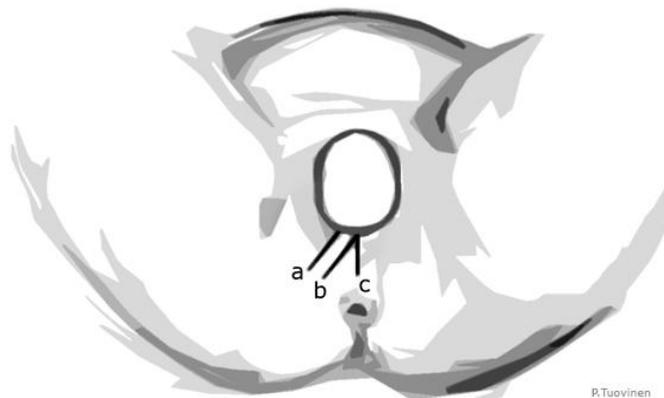
Episiotomy was adopted worldwide as a routine procedure during the first half of the last century at the same time that there was a shift from home births to hospital births, although there was no strong scientific evidence of its effectiveness. In the 1980s and 1990s, however, its routine use was questioned not only in the USA but also in the UK, Europe, Japan and Australia. (Lede et al. 1996, Harrison et al. 1984.) In the USA, the practice was considerably more established since it had been routine for more than four decades, whereas in the UK it was challenged at the same time that its use was becoming routine (Graham 1997). Nowadays, its use varies greatly throughout the world; for example, in Europe in 2004 it was performed on 52% of childbearing women in Italy, 16% in England and Norway and 9.7% in Denmark (EURO-PERISTAT Project 2008). In Finland, episiotomies have been performed since the beginning of the 20th century, when women started to give birth in hospitals (Halmesmaki, 2000). The operation was especially common in the 1980s, but since then its use has been in constant decline, while OASR rates have increased substantially. In 1997, it was performed on 42.1% of all women but on only 29% in 2007 and 25.2% in 2009 (The National Institute for Health and Welfare 2010a).

There are at least three types of episiotomy; midline, mediolateral and lateral (ClearyGoldman and Robinson, 2003, Tincello, et al, 2003, Soiva, 1968), as shown in Figure 1. The midline type of episiotomy is the preferred technique in the USA, while the mediolateral approach is preferred in Europe. In Finland, episiotomy is exclusively lateral, an approach that has rarely been described in research, but has been presented in some studies and obstetric textbooks. A Cochrane review of eight randomized controlled trials (n=5,541) has found that restrictive episiotomy (28.40%) policy appears to have a number of benefits such as reduced posterior perineal trauma, less suturing and fewer complications, although no difference in severe vaginal or perineal tears in compared to routine use of

the it (75.15%). Results for restrictive vs. routine mediolateral vs. midline episiotomy were similar to the overall comparison. (Carroli & Mignini 2009.)

### 2.5.2 Manual perineum protection

A wide variety of manual perineum protection techniques have been practiced, but in most studies these were poorly described or not described at all. Generally, the results relating to the success of manual perineum protection were unclear. Two cohort studies indicated that manual perineum protection (although undefined) decreased the risk of OASR (HastingsTolsma et al. 2007, Samuelsson et al. 2000), but the results of randomized trials were inconsistent. Two randomized controlled trials found no significant differences between the hands-on method, in which the midwife's hands put pressure on the baby's head and support ('guard') the perineum, and the hands-poised method, or between Ritgen's Manoeuvre and hands-on control of the expulsion of the fetal head; one study suggested that the hands-poised technique was more suitable for protecting the perineum (Jonsson, et al. 2008, Mayerhofer et al. 2002, McCandlish et al. 1998).



*Figure 1. Three episiotomy types adopted by Soiva: a) lateral, b) mediolateral and c) midline episiotomy (Soiva 1968).*

It has been suggested that unrushed and controlled birth of the infant's head may help reduce obstetric trauma in normal, spontaneous vaginal births. One interventional program in Norway showed that slowing the delivery of the infant's head and instructing the mother not to push while the

head is delivered, decreased OASR rates significantly from 4.0% to 1.2% during the study period (Hals et al. 2010, Laine et al. 2008). In addition, delivery of the infant's head between contractions was associated with reduced trauma to the genital tract (Albers et al. 2006b).

### **2.5.3 Maternal positions**

The optimal maternal positions during the second stage of birth are unclear. Physiological benefits associated with an upright rather than recumbent position include the positive effect of gravity on the uterus, a lower risk of aortocaval compression and stronger contractions, improved alignment of the infant's head for passage through the pelvis and an increase in dimensions (Gupta & Nikodem 2000). The results of two systematic reviews concerning randomized controlled trials and a retrospective cohort study suggested that maternal positions during the second stage of birth had little effect on perineal outcomes, and consequently women should be encouraged to give birth in the position they find most comfortable (Soong & Barnes 2005, Gupta & Hofmeyr 2004, Eason et al. 2000). However, three retrospective register based cohort studies found that giving birth in a lateral position resulted in the most favorable perineal outcomes (HastingsTolsma et al. 2007, Shorten et al. 2002, Albers et al. 1996).

### **2.5.4 Pushing techniques**

There are different approaches to managing the second stage of birth, for example, onset and methods of pushing. The urge to bear down begins naturally when the head of the infant becomes visible in the vulva (delayed pushing), but there are also practices in which women begin pushing as soon as the cervix is ten centimeters dilated (early pushing) (Hellman and Prystowsky 1952). Prolonging the second stage of birth was considered to pose a particular risk to the fetus the idea has been disproved by at least three observational studies (Cheng et al. 2004, Myles & Santolaya 2003, Menticoglou et al. 1995). A review of randomized controlled trials (Roberts et al. 2004) showed that delayed pushing generally prolonged the second stage of birth and allowed spontaneous descent and rotation of the infant's head, and consequently decreased the need for operative vaginal deliveries, and reduced rates of second stage caesarean section in comparison with early pushing; this was confirmed by a systematic review of randomized controlled studies involving women who used epidural analgesia (Brancato et al. 2008). However, there were no differences in episiotomy or perineal injury rates between these two second stage care practices (Roberts et al. 2004, Brancato et al. 2008).

Two basic pushing methods have been described: Valsalva coached pushing (closed glottis pushing while holding the breath), which has usually been used when women are encouraged to push in the early second stage of birth; and spontaneous pushing (open glottis pushing while breathing out) when women feel the urge to bear down. It has been reported that women have been more satisfied with

spontaneous pushing than with Valsalva pushing (Yildirim & Beji 2008). Results of three randomized controlled trials indicated that there is no difference in perineal tearing between the groups of women who used spontaneous or coached pushing methods during the second stage of labor (Yildirim & Beji, 2008, Parnell et al. 1993, Thomson 1993).

### **2.5.5 Other techniques**

Midwives have used a variety of other techniques, such as perineal massage, warm compresses and oiling, in the belief that birth injuries can be reduced. The results of Cochrane review of three randomized controlled trials (n=2,434) showed that antenatal perineal massage reduced the risk of perineal trauma and the need for episiotomies (Beckmann & Garrett 2006), but perineal massage during the birth did not (Albers et al. 2005, Stamp et al. 2001). The results of one randomized controlled trial and two retrospective cohort studies found that use of warm compresses reduces the risk of perineal trauma and perineal pain (Dahlen et al. 2007, HastingsTolsma et al. 2007, Albers et al. 1996). Conversely, the use of oil or lubricant increased the risk of perineal injury (HastingsTolsma et al. 2007, Albers et al. 1996).



## 3 Obstetric anal sphincter rupture (OASR) and its risk factors

### 3.1 DEFINITION OF OASR

OASR encompasses both third- and fourth-degree perineal ruptures, which are subdivided into four classes (Table 1). A third-degree perineal rupture is defined as a partial or complete disruption of the anal sphincter, which may involve either or both the external (EAS) or the internal anal sphincter (IAS) muscles. However, the classification of third degree tears used to be obscure since a third degree rupture was recorded only if the anal sphincter was completely disrupted or if the rupture involved the anal sphincter. (Sultan & Thakar 2002.) In 1999, Sultan provided a subclassification for third degree ruptures (Sultan 1999), which has been adopted universally, for instance, by the British Royal College of Obstetricians and Gynaecologists (RCOG).

*Table 1. Current classification of perineal ruptures (Sultan 1999)*

<b>INJURY</b>	<b>DEFINITION</b>
First degree	Injury to perineal skin only
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter
Third degree	Injury to the perineum involving the anal sphincter complex
3a	<50% of external sphincter thickness is torn
3b	>50% of external sphincter thickness is torn
3c	Both external anal sphincter and internal anal sphincter torn
Fourth degree	Injury to external and internal sphincter and anal epithelium

### 3.2 MECHANISM OF INJURY

The anal sphincter can be damaged in three ways during childbirth: a direct mechanical or traumatic injury, neurological injury or combined mechanical and neurological injury (Power et al. 2006). A direct mechanical trauma is a visible rupture of external or internal anal sphincter muscle or, rarely, an occult injury (recorded in 1.2% of cases) may be noted on endoanal ultrasound or sonographic sphincter assessment (Andrews et al. 2006a, Power et al. 2006). The external sphincter damage occurs only in the presence of a tear or episiotomy, and correspondingly internal sphincter injury occurs sometimes when the perineum remains intact, due to descent of the infant's head (Sultan et al. 1993).

The risk of mechanical trauma is greatest during a woman's first vaginal delivery, especially in operative vaginal deliveries, because the tissue has to stretch to accommodate the increasing diameter of the infant's head much more rapidly than it would during a spontaneous delivery (Pearse 1963). In particular, women with a perineal length  $\leq 3$  cm are at greater risk of OASR (Aytan et al. 2005). Neurological injuries of the pudendal nerve may result particularly from the first vaginal delivery due to tissue stretching or persistent nerve compression by the fetal head as a result of fetal macrosomia or a prolonged active second stage of the birth (Fynes et al. 1999, Sultan et al. 1994). It has been suggested that use of epidural analgesia protracts the passive second stage of birth, thus increasing the risk of pudendal nerve injury (Donnelly et al. 1998). Most women with impaired fecal continence after their first delivery experience deterioration of the condition after subsequent vaginal deliveries, since damage to the pudendal nerves is cumulative with successive vaginal deliveries (Fynes et al. 1999, Donnelly et al. 1998, Sultan et al. 1993).

### 3.3 MANAGEMENT

**Surgical techniques.** Systematic clinical examination of the vagina and perineum after all vaginal deliveries is important in order to identify possible injuries prior to suturing (Dudding et al. 2008, Eogan & O'Herlihy 2006). There are two recognized methods for the surgical repair of damaged external anal sphincter: end-to-end and overlapping methods. In the end-to-end method, the torn ends of the external anal sphincter are brought together and sutured without any overlap of the muscle. In the overlap method, the torn ends of the external anal sphincter are brought together and sutured by overlapping one end of the muscle over the other. (Fernando et al. 2006a, Sultan et al. 1999.) Overall, the outcomes of these two techniques have been unclear, but repair carried out by appropriately trained staff has been associated with low long term morbidity (Williams et al. 2006).

The primary repair is usually performed immediately, but if a skilled operator is not immediately available delayed primary repair within 24 hours is possible (Leeman et al. 2003). Further, if the injury has been missed or if the primary repair has failed, secondary repair, which has been related to improved sphincter function, can be performed after several months by a colorectal surgeon (Pinta et al. 2003, Oliveira et al. 1996). Suture materials are recommended to be slowly absorbed synthetic monofilaments, such as polyglyconate or polydioxone (National Centre for Women's and Children's Health 2007).

