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Does an intervention programme reduce the risk of obstetric anal sphincter injury? A cohort study

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Abstract

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

Design Population based cohort study.

Setting University hospital setting in Oslo, Norway.

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

Main outcome measures

Information on maternal, obstetrical and fetal risk factors for OASIS was collected from the hospital obstetric database. Univariate analyses and multivariate logistic regression analyses, presenting adjusted odds ratios for OASIS, were performed.

Results The OASIS incidence was significantly reduced by 50%, from 4.0% (591/14787) in the first time period to 1.9% (316/16922) in the second. This reduction could not be explained by changes in population characteristics or OASIS risk factors during the study years. The reduction of incidence of OASIS between the two study periods was consistent across subgroups of women; regardless of parity, delivery method and infant birth weight.

Conclusion A marked reduction in the incidence of OASIS occurred in all studied subgroups of women after implementing the training programme for perineal protection. The training programme is a low-resource and low-cost intervention and is easily generalisable and applicable to other settings. Effective perineal protection procedures aiming at reducing incidence of OASIS should be offered to all delivering women, not only to women in high risk groups.

Introduction

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

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

The incidence of OASIS varies between countries and delivery units,[3-5, 15]. A steadily increasing incidence of OASIS has been reported in the Nordic countries over the last decades,[2, 5, 15, 16]. Factors such as alterations in patient population over time (increasing maternal age, larger infants and increased use of instrumental delivery) have been studied, but such factors cannot alone explain the increasing OASIS incidence [5, 15]. In 2004 the Norwegian National Board of Health criticized the delivery units for a high incidence of OASIS, at that time being 4.5% of vaginal deliveries, and required that hospitals should implement programs to reduce the OASIS incidence. Programs to introduce manual perineal protection in the second stage of delivery were implemented in many Norwegian hospitals, and a reduction in OASIS incidence was achieved,[17, 18]. Similar association between changed clinical routines during the second stage of delivery and a reduction in OASIS incidence is described in a U.S. study,[19].

In the Obstetric Department at Oslo University Hospital, Ullevål, attempts to reduce the OASIS incidence were developed in steps, starting in 2006 with more focus on the OASIS issue in clinical meetings, whereas practical training to improve protection of perineum during

second stage of delivery started in 2008. Such training programmes have previously been described in two studies,[17, 18].

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

Methods

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

Databases and participants

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

Women with obstetric anal sphincter injury (OASIS) were identified from the labour protocols at the delivery unit and validated against individual electronic and paper-based medical charts (by the first author: KL). Surgery notes for the OASIS repair in the medical record for each case were carefully read, and false positive cases were excluded (n=22). In addition, patients with the diagnosis OASIS (ICD-10 code O70.2 or O70.3) were identified from the electronic hospital discharge register and 13 additional patients with OASIS were

identified. After excluding women delivered with caesarean section, preterm deliveries (< week 32), triplets and quadruplets, the study population comprised 31 709 deliveries, of which 907 women with OASIS.

Definition and diagnostics of OASIS

Obstetric anal sphincter injury was defined as any degree of injury in the anal sphincter muscle (3A, 3B, 3C and 4th degree perineal tears, identified by the diagnoses O70.2 and O70.3 in the ICD-10 system),[20].

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

Risk factors for OASIS

Information on maternal, obstetrical and fetal risk factors for OASIS was collected, including maternal age, parity, year of delivery, labour induction, delivery method, duration of second stage of labour, epidural use, episiotomy, persistent occiput posterior presentation, shoulder dystocia, infant birth weight and infant head circumference (Table 1).

Table 1 Clinical characteristics and obstetric interventions for the whole study population. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women		Multiparous women	
Time period	**2003-05**	**2008-10**	**2003-05**	**2008-10**
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
Risk factors				
Age, years	*P*<0.001		*P*<0.001	
15-29	48.3 (n=3885)	43.8 (n=3872)	27.4 (n=1849)	21.4 (n=1730)
30-34	39.3 (n=3164)	40.8 (n=3604)	42 (n=2823)	40.7 (n=3287)
35-51	12.4 (n=1002)	15.4 (n=1361)	30.6 (n=2064)	37.9 (n=3068)
Birthweight, grams	*P*=0.003		*P*=0.60	
720-2999	16.4 (n=1321)	16.4 (n=1446)	11.8 (n=794)	11.6 (n=938)
3000-3499	37.9 (n=3050)	39.3 (n=3470)	32.5 (n=2191)	32 (n=2591)
3500-3999	33.2 (n=2670)	33.8 (n=2983)	36.3 (n=2447)	37.5 (n=3029)
4000-4499	11.0 (n=885)	9.3 (n=821)	15.6 (n=1049)	15.4 (n=1247)
4500-5850	1.6 (n=125)	1.3 (n=117)	3.8 (n=255)	3.5 (n=280)
Delivery method	*P*<0.001		*P*=0.45	
Spontaneous	81.5 (n=6558)	78.3 (n=6918)	96.2 (n=6479)	96.4 (n=7793)
Ventouse	16.5 (n=1331)	20.4 (n=1802)	3.5 (n=234)	3.4 (n=273)
Forceps	2.0 (n=162)	1.3 (n=117)	0.3 (n=23)	0.2 (n=19)
Episiotomy, all vaginal	*P*<0.001		*P*=0.066	
deliveries	31.4 (n=2528)	36.2 (n=3203)	7.3 (n=492)	8.1 (n=656)
Episiotomy, spontaneous	*P*=0.006		*P*=0.98	
deliveries	24.7 (n=1620)	22.7 (n=1569)	6.1 (n=396)	6.1 (n=477)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	60.8 (n=908)	85.1 (n=1634)	37.4 (n=96)	61.3 (n=179)
Duration 2nd stage, min	*P*=0.057		*P*=0.45	

The intervention programme

The need to reduce the incidence of OASIS was discussed among delivery personnel in clinical meetings from 2006. An intervention programme was implemented from 2008, including both midwives and physicians at the Department of Obstetrics and Gynaecology. First part of the training included a practical hands-on training on a pelvic delivery model and the second part included hands-on supervision during the second stage of delivery. The perineum protection programme consisted of four components during the last part of second stage of delivery, when the baby's head is crowning: slowing the delivery of the baby's head with one hand, supporting perineum with the other hand and asking the delivering woman not to push. The fourth part of the intervention was education in correct performing of episiotomy. At our department, episiotomy is performed only when indicated, for example due to fetal distress or imminent severe perineal tear. The main focus of this intervention step was to avoid median cuts of episiotomy technique, when performed, due to the augmented risk of OASIS associated with median episiotomies,[21].

Comparison of groups

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

Statistical analysis

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

Continuous data were categorised and the independent variables are presented as frequencies. Univariate analysis was performed to explore the significant risk factors. Significant and borderline-significant variables were included in the multivariate analysis. Univariate analyses were performed by Chi-square test. A significance level of 5% was chosen in all analyses. Adjusted odds ratios (aORs) for OASIS with 95% CI are reported from multivariate logistic regression analyses. The data were analyzed by using PASW (Predictive Analytics SoftWare, SPSS Inc., version 19.0, Chicago, IL).

Results

Overall incidence of anal sphincter injury in vaginal deliveries was significantly reduced by 50%, from 4.0% (591/14787) in the first time period (2003-5) to 1.9% (316/16922) in the second time period (2008-10). The reduction of OASIS incidence was of similar magnitude across all studied subgroups defined by risk factors, for both primi- and multiparous women (Table 2).

Table 2 Incidence of OASIS in different subgroups of women. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women			**Multiparous women**		
Time period	**2003-05**	**2008-10**		**2003-05**	**2008-10**	
OASIS	6.1 (489/8051)	3.0 (263/8837)		1.5 (102/6736)	0.7 (53/8085)	
Risk factors						
Age, years			*P*			*P*
15-29	5.5 (212/3885)	2.8 (107/3872)	<0.001	1.4 (25/1849)	0.5 (9/1730)	0.01
30-34	6.7 (212/3164)	3.3 (118/3604)	<0.001	1.6 (45/2823)	0.7 (22/3287)	0.001
35-51	6.5 (65/1002)	2.8 (38/1361)	<0.001	1.6 (32/2064)	0.7 (22/3068)	0.004
Birthweight, grams						

720-2999	3.0 (39/1321)	1.6 (23/1446))	0.016	0.4 (3/794)	0.5 (5/938)	0.63
3000-3499	4.4 (135/3050)	2.6 (90/3470)	<0.001	0.8 (18/2191)	0.4 (10/2591)	0.049
3500-3999	7.2 (192/2670)	3.4 (101/2983)	<0.001	1.3 (33/2447)	0.6 (19/3029)	0.006
4000-4499	11.2 (99/885)	4.8 (39/821)	<0.001	3.2 (34/1049)	0.7 (9/1247)	<0.001
4500-5850	19.2 (24/125)	8.5 (10/117)	0.017	5.5 (14/255)	3.6 (10/280)	0.28
Delivery method						
Spontaneous	4.8 (318/6558)	2.5 (170/6918)	<0.001	1.4 (91/6479)	0.6 (45/7793)	<0.001
Ventouse	10.8 (144/1331)	5.0 (90/1802)	<0.001	3.4 (8/234)	2.9 (8/273)	0.75
Forceps	16.7 (27/162)	2.6 (3/117)	<0.001	13.0 (3/23)	0 (0/19)	0.10
Episiotomy, all deliveries						
Yes	6.6 (166/2528)	3.0 (96/3203)	<0.001	2.0 (10/492)	1.8 (12/656)	0.80
No	5.8 (323/5523)	3.0 (167/5634)	<0.001	1.5 (92/6244)	0.6 (41/7429)	<0.001
Episiotomy, spontaneous deliveries						
Yes	4.0 (65/1620)	2.2 (34/1569)	<0.003	1.3 (5/396)	1.3 (6/477)	1.00
No	5.1 (253/4938)	2.5 (136/5349)	<0.001	1.4 (86/6083)	0.5 (39/7316)	<0.001
Episiotomy, instrumental deliveries						
Yes	11.1 (101/908)	3.8 (62/1634)	<0.001	5.2 (5/96)	3.4 (6/179)	0.45
No	12.0 (70/585)	10.9 (31/285)	0.64	3.7 (6/161)	1.8 (2/113)	0.34
Duration 2nd stage, min						
0-09	4.6 (13/281)	3.3 (9/273)	0.42	0.9 (20/2335)	0.4 (10/2390)	0.058
10-29	4.0 (99/2455)	2.9 (74/2591)	0.02	1.5 (50/3361)	0.5 (21/4505)	<0.001
30-59	5.5 (180/3290)	2.5 (93/3673)	<0.001	2.9 (24/839)	1.7 (16/957)	0.09
60-205	9.7 (193/1994)	3.8 (87/2288)	<0.001	4.0 (7/174)	2.3 (5/219)	0.32
Epidural						
Yes	6.5 (228/3494)	3.0 (128/4267)	<0.001	2.0 (20/1008)	0.8 (12/1419)	0.015