**Immediate post-partum management.** Immediately after the primary repair of OASR, the use of broad-spectrum antibiotics, possibly including metronidazole, has been recommended because infection increases the risk of anal incontinence and fistula (National Centre for Women's and Children's Health 2007, Fernando et al. 2002). Furthermore, randomized controlled studies have led to recommendations that postoperative laxatives be used for three to ten days because hard stools can damage the repair (Mahony et al. 2004, Sultan et al. 1999).

### **3.4 INCIDENCE, TRENDS AND RISKS FACTORS FOR OASR: A SYSTEMATIC LITERATURE REVIEW**

This literature review focuses on factors related to the findings of the present study, and covering the period from 1997 to 2010; most of the studies discussed originated from Europe where mediolateral episiotomy is preferred (Table 2). Studies on midline episiotomy, the preferred option in, for example, the USA and those in which the episiotomy type was not defined were excluded. The review is based on searches in the electronic databases PubMed, Cinahl, and Cochrane for the keywords "obstetric anal sphincter injury", "obstetric anal sphincter laceration", "obstetric anal sphincter rupture", "obstetric anal sphincter tear", episiotomy, "adverse outcome", and "time factor" (Table 2). The computer search was accompanied by manual searching of journals and reference lists in papers already identified. The criteria for including papers were that the study must have been published in English in a scientific journal.

Table 2. The results of the literature search of three electronic databases

Electronic database	Keywords	Number of references
PubMed	"obstetric anal sphincter injury" OR "obstetric anal sphincter laceration" OR "obstetric anal sphincter rupture" OR "obstetric anal sphincter tear"	59
PubMed	mediolateral episiotomy	72
PubMed	episiotomy	849
Cinahl	"obstetric anal sphincter injury" OR "obstetric anal sphincter laceration" OR "obstetric anal sphincter rupture" OR "obstetric anal sphincter tear"	22
Cinahl	mediolateral episiotomy	16
Cinahl	episiotomy	649
Cochrane Library		5
	Total number of accepted studies in literature review	24

Most of the accepted studies were retrospective register based cohort or case-control studies, and only one was a randomized controlled trial. Of the studies, 12 were retrospective population based register studies covering the total population or the hospital based population (n=9,178-2,101,843). Two of these were from the USA where midline episiotomy is the preferred technique.

### 3.4.1 Incidence and trends

The incidence of OASRs varies widely between the European countries: in 2004 the incidence of OASRs ranged from 0.2% in Italy to 3.5% in Portugal, Norway and Denmark. However, it should be noted that data on perineal tears are available from only a few European countries. (EURO-PERISTAT Project 2008.) In the Nordic countries, this information was derived from national birth registers, and the data quality has been confirmed by validity declarations and by several independent studies (Baghestan et al., 2010, Laine et al. 2009, Gissler et al. 1997). In the Nordic countries, there have been substantial increases in OASR rates during recent decades; for example, in Norway from 1.6% in 1968 to 4.1% in 2004, and in Sweden from 0.5% in 1973 to 4.2% in 2004 (Laine et al. 2009). In Finland, the incidence of OASRs is notably lower, but the trend is also increasing: from 0.2% in 1997 to 1.0% in 2009 (The National Institute for Health and Welfare 2010b). However, there may have been differences, especially in the classification of third degree ruptures (Sultan & Thakar 2002). In the Nordic countries, perineal injuries have been classified according to ICD-10 codes (third degree O70.2 and fourth degree O70.3) since 1996, and thus third degree ruptures were pooled. In the USA, where midline episiotomy is preferred, frequencies of 3.5% among vaginal deliveries and 15.3% among assisted deliveries in 2004 have been reported (Frankman et al. 2009).

### 3.4.2 Parity

Primiparity has been shown to be associated with an increased risk of OASR, and the risk declines with each subsequent delivery (Baghestan et al. 2010, Elfaghi et al. 2004). It has been suggested that the increased risk of OASR in primiparous women is in the order of 1.9-7.5 -fold in comparison with multiparous women (See Table 3), which includes studies on risk factors for OASR published between 1997 and 2010.

### 3.4.3 Maternal age

It has been suggested that maternal age affects the risk of OASR. The results of a retrospective register based cohort study (n=10,314) suggested that women between 31 and 35 years carried an approximately 2.9-fold greater risk of OASR than those under 20 years of age (Revicky et al. 2010). Another study found that the risk of OASR was about five-fold greater in women who delivered when older than 35 years than in younger women (Jander & Lyrenas 2001). The suggested mechanisms were loss of strength and function of connective tissues, which decrease with age (Silver et al. 2003, Wilmore 1991).

### 3.4.4 Birth weight

High birth weight has been found to be associated with increased risk of OASR (Eskandar & Shet 2009, de Leeuw et al. 2008, Aukee et al. 2006). A birth weight above 4000 grams has been found to be associated with a 1.7-16.9-fold increase in the risk of OASR (Table 3). A large national register based cohort study from Norway showed that birth weights above 4000 grams and above 4500 grams increased the risk of OASR by as much as 2.7 and 4.2 times, respectively, compared with a birth weight of 3000-3499 grams (Baghestan et al. 2010).

### 3.4.5 Prolonged second stage of birth

The risk of OASR has been found to increase by factors of 2.1, 2.3, and 3.6 when the duration of the second stage is  $\geq 90$ ,  $\geq 110$  and  $\geq 160$  minutes, respectively compared with it lasting 60 minutes. Furthermore, a second stage of birth over 110 minutes combined with an infant's head circumference over 35.5 cm increased the risk of OASR 5.3-fold. (Valsky et al. 2009.) A previous studies has demonstrated that if bearing down lasts more than 60 minutes, the risk of OASR is increased by a factor of 3.6 compared with it lasting less than 60 minutes (Samarasekera et al. 2009). Bearing down for less than 30 minutes is associated with 53% lower risk than bearing down for longer than this (Samuelsson et al. 2000). Overall, it should be noted that the second stage of birth was not described or was only poorly described or subdivided in most studies that we examined; this is an important consideration when assessing the results with respect to the risk factors for OASR.

### 3.4.6 Operative vaginal deliveries

A review of randomized controlled trials suggested that vacuum assistance is preferable to the use of forceps, because it was less likely to cause serious maternal injury, although it is more likely to cause neonatal cephalhaematoma and retinal hemorrhages (Johanson & Menon 2000). The results of previous studies indicate that both methods of operative vaginal delivery are attributable risks of OASR. Forceps increased the risk of OASR by a factor of 1.5 to 27, but the risk associated with vacuum assistance was lower, generally by a factor of 1.4 to 8.2, as shown in Table 3.

### 3.4.7 Episiotomy

Most of the studies found that mediolateral episiotomy had no effect on OASR or it had a protective effect, especially in operative vaginal deliveries (Table 3). A possible methodological problem was that in most of the studies risk factors of OASR were not analyzed separately for primiparous and multiparous women. The results of a large national birth register study showed that episiotomy was an indifferent factor among primiparous women but increased the risk 1.3-fold among multiparous women (Baghestan et al. 2010). The results of one case-control study with a smaller sample size (n=254) showed that performing episiotomy increased the risk of OASR four-fold (Andrews et al. 2006b), but inadequate sample size may have caused a bias. Furthermore, it should be noted that results may also be affected by different episiotomy rates, because very limited use of episiotomy might result in confounding by indication. Episiotomy rates ranged from 11% to 54% and even 78.9% among operative vaginal deliveries. In some of the studies, the episiotomy rate was not presented.

The results of one large population based register study from the USA indicated that the use of midline episiotomy decreased the risk of 3<sup>rd</sup> degree rupture by 11% but increased the risk of 4<sup>th</sup> degree ruptures 1.1-fold (Handa et al. 2001). Two other studies suggested that midline episiotomy increased the risk of OASR 3.2-5.3-fold (Fitzgerald et al. 2007, Dandolu et al. 2005). It has been suggested that mediolateral episiotomy, with a greater cutting angle away from anus, reduces the risks of OASR more than the midline technique (Eogan et al. 2006, Aytan et al. 2005).

### 3.4.8 Pain relief

Various non-pharmacological and pharmacological methods of relieving pain during birth have been advocated. Non-pharmacological methods include, for example, maternal movement and positions, massage, relaxation, breathing, acupuncture, aromatherapy, transcutaneous electrical nerve stimulation, water immersion, and intradermal injection of sterile water. Pharmacological treatment of labor pain was introduced in the mid-nineteenth century. These methods are classified as either systemic or locoregional. Systemic administration includes intravenous, intramuscular, and inhalation routes such as nitrous oxide gas. (Bricker & Lavender 2002, Rosen 2002.) Local injection

may also be administered to achieve paracervical or pudendal nerve block (Junttila et al. 2009). Regional techniques include epidurals, spinals and combined spinal-epidurals, which have been considered to be the only consistently effective means of relieving pain during labor (Bucklin et al. 2005). Epidural and spinal techniques were used on about 61% of women in Finland in 2009 (The National Institute for Health and Welfare 2010a).

Studies examining the association between non-pharmacological pain relief methods and perineal outcomes are rare. The results of previous systematic reviews suggest that water immersion during labor is not associated with perineal outcomes (Cluett & Burns 2009). Published results concerning the association between epidural analgesia and OASR were contradictory. Most of the studies found that it decreased the risk of OASR, with figures in the range 12-69%, and one case-control study found that it increased the risk 8-fold (Eskandar & Shet 2009, Dahl & Kjolhede 2006, Spydslaug et al. 2005, Poen et al. 1997). Previous studies have suggested that paracervical block increases the risk of OASR by a factor of ca. 1.4 to 2.2, whilst results relating to pudendal block are ambiguous (Baumann et al. 2007, Dahl & Kjolhede 2006).

#### **3.4.9 Occiput posterior presentation**

Occiput posterior (OP) is the most common abnormal fetal head position. Previous studies have shown the prevalence of the OP position in full term, vertex, singleton births to be about 15-20% during the early stage of labor, and about 5% at birth (Gardberg et al. 1998). The OP position has been associated with a higher rate of complications during labor and birth, including prolonged labor, dystocia, chorioamnionitis, OASR, operative vaginal delivery, and caesarean section (Ponkey et al. 2003, Gardberg et al. 1998). The results of previous studies suggest that the OP position increases the risk of OASR by a factor of 2 to 70 (Eskandar & Shet 2009, de Leeuw et al. 2008, Aukee et al. 2006).

#### **3.4.10 Other obstetric risk factors**

Other risk factors for OASR include previous OASR, use of oxytocin, and a large fetal head circumference. Women who had had OASR in previous deliveries had about a four to six times increased risk of OASR (Power et al. 2006, Spydslaug et al. 2005, Elfaghi et al. 2004). The use of oxytocin increases the risk of OASR two-fold (Prager, et al, 2008), whilst a fetal head circumference >35.5 cm increased the risk of OASR 3.34-fold (95% CI 1.33-8.42) (Valsky 2009).

Published results suggested that obese women were more likely to suffer from urinary and fecal incontinence and perineal trauma but less likely to sustain an OASR (Baumann et al. 2007, Albers et al. 2006a, Schytt et al. 2004, Uustal Fornell et al. 2004).

### 3.4.11 Time of birth

It has been suggested that quality of care and adverse healthcare events are related to working conditions, including workload, skill-mix and staffing (Currie et al. 2005, Hurst 2005). The likelihood of adverse events in obstetric care has been shown to increase during evenings and night shift. A large population based birth register study (n=2,102,324) from Sweden found that early neonatal mortality and early neonatal mortality related to asphyxia increased by 30% (relative risk 1.30, 95% CI 1.10-1.57), and 70% (relative risk 1.70, 95% CI 1.22-2.38), respectively, at night (9.00 pm to 9.00 am) (Luo & Karlberg 2001). Furthermore, the results of another Swedish population based retrospective cohort study (n=694,888) found that the risk of neonatal death increased by 28% (adjusted OR 1.28, 95% CI 1.13-1.46) at night (8.00 pm to 7.59 am), but there were no difference in intrapartum death between daytime and night (Stephansson et al. 2003). A population register based study from the Netherlands confirms the results of the Swedish studies, and found that compared to figures for tertiary centers operating during the day, perinatal mortality was increased by 32% (OR 1.32, 95% CI 1.15-1.52) in the evening and by 47% (OR 1.47, 95% CI 1.28-1.69) at night in nontertiary hospitals, and by 20% (OR 1.20, 95% CI 1.06-1.37) at night in tertiary centers (de Graaf et al. 2010).