No	5.7 (261/4557)	3.0 (135/4570)	<0.001	1.4 (82/5728)	0.6 (41/6666)	<0.001
Shoulder dystocia						
Yes	15.8 (12/76))	14.1 (9/64)	0.78	5.7 (5/87)	4.1 (3/73)	0.64
No	6.0 (477/7975)	2.9 (254/8773)	<0.001	1.5 (97/6649)	0.6 (50/8012)	<0.001
Occiput posterior presentation						
Yes	11.4 (20/176)	6.9 (17/245)	0.11	0.7 (1/150)	1.7 (4/237)	0.39
No	6.0 (469/7875)	2.9 (246/8592)	<0.001	1.5 (101/6586)	0.6 (49/7848)	<0.001
Induced labour						
Yes	5.5 (75/1365)	3.0 (50/1650)	0.001	1.3 (12/903)	0.7 (9/1269)	0.18
No	6.2 (414/6686)	3.0 (213/7187)	<0.001	1.5 (90/5833)	0.6 (44/6816)	<0.001

The incidence of OASIS over the study years is displayed in Figure 1, demonstrating a reduced incidence of OASIS, which in time follows the implementation of the perineum support program for the staff. Figure 1 also demonstrates a similar reduction of OASIS incidence for the different delivery methods (operative and spontaneous vaginal delivery) between the two study periods: in spontaneous deliveries the OASIS incidence was reduced from 3.1% (409/13037) to 1.5% (215/14711) and in ventouse from 9.7% (152/1565) to 4.7% (98/2075). Forceps is less used in our department, but a significant OASIS reduction was also observed in forceps deliveries from 16.2% (30/185) to 2.2% (3/136).

Population characteristics across the study years

Overall changes in population characteristics between the two time periods were small, but the prevalence of older women (>35 years) was significantly higher in the second period (2008-10), and use of ventouse delivery, episiotomy, epidural and induction of labour was

more frequent (Table 1). Primiparous women comprised 85% of the women with OASIS, but represented only 53.3 % of the overall study population.

Primiparous women

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

Table 3 Clinical characteristics and obstetric interventions among primiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Primiparous women	**2003-05**		**2008-10**	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
n deliveries	n=489	n=7562	n=263	n=8574
Incidence OASIS	6.1 (489/7562)		3.0 (263/8574)	
Risk factors	%		%	
Age, years	*P*=0.08		*P*=0.39	
15-29	43.4 (n=212)	48.6 (n=3673)	40.7 (n=107)	43.9 (n=3765)
30-34	43.4 (n=212)	39 (n=2952)	44.9 (n=118)	40.7 (n=3486)
35-51	13.3 (n=65)	12.4 (n=937)	14.4 (n=38)	15.4 (n=1323)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	8.0 (n=39)	17.0 (n=1282)	8.7 (n=23)	16.6 (n=1423)
3000-3499	27.6 (n=135)	38.5 (n=2915)	34.2 (n=90)	39.4 (n=3380)
3500-3999	39.3 (n=192)	32.8 (n=2478)	38.4 (n=101)	33.6 (n=2882)
4000-4499	20.2 (n=99)	10.4 (n=786)	14.8 (n=39)	9.1 (n=782)

4500-5850	4.9 (n=24)	1.3 (n=101)	3.8 (n=10)	1.2 (n=107)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	65.0 (n=318)	82.5 (n=6240)	64.6 (n=170)	78.7 (n=6748)
Ventouse	29.4 (n=144)	15.7 (n=1187)	34.2 (n=90)	20.0 (n=1712)
Forceps	5.5 (n=27)	1.8 (n=135)	1.1(n=3)	1.3(n=114)
Episiotomy, all vaginal deliveries	*P*=0.21		*P*=0.93	
	33.9 (n=166)	31.2 (n=2362)	36.5 (n=96)	36.2 (n=3107)
Episiotomy, spontaneous deliveries	*P*=0.07		*P*=0.40	
	20.4 (n=65)	24.9 (n=1555)	20.0 (n=34)	22.7 (n=1535)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	59.1 (n=101)	61.0 (n=807)	66.7 (n=62)	86.1 (n=1572)
Duration 2nd stage, min	*P*<0.001		*P*=0.07	
0-09	2.7 (n=13)	3.5 (n=268)	3.4 (n=9)	3.1 (n=264)
10-29	20.2 (n=99)	31.2 (n=2356)	28.1 (n=74)	29.4 (n=2517)
30-59	36.8 (n=180)	41.1 (n=3110)	35.4 (n=93)	41.8 (n=3580)
60-205	39.5 (n=193)	23.8 (n=1801)	33.1 (n=87)	25.7 (n=2201)
Missing data (n=4/n=27)	0.8 (n=4)	0.4 (n=27)	0 (n=0)	0.1 (n=12)
Epidural	*P*=0.14		*P*=0.90	
	46.6 (n=228)	43.2 (n=3266)	48.7 (n=128)	48.3 (n=4139)
Shoulder dystocia	*P*<0.001		*P*<0.001	
	2.5 (n=12)	0.8 (n=64)	3.4 (n=9)	0.6 (n=55)
Occiput posterior presentation	*P*=0.003		*P*<0.001	
	4.1 (n=20)	2.1 (n=156)	6.5 (n=17)	2.7 (n=228)
Induced labour	*P*=0.32		*P*=0.89	
	15.3 (n=75)	17.1 (n=1290)	19.0 (n=50)	18.7 (n=18.7)

In a multivariate regression analysis (Table 4), large infant birth weight, instrumental delivery, prolonged second stage and occiput posterior presentation were significant risk factors for OASIS in the first study period. In the second study period, when the incidence of OASIS was reduced, only instrumental delivery and fetal occiput posterior presentation remained significant risk factors for OASIS. The OASIS risk was markedly reduced from the first to the second time period and the first time period emerged as one of the most important OASIS "risk factors" in our study. OR for OASIS in the logistic regression analysis for the first study period as compared to the second was 2.10 (95% CI 1.76 to 2.40).

Table 4 Risk factors for OASIS in the multivariate regression model (adjusted odds ratio (aOR) and 95% confidence intervals).

	Primiparous women		**Multiparous women**	
Time period	**2003-05**	**2008-10**	**2003-05**	**2008-10**
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
n OASIS	489	263	102	53
Incidence OASIS	6.0 %	3.0%	1.5%	0.7%
Risk factors	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Age, years				
15-29	0.90 (0.72 to 1.08)	0.90 (0.67 to 1.15)	0.99 (0.60 to 1.64)	0.86 (0.40 to 1.90)
30-34	1	1	1	1
35-51	0.96 (0.71 to 1.28)	0.84 (0.58 to 1.22)	0.91 (0.57 to 1.44)	0.95 (0.52 to 1.75)
Birthweight, grams				
720-3499	0.70 (0.55 to 0.87)	0.80 (0.60 to 1.08)	0.46 (0.25 to 0.82)	0.93 (0.44 to 1.94)
3500-3999	1	1	1	1
4000-5850	1.50 (1.16 to 1.92)	1.26 (0.87 to 1.83)	2.81 (1.73 to 4.58)	1.19 (0.58 to 2.45)
Delivery method				
Spontaneous	1	1	1	1

Instrumental	2.10 (1.71 to 2.68)	2.46 (1.74 to 3.47)	2.19 (1.02 to 4.73)	1.72 (0.64 to 4.66)
Episiotomy				
No	1	1	1	1
Yes	0.72 (0.58 to 0.90)	0.52 (0.38 to 0.73)	0.92 (0.46 to 1.87)	1.57 (0.71 to 3.49)
Duration 2nd stage, min				
0-29	0.80 (0.62 to 1.02)	1.18 (0.87 to 1.60)	0.50 (0.31 to 0.82)	0.34 (0.18 to 0.64)
30-59	1	1	1	1
60-205	1.40 (1.15 to 1.79)	1.29 (0.95 to 1.75)	1.03 (0.41 to 2.58)	0.83 (0.28 to 2.48)
Epidural				
No	1	1	1	1
Yes	0.95 (0.78 to 1.15)	0.86 (0.67 to 1.12)	1.15 (0.69 to 1.93)	0.88 (0.44 to 1.76)
Shoulder dystocia				
No	1	1	1	1
Yes	1.58 (0.83 to 1.39)	3.73 (1.76 to 7.90)	1.58 (0.60 to 4.16)	2.25 (0.50 to 10.10)
Occiput posterior presentation				
No	1	1	1	1
Yes	1.72 (1.04 to 2.82)	2.40 (1.42 to 4.06)	0.24 (0.03 to 1.78)	1.95 (0.66 to 5.73)
Induced labour				
No	1	1	1	1
Yes	0.77 (0.60 to 1.00)	0.92 (0.66 to 1.27)	0.86 (0.46 to 1.60)	0.81 (0.37 to 1.77)

Frequency of episiotomy use in spontaneous deliveries of primiparous women was reduced from the first time period to the second, and increased in instrumental deliveries (Table 1). When adjusted for risk factors in the multivariate analysis, episiotomy appeared as a protective factor for OASIS in both time periods for primiparous women (Table 4).

Primiparous women with a previous caesarean section only, and no previous vaginal delivery (n=440), had an increased OASIS risk compared to women with no previous delivery OR=2.2 (95% CI 1.6 to 3.1), both in the first time period (11.5% and 5.9%, respectively, *P*=0.001) and in the second (6.7% and 2.9%, respectively, *P*=0.001). Also in this subgroup, the OASIS incidence was reduced with 50% after implementation of the perineal protection programme. When the various study analyses were performed without this small subgroup of vaginal primiparous women with one previous caesarean only, the study conclusions remained unaltered, as expected due to the small number of women in this subgroup.