Two published studies reported an association between OASR and time of birth. A case-control study (n=428) found that giving birth late at night (3.00 am to 6.00 am) increased the risk of OASR two-fold (aOR 2.07, 95% CI 1.06-4.02) (Jander & Lyrenas 2001). However, the results of a retrospective population based register study (n=37,332) from the USA found that the risk of OASR was 30% higher during the daytime/early evening compared to night-time/early morning due to the greater use of obstetric interventions (Webb & Culhane 2002).

Table 3. Studies on the association between obstetric interventions, demographic characteristics and OASR in studies published in 2010–1997, odds ratios 95% confidence intervals.

Study	Methods	Primipara	Maternal age	Birth weight	Prolonged second stage of birth	Operative vaginal	Episiotomy (rate), ml=mediolateral, m=midline	Epidural analgesia	Occiput posterior
Baghestan et al 2010	National birth register, n=1,673,442, 1967-2004, Norway	aOR 4.8 (4.7-5.0)		4,000-4,499g aOR 2.7 (2.6-2.7) 4500-4999g aOR 4.2 (4.0-4.4)		vacuum aOR 2.0 (1.9-2.1) forceps aOR 3.9 (3.7-4.0)	ml (na) * ns **aOR 1.3 (1.2-1.5) with vacuum *aOR 0.8 (0.76-0.9) **ns		
Revicky et al. 2010	Retrospective, cohort, n=10,314, 2000-2008, UK	aOR 3.19 (2.50-4.09)	<20 ref 21-25, ns 26-30 aOR 2.50 (1.61-3.89) 31-35 aOR 2.92 (1.86-4.57) 36-40 aOR 2.83 (1.68-4.70) ≥41 ns	>4000g aOR 12.90 (2.78-59.88)		vacuum aOR 2.28 (1.65-3.15) forceps aOR 3.98 (2.64-6.00)	ml (16%) No mediolateral episiotomy aOR 1.46 (1.05-2.05)	ns	
Eskander & Shet 2009	Retrospective, cohort, n=2,278, 2005-2006, UK	uOR 5.8 (2.7-12.0)	ns	ns		ns	ml (14%) ns	ns	uOR 69.8 (14.0-84.0)
Samarasekera et al 2009	Case-control, n=125, 1981-1993, UK	aOR 7.26 (1.85-28.45)	ns	aOR 5.37 (1.18-24.48)	>60 min aOR 3.59 (1.12-11.48)	forceps aOR 15.49 (3.64-65.75)	ml (54%) aOR 0.08 (0.02-0.31)		
Valsky et al. 2009	Cohort, observational, n=210, 2006-2008, Israel			≥110 min. aOR 2.27 (1.07-4.81)					

(aOR=adjusted Odds Ratio, adjusted for confounding factors found in the study, uOR=unadjusted Odds Ratio, ns=not statistically significant, \*Primiparous, \*\*Multiparous)  
Table 3 continues

Table 3 continued

Study	Methods	Primipara	Maternal age	Birth weight	Prolonged second stage of birth	Operative vaginal	Episiotomy (rate), ml=mediolateral, m=midline	Epidural analgesia	Occiput posterior
de Leeuw et al. 2008	Population based register, cohort, n=21,254, 1994-1995, Netherlands	aOR 1.94 (1.56-2.41)					ml (78.9%) with operative vaginal aOR 0.11 (0.09-0.13)		aOR 2.01 (1.54-2.62) with vacuum
Murphy et al 2008	RCT, n=200, Ireland						with operative vaginal aOR 0.72 (0.28-1.87)		
FitzGerald et al 2007	Prospective cohort, n=797, USA					forceps *aOR 13.6 (7.9-23.2)	m *aOR 5.3 (3.8-7.6)	*aOR 41.0 (13.5-124.4)	
Prager et al 2007	Retrospective, cohort, n=2000, 2005-2006, Sweden and Italy		*ns	4,000-4,499 g *aOR 1.98 (0.72-5.49) >4500 g *aOR 6.21 (1.76-1.99)	*ns	vacuum *aOR 2.30 (1.38-3.81)	ml (17%) *ns	*ns	
Andrews et al 2006	Prospective cohort, n=254, 2003-2004, UK			*ns	*ns		ml (41%) *aOR 4.04 (1.71-9.56)		
Aukee et al 2006	Retrospective cohort, n=9,178, 1997-2001, Finland	aOR 5.42 (2.37-12.39)		aOR 3.01 (1.50-6.05)		vacuum aOR 2.98 (1.37-6.48)	ml (38%) *aOR 0.33 (0.15-0.72)	ns	aOR 5.64 (1.63-19.52)

(aOR=adjusted Odds Ratio, adjusted for confounding factors found in the study, uOR=unadjusted Odds Ratio, ns=not statistically significant, \*Primiparous, \*\*Multiparous)  
Table 3 continues

Table 3 continued

Study	Methods	Primipara	Maternal age	Birth weight	Prolonged second stage of birth	Operative vaginal	Episiotomy (rate), ml=mediolateral, m=midline	Epidural analgesia	Occiput posterior
Dahl & Kjølshede 2006	Case-control, n=981, 1990-1999, Sweden		*ns			vacuum *aOR 5.36 (2.78-10.32)	ml (23%) *aOR 0.29 (0.14-0.63)	*aOR 0.31 (0.15-0.61)	
Dandolu et al 2005	Population based register, cohort, n=258,507, 1990-1991, USA					vacuum uOR 2.58 (2.48-2.68) forceps with vacuum uOR 3.84 (3.70-3.99)	m (na) uOR 3.19 (3.07-3.33) with vacuum uOR 2.93 (2.81-3.05)		
Hudelist et al 2005	Case control, n=201, 1999-2003, Austria			high birth weight aOR 1.68 (1.18-2.41)			ml (44%) ns		
Sheiner et al 2005	Population based register, cohort, n=98,524, 1988-1999, Israel	ns		aOR 2.5 (1.2-4.9)		vacuum aOR 8.2 (4.7-14.5) forceps aOR 26.7 (8.0-88.5)	ml (30%) ns		
Spydslaug et al 2005	Population based register, n=486,463, 1967-1998, Norway			4,500-4,999 g aOR 16.9 (12.8-22.4) >5,000 g aOR 23.6 (16.5-33.6)		vacuum aOR 1.4 (1.1-1.7) forceps aOR 5.1 (4.3-6.0)	ml (na)	aOR 0.8 (0.6-0.9)	

(aOR=adjusted Odds Ratio, adjusted for confounding factors found in the study, uOR=unadjusted Odds Ratio, ns=not statistically significant, \*Primiparous, \*\*Multiparous)  
Table 3 continues

Table 3 continued

Study	Methods	Primipara	Maternal age	Birth weight	Prolonged second stage of birth	Operative vaginal	Episiotomy (rate), ml=mediolateral, m=midline	Epidural analgesia	Occiput posterior
Elfaghi et al 2004	National birth register, cohort, n=1,665,900, 1973-1997, Sweden	aOR 5.28 (5.0-5.56)	<20 aOR 0.57 (0.51-0.64) 20-24 aOR 0.73 (0.69-0.77) 25-29 aOR 1.22 (1.16-1.28) 30-34 aOR 1.35 (1.27-1.44) >40 ns	4,000-4,400 g aOR 2.34 (2.21-2.46) 4,500-4,900 g aOR 3.77 (3.46-4.10) 5,000-5,400 g aOR 5.66 (4.67-6.86)					
Gupta et al 2003	Population based register, cohort, n=16,172, 1990-1999, UK			macrosomic infant *aOR 2.8 (1.8-4.6)		*ns	ml (40%)		
Williams 2003	Retrospective cohort, n=10,382, 1997-1999, UK	aOR 4.89 (13.55-6.75)		aOR 2.97 (1.81-4.88)	primiparous >2.5 h/ multiparous >1 h aOR 2.36 (1.25-4.46)				
de Leeuw et al 2001	Population based register, n=284,784, 1994-1995, Netherlands	aOR 2.39 (2.24-2.56)		aOR 1.73 (1.52-1.98)		vacuum aOR 1.68 (1.52-1.86) forceps aOR 3.53 (3.11-4.02)	ml (34%) aOR 0.21 (0.19-0.23)		

(aOR=adjusted Odds Ratio, adjusted for confounding factors found in the study, uOR=unadjusted Odds Ratio, ns=not statistically significant, \*Primiparous, \*\*Multiparous)  
Table 3 continues

Table 3 continued

Study	Methods	Primipara	Maternal age	Birth weight	Prolonged second stage of birth	Operative vaginal	Episiotomy (rate), ml= mediolateral, m= midline	Epidural analgesia	Occiput posterior
Handa et al 2001	Population based register, cohort, n=2,101,843, 1992-1997 USA					vacuum (2.21-2.40) forceps aOR 1.45 (1.37-1.52)	m (na) third degree aOR 0.89 (0.86-0.92) fourth degree aOR 1.12 (1.05-1.19)		
Jander et al 2001	Case-control, n=418, 1995-1996, Sweden	aOR 7.55 (3.72-15.29)	>35 aOR 4.79 (1.93-11.88)	aOR 3.98 (2.12-7.47)	vacuum aOR 3.49 (1.27-9.58)	vacuum	ml ns m aOR 3.44 (1.25-9.49)	ns	
Samuelsson et al 2000	Prospective cohort, n=2,883, 1995-1997, Sweden			aOR 2.02 (1.30-3.16)	pushing time <30 min aOR 0.47 (0.24-0.91)		ml (11%) ns		
Poen et al 1997	Case-control, n=822, 1989-1994, Netherlands			aOR 2.05 (1.09-3.85)	>60min ns	forceps aOR 3.34 (1.64-6.89)	ml (37%) aOR 0.54 (0.31-0.94) *aOR 0.37 (0.19-0.72)	aOR 8.0 (1.41-45.29)	

(aOR=adjusted Odds Ratio, adjusted for confounding factors found in the study, uOR=unadjusted Odds Ratio, ns=not statistically significant, \*Primiparous, \*\*Multiparous)

### 3.5 OUTCOME OF OASR

Studies that have looked at the outcome of primary repairs have suggested that OASR results in anal incontinence in ca. 20-60% and fecal urgency in 4-25% of those affected (Tjandra et al. 2008, Molander et al. 2007, Kairaluoma et al. 2004, Pinta et al. 2004a, Pinta et al. 2004b, Sultan et al. 1994). The wide variation might be explained by training of staff, since repair carried out by appropriately trained staff has been associated with low long term morbidity (Williams et al. 2006) or the degree of perineal rupture. Pain, sexual problems and emotional impacts have also been reported (Boij et al. 2007, Williams et al. 2005a).

A Cochrane review of three randomized controlled trials suggested (n=279) that, compared with immediate primary end-to-end repair of OASR, early primary overlap repair appeared to be associated with lower risks of fecal urgency and anal incontinence symptoms. However, the data available were limited and the experience of the surgeon was not addressed in the three studies reviewed; consequently it was considered inappropriate to recommend one type of repair over the other. (Fernando et al. 2006a) Furthermore, the results of one randomized controlled trial suggested that primary overlap repair of the external sphincter was associated with a significantly lower incidence of fecal incontinence (Fernando et al. 2006b), which was confirmed by one retrospective study (Lepisto et al. 2008). However, results of two randomized controlled trial suggested that there was no difference in anal incontinence symptoms between these two techniques (Rygh & Korner 2010, Garcia et al. 2005).

In the long-term, 30-60% rates of anal incontinence and 10-30% of fecal urgency have been reported, indicating that the two may occur at similar levels (Nordenstam et al. 2009, Mous et al. 2008, Samarasekera et al. 2008, Wagenius & Laurin 2003, De Leeuw et al. 2001). The results of two follow-up studies showed that women with an OASR at the index delivery had a more severe incontinence score for flatus and liquid stool 10 years after the initial injury compared with women without sphincter laceration (Nordenstam et al. 2009, Fornell et al. 2005). Women who have suffered OASR are at increased risk of permanent anal incontinence or worsening of the symptoms in subsequent pregnancies (Elfaghi et al. 2004, McKenna et al. 2003), and thus considering an elective caesarean section has been encouraged (Nordenstam et al. 2009, McKenna et al. 2003, Fitzpatrick et al. 2002). Overall, the variation in follow-up time periods and lack of validated questionnaires complicates the analysis of previous results (Fernando et al. 2006a). However, use of St. Mark's incontinence score in the follow-up of women after primary repair of OASR has been recommended (Roos et al. 2009).

Obstetric injury results in substantial economic costs, including primary and secondary surgical repair, extended stays in hospital after childbirth, follow-up and physiotherapy (Tan et al. 2008, Mellgren et al. 1999). For example, Mellgren et al. (1999) reported that the average cost per patient was \$17,166 (Mellgren et al. 1999). However, the monetary value is not the only point to consider, since OASR might cause lifelong suffering in affected women (Williams et al. 2005a).



## 4 Purpose of the study

The purpose of this retrospective register based study was to identify the risk factors for OASR, to discover how they interact with each other, and to describe the trends in OASR and episiotomy between 1997 and 2007 in Finland among vaginally delivered women, including all presentations and assisted deliveries. The research questions were:

1. What are the risk factors for obstetric anal sphincter ruptures, and how they interact with each other?
2. What are the causes of the increasing trend in OASR?
3. Does the risk of OASR vary between delivery hospitals?
4. Is the risk of OASR affected by time of birth (night shift, weekend, vacation)?
5. Is the hospital's episiotomy policy affected by known OASR risks and whether the hospital's episiotomy policy affects the risk of OASR?

The aim of the study was to produce a body of knowledge and evidence that could be used to aid in the prevention of obstetric anal sphincter ruptures and to audit midwifery and obstetric care practices and education in order to aid in their development.



## 5 Material and methods

### 5.1 DATA AND POPULATION

This was an observational retrospective population based register study covering the years 1997-2007. The data came from Medical Birth Register (MBR) and Hospital Discharge Register (HDR). The study population consisted of the 514,741 women (217,778 primiparous and 296,963 multiparous women) who gave birth to singleton babies, vaginally (including all presentations and assisted deliveries) in Finland. Caesarean sections and multiple births were excluded. The total population was used in Studies I, II and IV. In Studies III and V, the deliveries from hospitals with <1,000 births annually were excluded in order to avoid bias, and the population included 424,297 vaginal deliveries (183,409 primiparous and 240,888 multiparous women).

### 5.2 MEDICAL BIRTH REGISTER AND HOSPITAL DISCHARGE REGISTER

The Medical Birth Register was established in 1987 and is currently compiled by the National Institute for Health and Welfare (THL). The database produced includes information on maternal and neonatal birth characteristics and perinatal outcomes (live-born or stillborn infants born after the 22nd week of gestation or weighing 500 g or more) for all women who have given birth in Finland and all newborn infants up to the age of seven days. For each infant, a form has to be filled in by the hospital covering the seven days. The form is sent electronically or rare in paper to THL. The validity of the data depends on reporting, and thus they are correct if they have been reported correctly. The data submitted to THL are checked, and missing information or information thought to be incorrect is queried by contacting the treating hospitals; corrections are then made. Some birth data are missing from the Medical Birth Register, and therefore it was supplemented with data compiled by the Population Register Centre on live births and with data compiled by Statistics Finland on stillbirths and deaths during the first week of life. After these additions, the data covered 100 % of birth events. (The National Institute for Health and Welfare 2010c.)

The content of the MBR has been changed three times, in 1990, 1996 and 2004, in order to improve its reliability and to bring the form more in line with present care practices, ensuring the greatest possible consistency of the definitions used in obstetric units. In 2004, some new variables on maternal background characteristics and outcomes, such as length of the first and active second stage of birth, maternal weight and height, the infant's head circumference, and pregnancy and labor diagnoses (ICD-10 codes) were introduced into the MBR. In addition, the content of some variables such as pain relief, and interventions was changed (The National Research and Development Centre for Welfare

and Health 2003). The definitions and concepts related to pregnancy and neonatality are based on the STAKES publication *Ohjeita ja luokituksia 1999:2 Tautiluokitus ICD-10*. (The National Institute for Health and Welfare 2010c.) The recording of most of the variables was based on check-boxes. Third and fourth degree ruptures are pooled in the MBR and registered by using a check-box. Registration of maternal weight and height, and birth weight base on open ended -box, and diagnosis on open diagnosis code.

Furthermore, information on OASR has been collected by the MBR since 2004. For the years 1997-2003, the information for OASR was taken from the Hospital Discharge Register (HDR), based on the ICD-10 codes O70.2 (3<sup>rd</sup> degree) and O70.3 (4<sup>th</sup> degree). The two data sources were linked together using the mothers' unique personal identification numbers. The HDR was established in 1969 and it contains information on all aspects of inpatient care (including all hospitalizations requiring an overnight stay) in public and private hospitals and outpatient visits to public hospitals (since 1998). The register contains information on the patient's background, hospitalization period, procedures and the main diagnosis plus up to two other diagnoses, recorded using the International Classification of Diseases (ICD) code (Eighth Revision [ICD-8] in 1969-1986, Ninth Revision [ICD-9] in 1987-1995, and Tenth Revision [ICD-10] since 1996). The data are sent electronically to the THL by the hospitals. (The National Institute for Health and Welfare 2010d.)

### 5.3 DATA ANALYSES

Sampling and data analysis methods for each Study are presented in Table 4.

**Variables.** All continuous variables were transformed into categorical variables. Maternal age ( $\leq 19$ , 20-29, 30-39,  $\geq 40$ ), birth weight ( $\leq 2999$ , 3000-3499, 3500-3999,  $\geq 4000$ ), and BMI ( $\leq 24.9$ , 25-29.9,  $\geq 30$ ) were classified according to international limits. Infant head circumference was classified as  $\leq 34$ , 35-36,  $\geq 37$  cm, and  $\leq 15$ , and duration of the active second stage of labor as 16-30, 31-45, 46-60,  $\geq 60$  minutes. In the present study, the active second stage of birth refers to the phase of active bearing down. Apart from the mode of delivery, hospital and the continuous variables, all of the other variables were dichotomous. In all of the analyses, data pertaining to third and fourth degree anal sphincter ruptures were pooled. Occiput posterior (OP) presentation was taken from ICD-10 codes.

**Statistical analyses.** The data were analyzed using SPSS for Windows version 16.0. Statistical differences in frequencies (categorical and dichotomous variables) between the subjects and the reference population or between groups were evaluated by Chi Square tests. The differences between continuous variables that were not normally distributed were evaluated by Mann Whitney or Kruskal-Wallis tests. A  $p$  value  $< 0.05$  was considered statistically significant. Possible confounding

factors were identified from maternal and neonatal background characteristics and perinatal outcomes. Multivariate analyses of significant ( $p < 0.25$ ) and some clinically important variables ( $p > 0.25$ ) were taken into account in the logistic regression analyses in order to model the risks of OASR within the total populations. All the variables were entered simultaneously, and the analyses were performed using a forward elimination procedure (Burns & Grove 2001). The basic multivariate analyses (Study I, Tables 3 and 4) were intended to determine risk factors for OASR separately among primiparous and multiparous women. After that, in the following studies (Studies II-V), further and more detailed analyses were performed; these are outlined in Table 4. Furthermore, to examine how obstetric interventions and demographic characteristics are related to OASR, the contribution of each of these factors was estimated using logistic regression (Van de Mheen et al. 1997, Belsley et al. 1980). Each variable was added separately to the multivariate model and the contribution of each factor was measured by the percentage reduction in the odds ratio of OASR compared to the first model. The formula used was:  $(OR \text{ Model B} - OR \text{ Model X}) / (OR \text{ Model B} - 1)$ . In addition, the number of women who needed to be treated (NNT) with episiotomy within each group in order to prevent a single OASR was calculated using risk reduction between deliveries with and without episiotomy, only if it was positive (Lubsen & Hoes 2000).

## 5.4 DEFINITIONS

Active second stage of birth is defined as the active phase of bearing down immediately prior to the delivery of the infant.

Body mass index (BMI), which is calculated by dividing body weight in kilograms by squared height in meters ( $\text{kg}/\text{m}^2$ ), is used to define maternal weight groups. Being overweight is defined as having a BMI in the range 25.1-29.9 and obesity is associated with a BMI over 30.

OASR is defined as a third-degree perineal rupture if it involves a partial or complete disruption of the anal sphincter, which may include either or both the external (EAS) or the internal anal sphincter (IAS) muscles. A fourth-degree degree rupture involves the internal anal sphincter and the anal epithelium. In Finland, third degree ruptures are pooled, and OASRs are classified by ICD-10 codes O70.2 (3<sup>rd</sup> degree) and O70.3 (4<sup>th</sup> degree).

Parity was classified as primiparous or multiparous. Women who were admitted for vaginal deliveries after a previous caesarean section for their first birth were classified as primiparous.

Table 4. Population, aim, approach and statistical analyses in each of the studies

Study	Population	Aim	Approach	Statistical analyses
Study I	514,741 (217,778 primiparous birth and 296,963 multiparous women)	To identify the possible risk factors for OASR in a setting with low overall incidence of perineal tears; and to assess differences (if any) in the incidence of OASRs and associated risk factors between primiparous and multiparous women.	Basic model: ORs were adjusted on the basis of demographic statistics, interventions and other obstetric information	Chi Square, Mann Whitney, Logistic regression, NNT
Study II	514,741 (217,778 primiparous birth and 296,963 multiparous women)	To describe the trends in obstetric anal sphincter rupture between 1997 and 2007 among vaginally delivered women (including all presentations and assisted deliveries) and to identify how changes in the population or use of interventions affected the rate.	ORs were adjusted according to five time periods: 1997-1999, 2000-2001, 2002-2003, 2004-2005, and 2006-2007.	Chi Square, Logistic regression
Study III	<ul style="list-style-type: none"> <li>•Population 1: 168, 637 women (73, 813 primiparous and 94, 824 multiparous) from five university hospitals</li> <li>•Population 2: 255, 660 women (109, 596 primiparous=first vaginal birth and 146, 064 multiparous) from 14 non-university hospital with more than 1,000 deliveries annually</li> </ul>	To assess whether treatment differences by delivery hospital, volume or teaching status, or the patient mix, have an impact on the use of interventions and differences in OASR rates, both over time and between institutions.	ORs were adjusted on the basis of the five university hospitals or the non-university hospitals, divided into three groups based on OASR rates (low, medium or high)	Chi Square, Kruskal-Wallis, Logistic regression
Study IV	514,741 (217,778 primiparous and 296,963 multiparous women)	To analyze whether deliveries during July, on weekends or at night had higher OASR risks compared with those at other times.	ORs were adjusted on the basis of July vs. other months, weekend (Saturday and Sunday) vs. other days, and night (00.00-07.59) vs. day (08.00-23.59)	Chi Square, Logistic regression
Study V	424,297 vaginal deliveries (183,409 primiparous and 240,888 multiparous women). from hospitals with more than 1,000 deliveries annually	To assess whether the hospital's episiotomy policy (episiotomy frequency and use among previously identified groups at risk of OASR) had an impact on OASR rates and risks among vaginally delivered women.	ORs were adjusted according to the hospitals' episiotomy use. Hospitals were divided into groups based on the episiotomy rate quartiles. The lowest and highest quartiles were compared against the hospitals with intermediate episiotomy rates, including the two quartiles around the median.	Chi Square, Kruskal-Wallis, Logistic regression, NNT

primiparous=first vaginal delivery

## **5.5 ETHICAL CONSIDERATIONS**

The THL gave the necessary authorization for the use of sensitive health register data in scientific research on 16.10.2008, as required by national data protection legislation (Finlex 1999). No informed consent of the individuals on the register was needed, since this study was completely based on anonymized register information. The use of registers allowed cost effective data collection because time-consuming and expensive gathering of new data were avoided (Sund 2003).