Multiparous women

In a univariate analysis for multiparous women (Table 5), instrumental delivery, prolonged second stage of delivery, shoulder dystocia, large infant head circumference (data not shown) and birth weight were significant risk factors for OASIS in both time periods. The OASIS risk was markedly reduced from the first to the second time period and the time period for the delivery was one of the most important "risk factors"; OR for OASIS in the logistic regression analysis for the first time period as compared to the second was 2.31 (95% CI 1.65 to 3.25).

Table 5 Clinical characteristics and obstetric interventions among multiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Multiparous women	**2003-05**		**2008-10**	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
n deliveries	n=102	n=6634	n=53	n=8032
Incidence OASIS	1.5 (102/6634)		0.7 (53/8032)	
Risk factors	%		%	
Age, years	*P*=0.79		*P*=0.71	

15-29	24.5 (n=25)	27.5 (n=1824)	17.0 (n=9)	21.4 (n=1721)
30-34	44.1 (n=45)	41.9 (n=2778)	41.5 (n=22)	40.6 (n=3265)
35-51	31.4 (n=32)	30.6 (n=2032)	41.5 (n=22)	37.9 (n=3046)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	2.9 (n=3)	11.9 (n=791)	9.4 (n=5)	11.6 (n=933)
3000-3499	17.6 (n=18)	32.8 (n=2173)	18.9 (n=10)	32.1 (n=2581)
3500-3999	32.4 (n=33)	36.4 (n=2414)	35.8 (n=19)	37.5 (n=3010)
4000-4499	33.3 (n=34)	15.3 (n=1015)	17.0 (n=9)	15.4 (n=1238)
4500-5850	13.7 (n=14)	3.6 (n=241)	18.9 (n=10)	3.4 (n=270)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	89.2 (n=91)	96.3 (n=6388)	84.9 (n=45)	96.5 (n=7748)
Ventouse	7.8 (n=8)	3.4 (n=226)	15.1 (n=8)	3.3 (n=265)
Forceps	2.9 (n=3)	0.3 (n=20)	0 (n=0)	0.2 (n=19)
Episiotomy, all vaginal deliveries	*P*=0.33		*P*<0.001	
	9.8 (n=10)	7.3 (n=482)	22.6 (n=12)	8.0 (n=644)
Episiotomy, spontaneous deliveries	*P*=0.80		*P*=0.43	
	5.5 (n=5)	6.1 (n=391)	13.3 (n=6)	6.1 (n=471)
Episiotomy, instrumental	*P*=0.57		*P*=0.42	
deliveries	45.5 (n=5)	37.0 (n=91)	75 (n=6)	60.9 (n=173)
Duration 2nd stage, min	*P*<0.001		*P*<0.001	
0-09	19.6 (n=20)	34.9 (n=2315)	18.9 (n=10)	29.6 (n=2380)
10-29	49.0 (n=50)	49.9 (n=3311)	39.6 (n=21)	55.8 (n=4484)
30-59	23.5 (n=24)	12.3 (n=815)	30.2 (n=16)	11.7 (n=941)
60-205	6.9 (n=7)	2.5 (n=167)	9.4 (n=5)	2.7 (n=214)
Missing data (n=4/n=27)	1.0 (n=1)	0.4 (n=26)	1.9 (n=1)	0.2 (n=13)
Epidural	*P*=0.21		*P*=0.36	
	19.6 (n=20)	14.9 (n=988)	22.6 (n=12)	17.5 (n=1407)

Shoulder dystocia	*P*=0.001		*P*<0.001	
	4.9 (n=5)	1.2 (n=82)	5.7 (n=3)	0.9 (n=70)
Occiput posterior presentation	*P*=0.39		*P*=0.046	
	1.0 (n=1)	2.2 (n=149)	7.5 (n=4)	2.9 (n=233)
Induced labour	*P*=0.62		*P*=0.80	
	11.8 (n=12)	13.4 (n=891)	17.0 (n=9)	15.7 (n=1260)

In the multivariate regression analysis (Table 4), macrosomia and instrumental delivery significantly increased the OASIS risk for multiparous women in the first time period, but not in the second. In the second time period, none of the identified OASIS risk factors were significant for multiparous women. However, OASIS cases were few (n=53) in this subgroup of women. In the multivariate analysis the effect of episiotomy was non-significant in both time periods (Table 4). However, multiparous women with episiotomy were very few in this study and interpretation of the results should be undertaken cautiously (Table 2 and 5).

Discussion

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

Strength and weaknesses of the study

Strength of this hospital-based large observational study includes a very low risk of diagnostic misclassification of the OASIS outcome as all OASIS diagnoses were validated for study purposes. This is in contrast to studies based on registries that are not primarily created for

research, but are established for other purposes for the health care providers. In our study, the medical records of all patients registered with an OASIS were carefully reviewed by one senior consultant (KL). In addition, OASIS cases were collected from all available sources (delivery unit protocols and hospital discharge lists, including ICD-10 codes and any codes for OASIS repair) for the study years. Another strength is that the study was carried out at in a single large hospital focusing on improved quality of primary diagnosis and repair of OASIS, and this reduces the risk of variations in clinical diagnosis and repair of OASIS. Strength of the study is also the unselected population of delivering women and a large number of deliveries.

A weakness of our study is that the use of perineum support method, if used during second stage of delivery, was not registered in the medical records, and therefore, use of perineum support could not be assessed directly in our retrospective study. However, if this method was not used in some deliveries during the second time period or was used in some deliveries during the first time period, our study would tend to underestimate the OASIS incidence reducing effect of the perineum protection intervention program, and hence, our efficacy estimates on reduction of OASIS from the intervention are minimum estimates.

Meaning of the study

The observed reduction in OASIS came rapidly after the introduction of the perineal support programme and the low OASIS incidence has lasted over the last years. The changes in clinical characteristics of the study population were very modest between the two time periods, and cannot explain the rapid reduction in the OASIS incidence. Without the intervention programme, we could have expected an increase in the OASIS incidence in the second time period, as one of the most important OASIS risk factors, instrumental delivery, became more frequent in the study population (Table 1) over the study years. In our study the

reduction of OASIS was surprisingly consistent in all subgroups defined by OASIS risk factors (Table 2). The decrease in OASIS incidence was similar in spontaneous and operative deliveries and in both parity groups (primiparous and multiparous), again surprising, as primiparity is one of the most important risk factors for OASIS, as is operative delivery,[5, 10, 15]. Interestingly, as shown in Figure 1, the 2010 OASIS incidence in women delivered by ventouse delivery is of similar low magnitude as the OASIS incidence in the spontaneous deliveries was back in 2005 (3.6 and 3.8%, respectively).

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

Comparison with other studies

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

A randomized controlled trial (RCT) would be the optimal design for evaluating the OASIS reducing effect of manual perineum protection, but carrying out such an RCT is challenging during delivery, due to contamination of methods in different study arms and problems with blinding of patients or staff. Previous RCTs have not shown a beneficial effect on OASIS by hands-on perineal protection, but the published RCTs have not described a structured training of the staff, such as the intervention programme of our study,[22]. These trials had problems with bias caused by contamination of compared methods and different use of medial episiotomy in the study arms,[23, 24], were under-powered to explore OASIS, or were not designed to assess OASIS, but perineal pain or perineal injury in general (including 1st and 2nd degree tears and episiotomy),[23-25]. The marked 50% reduction in the OASIS incidence obtained in our delivery unit appeared simultaneously with the introduction of a manual perineal protection during second stage of labour. Thus, as the main difference for our study population between the two time periods was a perineum protection training programme, we conclude that it is most likely that such a perineal protection programme has a beneficial effect in reducing the OASIS incidence, both for primiparous and multiparous women, despite the lack of an RCT supporting this conclusion. Previous studies describe OASIS risk factors following an increased incidence of this obstetrical complication,[1, 5, 10, 11, 15], and we are not aware of any other study exploring the reduced OASIS incidence by different risk factor groups.

Use of episiotomy was registered in our study, but type of episiotomy was not registered, and improvement of performed episiotomy technique in order to avoid median cuts was a part of the training package at our delivery unit. Medial and close to medial episiotomies have a higher risk for OASIS,[21]. Large register studies show that mediolateral and lateral episiotomies have a protecting effect against OASIS, particularly among primiparous women and in instrumental deliveries,[9, 10, 26-28]. During the study period, the

use of episiotomy in our hospital decreased slightly in spontaneous deliveries in primiparous women (from 24.7 to 22.7%), but increased in instrumental deliveries in primiparous women (from 60.8 to 85.1%) (Table 1), and was shown to be a protective factor against OASIS for primiparous women in both time periods (Table 4). Since episiotomy was used only when indicated, we assume that our staff managed to select the truly high risk patients in need for episiotomy to reduce the risk of OASIS. Differences in effect of episiotomy between different parity groups on OASIS occurrence can be explained by indication bias, a mix between cause and effect, as episiotomy is used in deliveries with high OASIS risk. Multiparous women needing episiotomy may represent a group of women with difficult delivery with many risk factors.

Research and policy implications

We expected a more notable reduction of the OASIS incidences in the subgroups with lower risk (low or normal infant birth weight), as compared to women with higher risk (large infant), if the perineal support program had been followed consistently in all deliveries. We believe that a non-consistent use of perineum support in deliveries with lower risk for OASIS could account for the results; the main clinical focus was on women with high risk for OASIS, based on publications focusing on such risk factors. It is well known that clinicians' working methods can be difficult to change,[29-31] and there was a low enthusiasm for a routinely performed perineal support (used in all deliveries, regardless of risk group) among the midwifery staff when the training program was introduced. Despite the promising 50% reduction of OASIS incidence over the last years, the hospital currently aims at further reducing the OASIS incidence. We have registered improved compliance to the perineum support programme among the staff over the last years, probably due to the promising OASIS results after implementation of the perineum support programme. The training programme for

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

Conclusions

Our observational study shows a large and rapid reduction in OASIS incidence following an introduction of a perineum support programme, across all risk groups of OASIS. We suggest that future OASIS research should focus more on variables connected to delivery procedures, including perineal protection procedures during delivery, and not restricting risk analyses to demographic and individual obstetric data of the delivering woman or the infant. Using manual perineal protection is a low-cost intervention with no identified side effects and requires no extra resources or equipment, except for training of the existing personnel. Attempts to create methods to predict OASIS on individual level have not been successful,[32-34] and we suggest that obstetrical interventions aiming at reducing the incidence of OASIS should be offered to all delivering women, not only to women in high risk groups.