## 6 Results

### 6.1 STUDY POPULATION

The mean maternal age ( $\pm$ SD) among the total population of primiparous ( $n=217,778$ ) was 27.1 ( $\pm 5.2$ ) (range 12-48) and that of multiparous women ( $n=296,963$ ) was 30.8 ( $\pm 5.1$ ; range 15-52). The means of fetal birth weights were 3,456 g ( $\pm 504$ ; range 131-5,780 g) and 3,637 g ( $\pm 514$ ; range 100-6675 g), respectively (Study I). Other demographic characteristics and the use of interventions among the total populations of primiparous women and multiparous women during the eleven year study period are presented in Table 5. These data relate to the primiparous and multiparous women with and without OASR; full data are presented in Tables 1 and 2 of Study I. Of the primiparous women (first vaginal delivery) 1.1% ( $n=2,315$ ) had OASR whereas 0.2% ( $n=534$ ) among multiparous women.

*Table 5. Demographic characteristics and use of interventions (%) among the total population of vaginally delivered primiparous and multiparous women between 1997 and 2007 in Finland*

<b>Demographic characteristic/ Intervention</b>	<b>First vaginal delivery, n=217,778</b>	<b>Multiparous women, n=296,963</b>
Maternal age (year)		
≤19	6.4	0.5
20-29	62.6	40.5
30-39	29.8	54.6
≥40	1.2	4.4
*BMI		
≤24.9	73.6	65.6
25-29.9	18.2	22.8
≥30	8.2	11.6
*Gestational diabetes	0.8	1.1
*Diabetes mellitus	0.04	0.03
Breech	0.8	0.6
Forceps	0.2	0.03
Vacuum assistance	15.0	2.2
Induction	15.4	16.7
Induction with prostaglandin	9.0	6.7
Augmentation with oxytocin	62.9	34.0
Episiotomy	63.5	15.5
Amniotomy	47.4	52.0
Epidural analgesia	60.7	19.8
*Spinal analgesia	1.7	5.9
Nitrous oxide gas	56.6	46.4
Paracervical block	14.6	23.8
*Length of active second stage of birth (min)		
≤15	23.8	76.7
16-30	30.9	15.9
31-45	18.8	4.2
46-60	10.5	1.5
≥61	16.0	1.7
Birth weight (g)		
≤2999	15.3	8.8
3000-3499	36.9	28.4
3500-3999	35.1	39.7
≥4000	12.7	23.1

(\*Gathered 2004-2007)

## 6.2 RISK FACTORS FOR OASR

Overall, the risk factors for OASR were mostly the same among primiparous and multiparous women. Unadjusted risk factors are presented in Tables 1 and 2 of Study I. These changed only a little in the multivariate analyses and, accordingly, the risk profiles remained unchanged except for episiotomy among primiparous women (Study 1, Tables 3 and 4). After adjustment, the risk for OASR among primiparous women included the use of forceps, increasing birth weight, vacuum assistance, occiput posterior presentation, maternal age  $\geq 20$ , and increasing length of the active second stage of birth, but decreased with use of nitrous oxide gas, episiotomy, and epidural analgesia, as shown in Figure 2. In addition, in vacuum assisted deliveries and in cases of occiput posterior presentation, episiotomy was associated, respectively, with a 30% and 58% decreased risk of OASR. The number of primiparous women who needed to be treated (NNT) with episiotomy in order to prevent one OASR during spontaneous vaginal deliveries was 909 (95% CI 769-1000), for vacuum-assisted deliveries the figure was 66 (95% CI 52-92), and among the primiparous women with occiput posterior presentation it was 15 (95% CI 12-21). The equivalent estimates among primiparous women with a prolonged active second stage of birth ( $\geq 61$  min) and with an infant weighing more than 4000 g were 385 (95% CI 278-625) and 149 (95% CI 130-175), respectively.

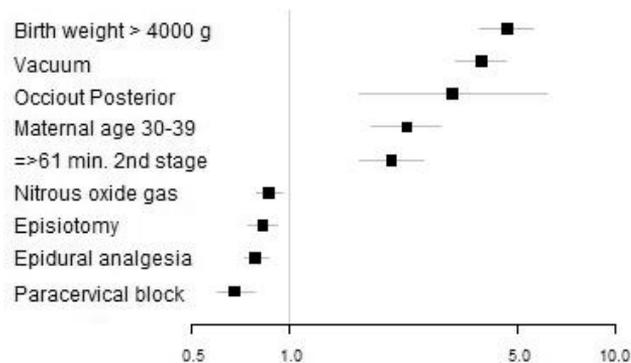


Figure 2. Adjusted risk factors (95% CI) for OASR among primiparous women (n=217,778) between 1997 and 2007 in Finland. The results were adjusted for mode of delivery, induction, prostaglandin, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, use of nitrous oxide gas, paracervical block, gestational diabetes, maternal age, BMI, length of active second stage of birth, birth weight, and head circumference. (Primiparous=first vaginal delivery)

Correspondingly, among multiparous women the greatest adjusted odd ratios were associated with the use of forceps, increasing length of the active second stage of birth, increasing birth weight,

vacuum assistance, episiotomy (OR 2.01, 95% CI 1.67-2.44), and epidural analgesia, as shown in Figure 3. There were any protective factors among the multiparous women.

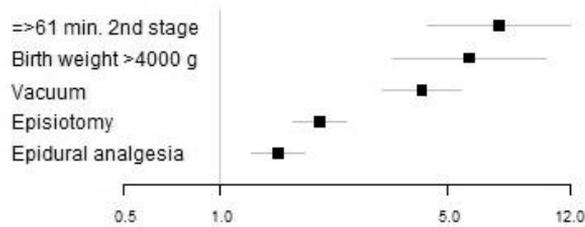


Figure 3. Adjusted risk factors (95% CI) for OASR among multiparous women (n=296,963) between 1997 and 2007 in Finland. The results were adjusted for mode of delivery, induction, prostaglandin, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, use of nitrous oxide gas, paracervical block, gestational diabetes, maternal age, BMI, length of active second stage of birth, birth weight, and head circumference.

### 6.3 TRENDS

In Finland, the overall incidence of OASR between 1997 and 2007 was low, amounting to 0.6%. Of the primiparous (first vaginal delivery) women who gave birth to singleton babies by vaginal delivery, 1.1% (n=2315), and of the multiparous ones 0.2% (n=534) had OASR. However, the rates increased consistently every year during the eleven-year study period especially among the primiparous women, as shown in Figure 4. The total rate was 0.2% in 1997 and 0.9% in 2007. (Study II)

In the period 2006-2007, after adjustments for patient-mix and well-known risk factors, the likelihood of primiparous women having OASR had increased by a factor of 3.27 (95% CI 2.86-3.75) and for multiparous women by a factor of 2.85 (95% CI 2.20-3.69) in comparison with 1997-1999 figures. The increasing trend of OASR could not be explained by demographic changes in the population or obstetric interventions. The number of vaginal deliveries has been remarkably constant, and therefore changes in subgroups at a higher risk of OASR, such as primiparous women, were slight. The most marked change that had the biggest impact on OASR rate was the increase in vaginally assisted delivery rate among both groups of women (Study II, Table 1). Overall, it appeared that the incremental contribution of vacuum assistance to OASR risk had grown and was estimated to have been in the order of 9% by the end of the study period; this was in line with its increased use (Study II, Table 2).

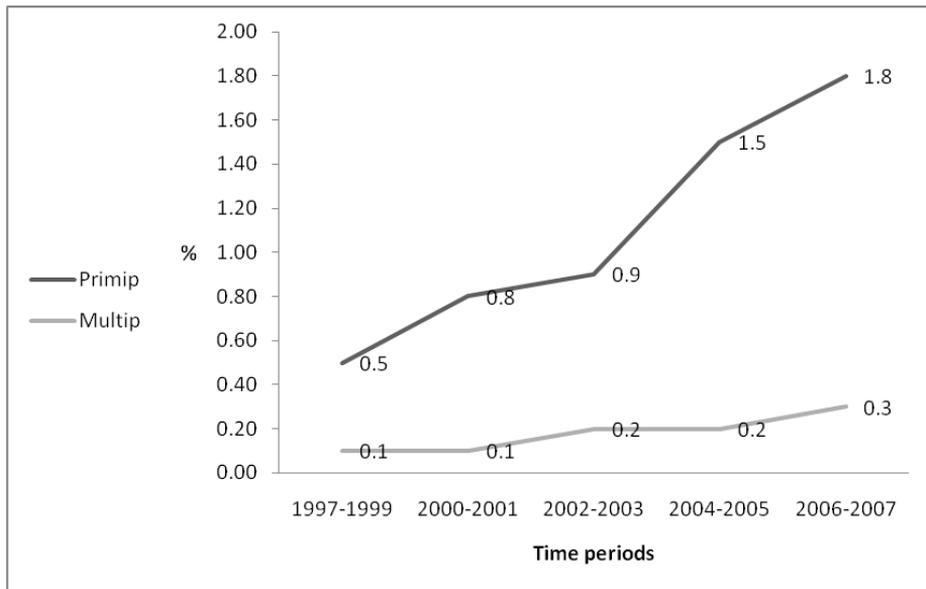


Figure 4. OASR rates among primiparous ( $n=217,778$ ) and multiparous ( $n=296,963$ ) women between 1997 and 2007 in Finland (Primiparous=first vaginal delivery)

Among the primiparous women, the use of episiotomy decreased the risk of OASR by 17%, and correspondingly among the multiparous women it increased the risk of OASR twofold. However, separate adjusted odds ratios for different time period among both groups of women showed that the role of episiotomy has changed over time, as shown in Figure 5. In primiparous women, episiotomy had a protective or indifferent effect until 2005, but after that it appeared to be a risk factor (OR 1.59, 95% CI 1.32–1.91). In multiparous women, episiotomy was an indifferent factor with respect to OASR until 2003 but after that it appeared to be a risk factor (in 2004–2005 OR 2.46, 95% CI 1.61–3.77, in 2006–2007 OR 7.57, 95% CI 5.39–10.62). Consequently, the association between episiotomy and OASR was far from clear, because episiotomy became a risk factor with respect to OASR while its use decreased. (Study II)

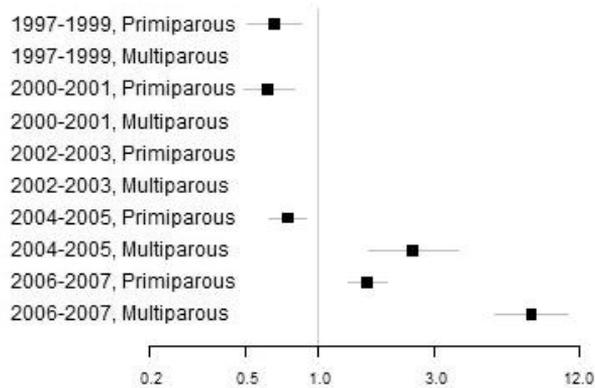


Figure 5. Adjusted odds ratios (95% CI) of OASR associated with episiotomy for primiparous ( $n=217,778$ ) and multiparous ( $n=296,963$ ) women in five time periods between 1997 and 2007 in Finland. The results were adjusted for mode of delivery, time periods, induction, oxytocin, episiotomy, occiput posterior presentation, epidural analgesia, spinal analgesia, nitrous oxide gas, paracervical block, maternal age, BMI, length of the active second stage of birth, and head circumference. (Primiparous=first vaginal delivery)

## 6.4 HOSPITAL DIFFERENCES

OASR rates among primiparous women (first vaginal delivery) varied from 0.7% to 2.1% ( $p \leq 0.001$ ) among the five university hospitals, and from 0.1% to 0.3% ( $p \leq 0.001$ ) in multiparous women. Correspondingly, in women giving birth at the 14 non-university hospitals, rates varied from 0.2% to 1.4% for primiparous and from 0.02% to 0.4% for multiparous women. The university hospitals that had high rates of OASR among primiparous women also tended to have high rates among multiparous women (Study III, Table 1). The main findings were that differences in OASR risks between hospitals were up to ca. threefold between university hospitals (Figure 6) and eightfold between non-university hospitals; neither the number of patients nor teaching status had a major impact on these outcomes (Study III, Tables 3 and 4). The difference in rates between teaching and non-teaching facilities (1.2% vs. 1.0%, respectively) were only ca. 13% for primiparous women and negligible for multiparous women (0.2%).