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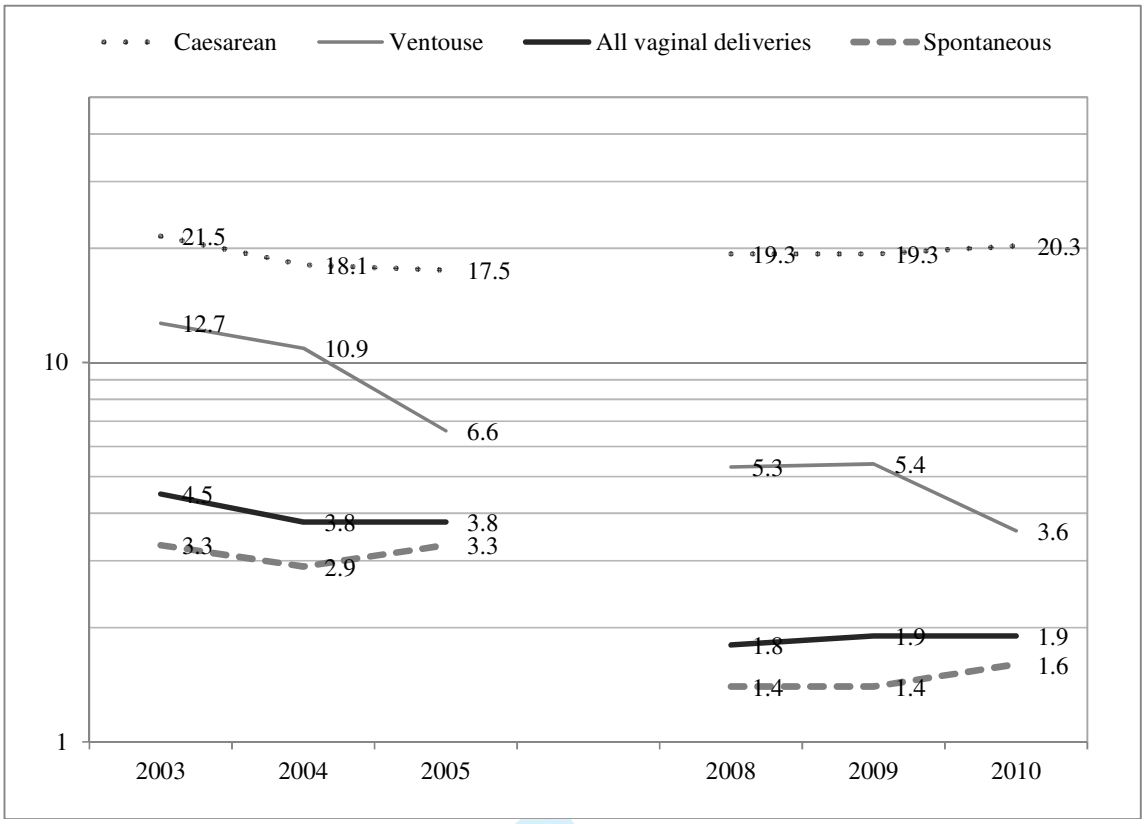

Figure 1. Frequency of OASIS (%) for different delivery methods during the study years. Frequencies of caesareans are also indicated.