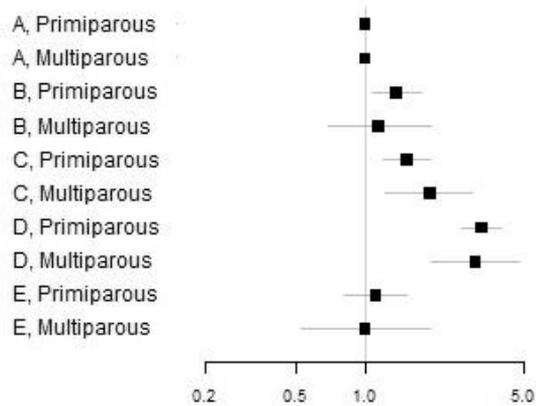


Figure 6. Adjusted odds ratios (95% CI) of OASR for primiparous ( $n=73, 813$ ) and multiparous ( $n=94, 824$ ) women in five university teaching hospitals between 1997 and 2007 in Finland. The results were adjusted for mode of delivery, hospitals, induction, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, use of nitrous oxide gas, paracervical block, maternal age, BMI, active second stage of birth, birth weight, and head circumference. (Reference=Hospital A) (Primiparous=first vaginal delivery)

## 6.5 TIME OF DAY AND SEASONAL VARIATIONS

The assessment of temporal patterns for OASR showed that occurrences of OASR were significantly lower during the night (00.00-07.59h) among both groups of women. Lower OASR rates on weekends (Saturday and Sunday), and in July were not statistically significant, as shown in Study IV (see Table 1). After adjustment for patient-mix and the use of interventions among the total population, the risk of OASR was 11% lower (95% CI 3-18%) during the night, and 15% (95% CI 3-26%) lower in July compared to other months (pooled) (Study IV, Table 2), as presented in Figure 7. The results showed that use of vacuum assistance and births involving infants weighing more than 4,000 grams were 0.8-1.3% ( $p \leq 0.001$ ) and 1.1-1.4% ( $p \leq 0.001$ ) lower, respectively, during the night. However, only approximately 14% of the increased OASR risk during the daytime could be explained by vacuum assistance and high birth weight (Study IV, Table 3).

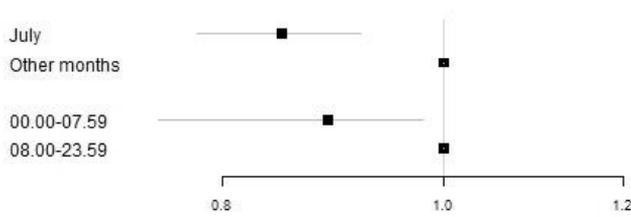


Figure 7. Adjusted OR of OASR in holiday and non-holiday time, and at night and during the daytime among the total population ( $n=514,741$ ). The results were adjusted for mode of delivery, time of birth, induction, amniotomy, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, paracervical block, maternal age, length of the active second stage of birth, and birth weight and time of birth (month, day of the week, time of birth). (References other months and 08.00-23.59)

## 6.6 HOSPITAL'S EPISIOTOMY POLICY

All hospitals annually with more than 1000 of deliveries were divided into three groups based on the episiotomy rate quartiles for the 11 years, with the data separated for primiparous (first vaginal delivery) and multiparous women. The low (L) and high (H) episiotomy use group included the lowest/highest 25% of the eleven-year range and the intermediate episiotomy use group (M) included the middle 50% of the eleven-year range. Figure 8 presents episiotomy use in each hospital district for primiparous women in 1997 and 2007. In the hospital district Helsinki and Uusimaa, there were four hospitals with more than 1000 deliveries annually. The maps show the mean episiotomy use among these hospitals, and four hospital districts (Länsi-Pohja, Kainuu, Mikkeli, Savonlinna) that only had smaller units (<1000 deliveries annually). The maps show that hospitals' episiotomy use has changed over time, and despite an overall reduction, its use has increased in five hospital districts. Consequently, it seems that use of episiotomy is mainly driven by local hospital policies and practices and is not associated with the hospital's geographical position or teaching status. (Study V)

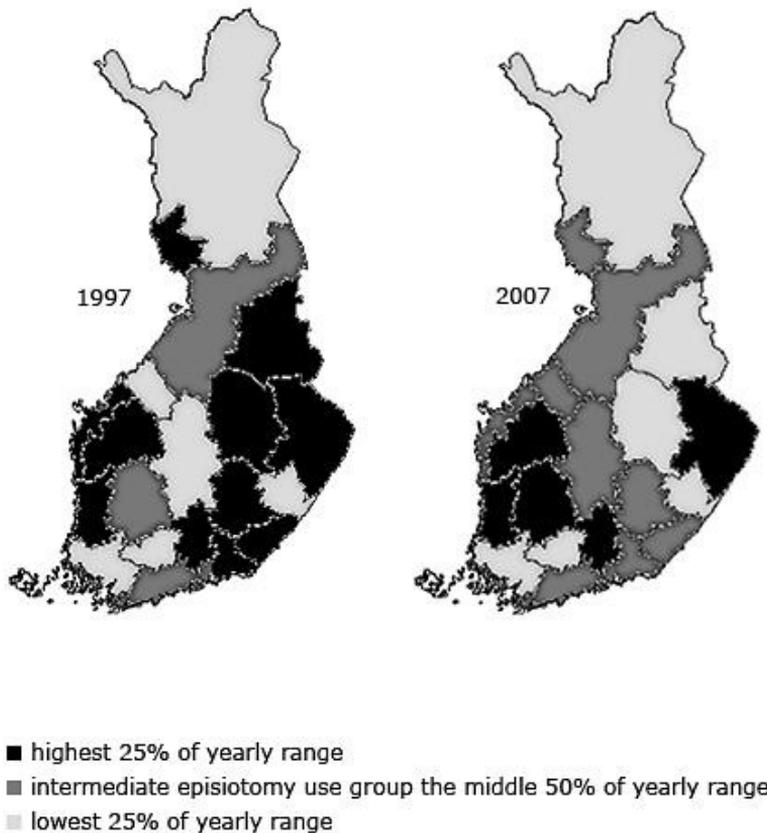


Figure 8. Episiotomy use groups among primiparous women in each hospital district in 1997 and in 2007 in Finland. (Primiparous=first vaginal delivery)

Eleven-year episiotomy rates in each episiotomy use group for primiparous women were 49.6%, 63.9% and 79.6%, and for multiparous women the rates were 9.9%, 13.9% and 24.5% (Study V, Table 1). Among both groups of women, the lowest OASR rates occurred among deliveries classified in the highest episiotomy rate quartile over time ( $p \leq 0.001$ ). In the highest episiotomy quartiles, the results of the multivariate analyses showed 39% (OR 0.61, 95% CI 0.52-0.71) and 45% (OR 0.60, 95% CI 0.42-0.72) lower OASR risks among primiparous and multiparous women, respectively compared to the lowest episiotomy use group (Figure 9). The differences in OASR risks between low and intermediate episiotomy use hospitals were not statistically significant. (Study V, Table 3). It is of note that hospitals may appear in different quartiles in different years during the study period. However, the results

remained unchanged after they were defined to the lowest (L) and highest (H) quartiles separately for each year. (Study V)

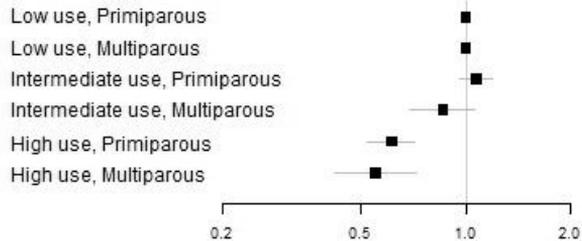


Figure 9. Adjusted risk factors for OASR in hospitals with different episiotomy rates among primiparous ( $n=183,409$ ) and multiparous ( $n=240,888$ ) women giving birth in hospitals with more than 1000 deliveries annually between 1997 and 2007 in Finland. The results were adjusted for maternal age, BMI, mode of delivery, induction, amniotomy, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, paracervical block, use of nitrous oxide gas and length of the active second stage of birth, birth weight, and hospital's episiotomy policy. (Reference=Low use)(Primiparous=first vaginal delivery)

## 6.7 SUMMARY OF THE MAIN FINDINGS

The two final multivariate models – one for primiparous and one for multiparous women – of risk factors for OASR, after adjusting for all confounding factors, which were performed for this summary, are presented in Tables 6 and 7.

Table 6. Adjusted Odds Ratios (OR) of OASR (n=2,315) among primiparous (=first vaginal delivery) women with vaginal deliveries (n=217,689).

<b>Delivery intervention/ characteristic</b>	<b>Adjusted OR</b>	<b>95 % CI</b>	<b>Adjusted p value</b>
<i>Mode of delivery</i>			
Spontaneous vaginal delivery	1		
Forceps	12.63	4.44-35.93	≤0.001
Vacuum assistance	3.87	3.27-4.58	≤0.001
<i>Episiotomy and spontaneous vaginal delivery</i>			
Episiotomy and vacuum assistance	0.61	0.51-0.72	≤0.001
*Occiput posterior presentation	1.65	1.16-2.35	0.005
Epidural analgesia	0.77	0.70-0.85	≤0.001
Nitrous oxide gas	0.88	0.81-0.96	0.003
Paracervical block	0.76	0.67-0.87	≤0.001
Augmentation with oxytocin	1.14	1.03-1.26	0.013
*Gestational diabetes	0.32	0.17-0.62	0.001
<i>Maternal age (year)</i>			
≤19	1		
20-29	1.74	1.36-2.21	≤0.001
30-39	2.24	1.75-2.86	≤0.001
≥40	1.62	1.04-2.52	0.034
<i>*Length of active 2<sup>nd</sup> stage of birth (min)</i>			
≤15	1.35	1.08-1.69	0.01
16-30	1.75	1.39-2.21	≤0.001
31-45	1.92	1.49-2.47	≤0.001
46-60	2.07	1.65-2.60	≤0.001
≥61			
<i>Birth weight (g)</i>			
≤2999	1		
3000-3499	1.93	1.61-2.33	≤0.001
3500-3999	2.99	2.50-3.58	≤0.001
≥4000	4.67	3.87-5.64	≤0.001
<i>Year of birth</i>			
1997-1999	1		
2000-2001	1.58	1.35-1.85	≤0.001
2002-2003	1.72	1.47-2.01	≤0.001
2004-2005	2.93	2.54-3.36	≤0.001
2006-2007	3.27	2.86-3.75	≤0.001
<i>Hospital</i>			
University hospital	1		
Non-university hospital (>1000 deliveries/year)	0.88	0.80-0.96	0.005
<i>Hospital's episiotomy use (%)</i>			
Low use (49.6)	1		
Intermediate use (63.9)	0.96	0.86-.06	0.40
High use (79.6)	0.69	0.60-0.79	≤0.001

The results were adjusted for mode of delivery, induction, prostaglandin, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, use of nitrous oxide gas, paracervical block, gestational diabetes, maternal age, BMI, length of active second stage of birth, birth weight, head circumference, five time periods, hospital type, and hospitals' episiotomy use. (\*Adjusted 2004-2007, n=62,065)

Table 7. Adjusted Odds Ratios (OR) of OASR (n=534) among multiparous women with vaginal delivery (n=296,836).

<b>Delivery intervention/ characteristic</b>	<b>Adjusted OR</b>	<b>95 % CI</b>	<b>Adjusted p value</b>
<i>Mode of delivery</i>			
Spontaneous vaginal delivery	1		
Forceps	10.81	2.61-44.76	0.001
Vacuum assistance	3.56	2.71-4.70	≤0.001
Episiotomy	2.33	1.91-2.83	≤0.001
Epidural analgesia	1.51	1.25-1.82	≤0.001
Induction with prostaglandin	0.69	0.48-0.99	0.04
<i>Maternal age (year)</i>			
≤29	1		
30-39	1.26	1.05-1.51	0.015
≥40	1.46	1.00-2.14	0.052
<i>*Length of active 2<sup>nd</sup> stage of birth (min)</i>			
≤15	1		
16-30	2.91	2.10-4.05	≤0.001
31-45	4.26	2.76-6.57	≤0.001
46-60	2.89	1.41-5.89	0.004
≥61	6.76	4.11-11.14	≤0.001
<i>Birth weight (g)</i>			
≤2999	1		
3000-3499	1.38	0.77-2.46	0.28
3500-3999	3.28	1.91-5.64	≤0.001
≥4000	5.82	3.39-10.00	≤0.001
<i>Year of birth</i>			
1997-1999	1		
2000-2001	1.14	0.83-1.54	0.42
2002-2003	1.59	1.19-2.12	0.002
2004-2005	2.11	1.61-2.77	≤0.001
2006-2007	2.85	2.20-3.69	≤0.001
<i>Hospital's episiotomy use (%)</i>			
Low use (9.9)	1		
Intermediate use (13.9)	0.79	0.63-0.99	0.04
High use (24.5)	0.60	0.45-0.80	≤0.001

The results were adjusted for mode of delivery, induction, prostaglandin, oxytocin, episiotomy, OP, epidural analgesia, spinal analgesia, use of nitrous oxide gas, paracervical block, gestational diabetes, maternal age, BMI, length of active second stage of birth, birth weight, head circumference, five time periods, hospital type, and hospitals' episiotomy use. (\*Adjusted 2004-2007, n=88,300)



## 7 Discussion

The purpose of the study presented herein was to identify the risk factors for OASR, to discover how they interact with each other, and to describe the trends in OASR and episiotomy in Finland between 1997 and 2007 among vaginally delivered women, including all presentations and assisted deliveries. The results of this study are relevant for developing midwifery, midwifery education and obstetric care practices. The risk factors for OASR among both groups of women were forceps delivery, a prolonged active second stage of birth, infants weighing more than 4000 grams, and vacuum assistance. The findings concerning the risk factors for OASR were in line with previous results but provided new information on the role of lateral episiotomy, and the etiology of OASR. Lateral episiotomy decreased the likelihood of OASR in primiparous (first vaginal delivery) but was a risk factor among the multiparous women. The risk of OASR increased by a factor of 3.28 among primiparous women, and by a factor of 2.83 among multiparous women between 1997 and 2007. Changes in population characteristics and in the use of interventions were small, and the increased OASR rate could not be explained by these. The only exception was vacuum assisted deliveries, which explained about 9% of the rising OASR risk. There were inter-hospital differences of 3.2 to 8.2 times with respect to OASR risks in primiparous and multiparous women, between the university teaching and non-university hospitals.

### 7.1 STRENGTHS AND WEAKNESSES

The present study has a number of strengths. The most important strength is that the register-based data covered the entire population and thus offered a comprehensive picture of trends and risks of OASRs separately for the primiparous and multiparous women during the study period. Furthermore, it was possible to evaluate the outcomes on several levels, for example, individual, institutional and national (Juntunen et al. 2008, Sund et al. 2004). In addition, the use of existing register data was economical, since it reduced the study cost and time spent on data collection (Gissler & Haukka 2004).

Potential weaknesses include coverage and quality of the data. This kind of register information might include errors and missing values because the data are produced mainly for administrative and statistical purposes, not primarily for research (Sund 2003, Burns & Grove 2001). The MBR has been shown to be reliable and covers all Finnish hospitals and all vaginally delivered women in Finland, thus minimizing potential selection bias (Laine et al. 2009, Gissler et al. 1995). Information on OASR has only been collected for the MBR since 2004. For the years 1997-2003, the information was taken

from the HDR, based on the ICD-10 codes O70.2 (3<sup>rd</sup> degree) and O70.3 (4<sup>th</sup> degree). This register is also mandatory and its completeness and quality have been shown to be high (Keskimäki & Aro 1991).

In 2006-2007, for example, it covered 95% of the OASRs recorded in the MBR. These two data sources were linked together using the mothers' unique personal identification numbers. ICD-10 codes were used to identify diagnoses and other morbidities, and the same diagnostic criteria applied to all hospitals.

In Finland, the ICD-10 classification was introduced in 1996, and thus the validity of recording has not been affected by changes in this classification. However, it can be argued that there may have been errors or inter-hospital differences in recognition of OASR, and thus the increasing trend of OASR in Finland or inter-hospital differences in OASR rates could be explained by registration procedures. Furthermore, for the years 1997-2003 the information about OASR was taken from the HDR and after that collected by the MBR, and it is possible that the substantial increase in OASR among primiparous women since 2004 (Figure 4) could be explained by a change in recording. However, it is noteworthy that the rate of OASR among multiparous women remained unchanged. It is very difficult to verify the actual cause, but a lack of incidents with specific ICD codes that resulted in surgical repair, requiring extra days of hospital suggests that under-recording is unlikely. Furthermore, it can be argued that recognition of the condition has improved over the time or that competence and accuracy in diagnosing OASR varies between the hospitals. However, despite primary repairs, 4-25% of those affected suffer fecal urgency (Tjandra et al. 2008, Molander et al. 2007, Kairaluoma et al. 2004, Pinta et al. 2004a, Pinta et al. 2004b, Sultan et al. 1994), and therefore underdiagnosis also seems unlikely.

In Finland, perineal ruptures are defined by Sultan's classification, but third degree ruptures are pooled and reported using the ICD-10 code O70.2; fourth degree ruptures are reported using the ICD-10 code O70.3. These codes were introduced in 1996. In the present study, 3<sup>rd</sup> and 4<sup>th</sup> degree ruptures were pooled and consequently it is unlikely that results were affected by changes in classification during the study period.

A possible source of bias was also that only limited numbers of birth characteristics or confounding factors were adjusted for in the multivariate logistic analyses; this is a limitation of the study. For example, duration of the passive second stage of birth, variations in techniques to protect the perineum, pushing method and maternal positions might have influenced the risk of OASR but the MBR does not contain such information. Furthermore, position of the fetal head at birth was not recorded routinely in the MBR, and, thus occiput posterior (OP) presentation was taken from ICD-10

codes, and it was obvious that relatively few OP positions had been recorded. In addition, data on some relevant variables, such as spinal analgesia, length of the active second stage, and weight of the mother were not collected before 2003, enabling us to use these variables in the multivariate analyses only from 2004 to 2007.

## **7.2 REFLECTION ON THE CLINICAL AND STATISTICAL SIGNIFICANCE OF THE RESULTS**

The results of the study clearly highlighted the value of national registers covering the total population for detecting trends in obstetric practices and outcomes. This is especially relevant for rare complications such as OASR, where hospital-based annual rates are likely to vary considerably, and changes in one unit may occur by chance or at least be interpreted as being the result of normal variation and a slow but constant increase is easily missed. In Finland, the overall incidence of OASR was low, amounting to 0.6%, whereas in other Nordic countries, and in the USA incidences of 3.6-4.2% and 3.5-15.3 %, respectively, have been reported (Frankman et al. 2009, Laine et al. 2009). In the Nordic countries, this information was obtained from national birth registers, the quality of which is assured by validity declarations; in addition, perineal injuries are classified according to the ICD-10 codes and thus it seems unlikely that differences in OASR rate between the Nordic countries could be explained by differences in recording procedures.

Overall, the results of the present study concerning the risk profile of OASR were mostly consistent with recent studies (Eskandar & Shet 2009, Samarasekera et al. 2009). The results provided new information on episiotomy, since performing lateral episiotomy decreased the risk of OASR on individual level by 17% among primiparous women (first vaginal delivery) but increased by a factor of two among multiparous women. However, the efficiency of it was poor since 909 (95% CI 769-1000) primiparous women must be exposed to the adverse effects of an episiotomy (Carroli & Mignini, 2009) in order to prevent one OASR. Previous results concerning the efficiency of episiotomy in vacuum assisted deliveries were in line with our results (Baghestan et al. 2010, de Leeuw et al. 2008, Murphy et al. 2008), but showed better efficiency, with only 12 mediolateral episiotomies needed to be performed to prevent one OASR (de Leeuw et al. 2008). The results of the present study suggest that 66 (95% CI 52-92) lateral episiotomies needed to be performed to prevent one OASR, which is clinically more acceptable than the efficiency in spontaneous vaginal deliveries. If episiotomy was used routinely in vacuum assisted deliveries among primiparous women, the frequency of OASR might have been decreased by 64 cases during the study period. Among the primiparous women giving birth to infants weighing over 4,000 grams, around 150 episiotomies would need to be performed to prevent a single OASR, thus indicating moderate efficiency. However, the prediction of macrosomia has been shown

to be inaccurate, with a sensitivity of only ca. 60-70% for clinical and ultrasonographic techniques (Weiner et al. 2002), thus increasing the selection bias.

The results of the present study showed that episiotomy was used almost routinely in primiparous women between 1997 and 2001 in Finland, but subsequently its use has constantly declined. The total episiotomy rate in Finland has been substantially higher than in the other Nordic countries, for example, in 2005 it was 30% in Finland but only 7-14% in Sweden, in Denmark and in Norway (Laine et al. 2009). In Finland, the incidence of OASR has increased while the use of episiotomy has decreased. Over the study period, the likelihood of primiparous and multiparous women having OASR increased by a factor of 3.28 and 2.83, respectively, which was in line with previous studies showing a substantial increase in OASR rates in other Nordic countries, but mostly for unidentified reasons (Baghestan et al. 2010, Laine et al. 2009, Elfaghi et al. 2004). In the USA, where midline episiotomy is favored, however, the reverse trend has been recorded, and thus the incidence of OASR has decreased while the use of episiotomy has decreased (Laine et al. 2009, Clemons et al. 2005). The results of the current study showed that the risk of OASR was 39% lower for primiparous women and 45% lower for multiparous women giving birth in hospitals included in the high compared to the low episiotomy quartiles (Study V, Table 3). However, the difference in episiotomy rate between high and low episiotomy use groups in primiparous women was 30% (79.6% vs. 49.6%) while that in OASR rate was 0.4% (0.7% vs. 1.1%, respectively), thus indicating poor efficiency in preventing OASR.

The results demonstrated that the association between episiotomy and OASR has changed during the study period among both groups of women. In primiparous women, episiotomy had a protective or indifferent effect until 2005, but after that it appeared to be a risk factor (OR 1.59, 95% CI 1.32-1.91) while in multiparous women it was an indifferent factor with respect to OASR until 2003 but after that it appeared to be a risk factor (in 2004-2005 OR 2.46, 95% CI 1.61-3.77, in 2006-2007 OR 7.57, 95% CI 5.39-10.62) (Study II). It is possible that while the overall use of episiotomy decreased, the clinical decision to cut the perineum prophylactically was made more often in those who were at a high risk of OASR than in low risk women, consequently there was confounding by indication. Therefore, women who underwent episiotomy were not comparable with those who did not; this could explain an approximately two-fold increased risk of OASR among the multiparous women with episiotomy who had multiple risk factors such as macrosomic infants and vacuum assistance, and consequently these deliveries were more frequently complicated. Of the multiparous women with OASR, 33% had an episiotomy while 15.5% of those who did not were affected by OASR. Consequently, the results of risk factors of OASR at the individual and the hospital level (high episiotomy use decreased the risk of OASR by 45% compared to low episiotomy use) were not contradictory, and episiotomy also had a protective effect in multiparous women.

Previous results on the association between episiotomy and OASR have been contradictory, which could be explained by different episiotomy types, lack or poor description of episiotomy or other methodological issues such as not considering the risk factors for OASR separately for primiparous and multiparous women (an issue that was addressed in the current study) or inadequate sample size. The protective role of episiotomy among primiparous women in the present study could be explained by the type of episiotomy, since it has been suggested that episiotomy involving a larger angle of cutting away from anus decreases the risks of OASR more than the midline type, which has previously been identified as a risk factor for OASR (Eogan et al. 2006, Aytan et al. 2005). Furthermore, the results of large population based studies were coherent and usually suggested that episiotomy is an indifferent or a protective factor; this indicates that a large sample size is needed in order to reveal the role of episiotomy in preventing OASRs, which have quite a low prevalence.

Inter-hospital differences in the risks of OASR were ca. 3- to 8-fold in primiparous and multiparous women, respectively, indicating that local norms for each hospital with respect to the care of women giving birth were of greater importance. Hospitals with high rates of OASR for primiparous women also had high rates for multiparous women, implying that treatment differences might have played a crucial role in the variations. There were, for example, striking 4.4-fold (range 21-92 min.) inter-hospital differences in the mean duration of the active second stage of labor in primiparous women when only university hospitals were considered, indicating differences in onset and methods of pushing. The university hospitals with the highest means for the active second stage of labor had the highest rates of OASR among both groups of women; this is in line with previous results suggesting that prolonged bearing down is associated with an increased risk of OASR (Samuelsson et al. 2000). In addition, episiotomy rates among primiparous women in university hospitals varied from 49.4% to 75.5%, reflecting local norms to promote selective or routine use of episiotomy. However, it is noteworthy that the risk of OASR on an individual level in primiparous women was the same in university hospitals A and E, which had the highest and the lowest episiotomy rates (Study IV, Tables 1 and 3), thus indicating that the role of episiotomy in preventing OASRs is not of great importance. Furthermore, it was not possible to evaluate the effect of each birth attendant's delivery routines on perineal outcomes, although this has been shown to be a significant factor, with a previous study suggesting that there were significant differences in OASR rates between birth attendants (Klein, et al, 1994). The results of the current study suggested that time of birth (night vs. day time, July vs. other months) were of minor importance to increasing the rate of OASR. The evidence was that the risk of OASR was 11% lower during the night and 15% lower in July.

### **7.3 GENERALIZABILITY OF THE RESULTS**

The results of the present study are likely to be generally applicable to hospitals in countries with very similar healthcare systems, i.e. those which provide free access to antenatal and obstetric services covering almost all deliveries. However, they are probably less applicable to countries with a very prominent private sector, since it has been suggested that patients admitted to private hospitals may be almost twice as likely to have assisted deliveries (Shorten & Shorten, 1999) or episiotomy (Shorten & Shorten, 2000) than those in public hospitals. Furthermore, the risk profile of OASR may be very different in countries with markedly lower or higher OASR rates. The type of episiotomy used, and the very different roles of professionals on duty, may also affect the outcomes considerably.

### **7.4 SUGGESTIONS FOR FURTHER RESEARCH**

This is a retrospective register-based study, using the MBR and HDR, presenting the risk factors for OASR, and describing the trends in OASR between 1997 and 2007 in Finland among vaginally delivered women. The MBR includes information on maternal and neonatal birth characteristics and perinatal outcomes, but there is a lack of information on practices during the second stage of birth, such as maternal positions, pushing methods or perineum protection techniques. Thus, further studies are needed to examine midwifery care practices during the second stage of labor as these can influence perineal outcomes. Such studies would facilitate the development of appropriate interventions to promote perineal integrity. Further, studies exploring the quality of life of women who have sustained OASR during childbirth should be undertaken.

## 8 Summary and conclusions

In Finland, the rate of obstetric anal sphincter rupture (OASR) has been quite low, but the trend is towards an increase: from 0.2% in 1997 to 1.0% in 2009. In 2008, OASRs occurred in 2.6%-5.6% of vaginal deliveries in the other Nordic countries and as many as 3-15% in the USA. It is noteworthy that differences in OASR rates may be affected by differences in reporting or diagnosing. In healthy young women, sphincter rupture following childbirth is the most common cause of anal incontinence, and this has long-term health impacts on affected women.

Factors associated with OASR have been widely recognized, but awareness of these does not always help to predict women who will be affected by OASR. The results of published studies indicate that primiparity, high birth weight, operative vaginal deliveries, a prolonged active second stage of birth, occiput posterior presentation, and midline episiotomy techniques are the risk factors of OASR. There are at least three episiotomy types: midline, mediolateral and lateral. The mediolateral technique has been associated with a decreased risk of OASR in comparison with the midline technique, but results of randomized controlled trials found no differences between these two techniques. Lateral episiotomy, the only technique used in Finland, has seldom been described in studies. Overall, evidence of the effects of perineal protection is sparse and suggested methods include avoiding episiotomy or favoring mediolateral episiotomy over the midline type, and favoring spontaneous or vacuum-assisted births over forceps delivery. Furthermore, manual perineum protection techniques, and unrushed delivery of the fetal head have been shown to reduce the risk of perineal ruptures.

Most of the studies have been performed outside Finland and the Nordic countries, and consequently there are some particular concerns. For example, the studies performed in countries with a prominent private healthcare sector, such as the USA, are probably less applicable to Finland, which provides free access to antenatal and obstetric services covering almost all deliveries. Furthermore, differences in episiotomy type and in the use of obstetric interventions, such as a higher episiotomy rate than in other Nordic countries, may also affect outcomes considerably. In addition, the risk profile of OASR may be very different in countries with markedly lower or higher OASR rates.

The purpose of this retrospective population based birth register study was to identify the risk factors for OASR, to discover how they interact with each other, and to describe the trends in OASR and episiotomy. The data originated from the Medical Birth Register and included all vaginally delivered women with singleton pregnancies, including all presentations and assisted deliveries (n=514,741) between 1997 and 2007 in Finland. For the years 1997-2003, the information about OASR was taken from the Hospital Discharge Register (HDR), based on the ICD-10 codes. Primiparous (n=2,315) and

multiparous women (n=534) with OASR were compared in terms of possible risk factors to primiparous (n=215,463) and multiparous (n=296,429) women without OASR, respectively, using stepwise logistic regression analysis.

The findings concerning the risk factors of OASR were in line with previous results but provided new information on the role of lateral episiotomy, and the etiology of OASR.

1. The risk factors for OASR among both groups of women were forceps delivery, a prolonged active second stage of birth, infant birth weight over 4000 grams, and vacuum assistance. Furthermore, occiput posterior presentation, and a maternal age over 20 years were significant risk factors of OASR among primiparous women, and epidural analgesia was significant among multiparous women. Lateral episiotomy decreased the likelihood of OASR in primiparous but not multiparous women.
2. Approximately 900 episiotomies must be performed in order to prevent one OASR in primiparous women, indicating the generally poor efficiency of the technique; the only exception was for vacuum assisted deliveries (NNT 66).
3. The association between episiotomy and OASR has changed during the study period among both groups of women. In primiparous women, episiotomy had a protective or indifferent effect until 2005, but after that it appeared to be a risk factor (OR 1.59, 95% CI 1.32–1.91) while in multiparous women it was an indifferent factor with respect to OASR until 2003 but after that it appeared to be a risk factor (in 2004–2005 OR 2.46, 95% CI 1.61–3.77, in 2006–2007 OR 7.57, 95% CI 5.39–10.62)
3. The likelihood of OASR has increased by a factor of 3.28 among primiparous and 2.83 among multiparous women. Changes in population characteristics and in the use of interventions were small, and these did not cause the increased OASR rate. The only exception was vacuum assisted deliveries, which explained about 9% of the rising anal rupture risk.
4. There were ca. three- to seven-fold inter-hospital differences in OASR rates between the university teaching and non-university hospitals. The differences were not explained by patient mix or the use of interventions, which indicates that OASRs might be preventable and that there is an important healthcare quality issue involved or there were differences in registration or diagnosing OASR.
5. The risk of OASR was 11% lower at night and 15% lower in July - the main holiday month - suggesting that OASR rates were not affected by night time and vacation.

6. Over the study period the use of episiotomy decreased constantly from 42% in 1997 to 29% in 2007, but there were striking differences between the hospitals. The risk of OASR appeared to be 39% lower in primiparous and 45% lower in multiparous women delivered in the hospitals where episiotomy was use was highest.

It is possible that while the use of episiotomy decreased, the clinical decision to cut the perineum prophylactically was made more often in those who were at a high risk of OASR than in low risk women, consequently there was confounding by indication. Therefore, women who underwent episiotomy were not comparable with those who did not, which could explain an approximately two-fold increased risk of OASR among the multiparous women, and the fact that the association between episiotomy and OASR has changed during the study period.

## **8.1 IMPLICATIONS**

Recommendations for midwifery, obstetric practise, education and administration are as follows. Awareness of the risk factors for OASR does not always help to predict who will be affected it and OASRs also occur in women without risk factors. It is important to protect the perineum of women with attributable risks of OASR. In particular, in cases of women with multiple risk factors, the possibility of sphincter disruption should be borne in mind. The results suggest that the use of lateral episiotomy should be restricted even among women with the highest risks; the exception being that in vacuum assisted deliveries routine use might be advisable for primiparous women. Vacuum assistance is a modifiable risk factor, and thus limiting its use might be advisable to limit OASRs. The occiput posterior position, which was included in the risk factors for OASR, should be recognized and corrected as early as possible to facilitate labor.

The obstetric anal sphincter rupture rate is a relevant quality indicator for patient safety and midwifery. A review of cases and routine collection of hospital-level benchmarking statistics on adverse obstetric events might help to improve midwifery and obstetric practices to prevent similar future events.



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**SARI RÄISÄNEN**

*Obstetric Anal Sphincter  
Ruptures*

*Risk Factors, Trends and Differences  
Between Hospitals*

Birth injuries have been chosen as one of the 21 indicators of patient safety by the Organisation for Economic Cooperation and Development (OECD) and in Nordic countries. Obstetric anal sphincter rupture (OASR) is a serious complication of vaginal delivery; it results in substantial economic costs and might cause lifelong suffering in affected women. The likelihood of OASR increased by ca. threefold among vaginal delivered women between 1997 and 2007 in Finland.



UNIVERSITY OF  
EASTERN FINLAND

PUBLICATIONS OF THE UNIVERSITY OF EASTERN FINLAND  
*Dissertations in Health Sciences*

ISBN 978-952-61-0360-0