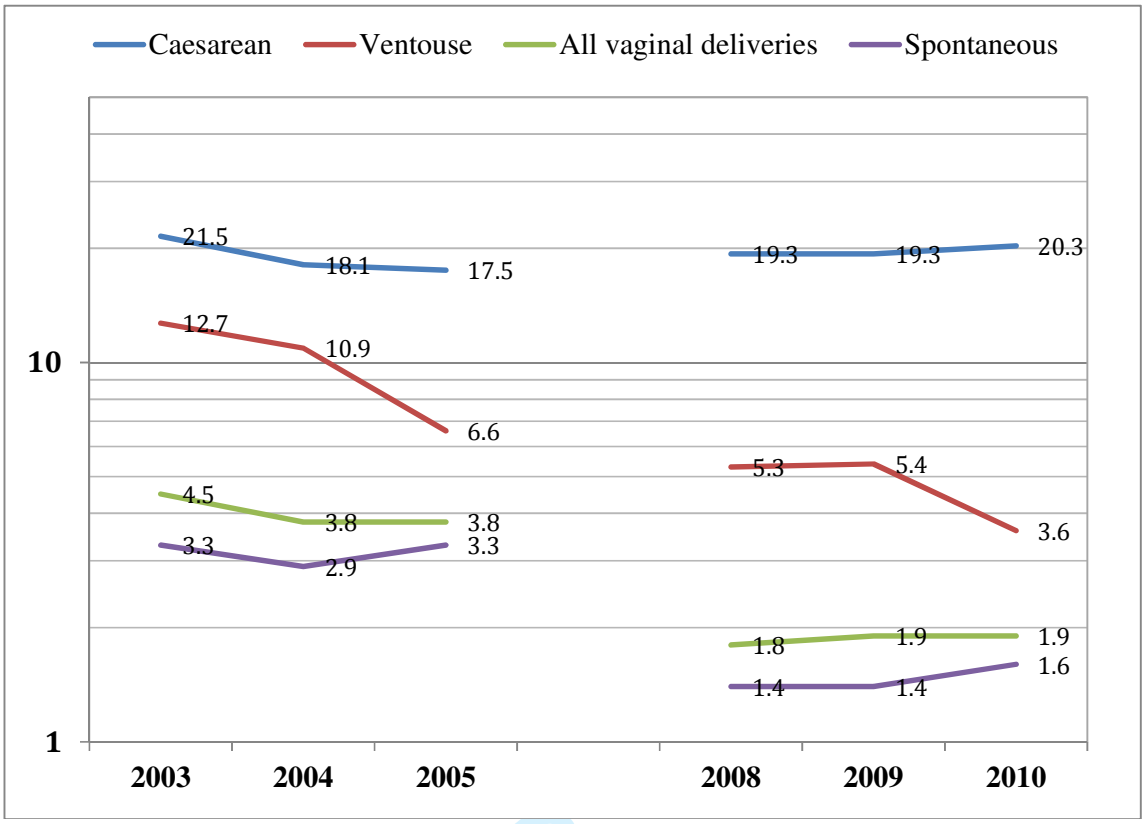

Figure 1 Frequency of OASIS (%) for different delivery methods during the study years. Frequencies of caesareans are also indicated.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1 ok	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2 ok	Explain the scientific background and rationale for the investigation being reported
Objectives	3 ok	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4 ok	Present key elements of study design early in the paper
Setting	5 ok	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6 ok	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7 ok	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*ok	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9 ok	Describe any efforts to address potential sources of bias
Study size	10 ok	Explain how the study size was arrived at
Quantitative variables	11 ok	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12 ok	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*ok	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*ok	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*ok	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16ok	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17ok	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18ok	Summarise key results with reference to study objectives
Limitations	19 ok	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20 ok	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21 ok	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22 ok	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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

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Primary Subject Heading:	Reproductive medicine, obstetrics and gynaecology
Secondary Subject Heading:	Reproductive medicine, obstetrics and gynaecology
Keywords:	Maternal medicine < OBSTETRICS, Urogynaecology < GYNAECOLOGY, EDUCATION & TRAINING (see Medical Education & Training), MEDICAL EDUCATION & TRAINING, obstetric anal sphincter injury, delivery

Abstract

Objective To compare the incidence of obstetric anal sphincter injuries (OASIS) in two time periods, before and after implementing a training programme for improved perineal support aimed at reducing the incidence of obstetric anal sphincter injuries. The secondary aim was to study incidence of obstetric anal sphincter injuries in subgroups defined by risk factors for OASIS.
Design Population based cohort study.
Setting University hospital setting in Oslo, Norway.
Participants Two cohorts of all delivering women in the largest hospital in Norway during two time periods (2003-2005 and 2008-2010) were studied. After excluding caesarean sections and preterm deliveries (< week 32), the study population consisted of 31 709 deliveries, among which 907 women were identified with obstetric anal sphincter injury.
Primary and secondary outcome measures Incidence of OASIS in two time periods. Maternal, obstetrical and fetal risk factors for OASIS was collected from the hospital obstetric database. Univariate analyses and multivariate logistic regression analyses, presenting adjusted odds ratios for OASIS, were performed.
Results The OASIS incidence was significantly reduced by 50%, from 4.0% (591/14787) in the first time period to 1.9% (316/16922) in the second. This reduction could not be explained by changes in population characteristics or OASIS risk factors during the study years. The reduction of incidence of OASIS between the two study periods was consistent across subgroups of women; regardless of parity, delivery method and infant birth weight.
Conclusion A marked reduction in the incidence of OASIS was observed in all studied subgroups of women after implementing the training programme for perineal protection. Further, this reduction could not be explained by the differences in patient characteristics across the study period. These findings indicate that the training programme with improved perineal protection markedly reduced the risk of OASIS.

Introduction

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

Risk factors for OASIS have been widely studied, with several hundred studies presently available in PubMed, assessing maternal, obstetric and fetal risk factors. Numerous factors have been investigated and focus has often been on factors that are not modifiable, such as maternal age, height, weight, ethnicity, fetal weight and head size. Most previous studies conclude that primiparity, large infant birth weight and instrumental delivery increase

the risk of OASIS, but when exploring factors such as maternal age (young or advanced), ethnicity, epidural use and episiotomy, the results are conflicting ,[9-14]. Risk factors unrelated to the delivering woman or the infant size, such as the accoucheurs' management of the second stage of delivery, have been less investigated.

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

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

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

Methods

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

Databases and participants

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

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

Definition and diagnostics of OASIS

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

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

Risk factors for OASIS

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

The intervention programme

The need to reduce the incidence of OASIS was discussed among delivery personnel in clinical meetings from 2006. An intervention programme was implemented from 2008, including both midwives and physicians at the Department of Obstetrics and Gynaecology. An external midwife was hired in from another hospital (where a similar programme was previously successfully implemented) to educate a group of trainer-midwives, who then further educated the entire midwife-staff. Physicians (both registrars and specialists) were educated in the perineal supporting technique and supervised by the first author (KL). First part of the training included a practical hands-on training on a pelvic delivery model and the second part included hands-on supervision in labour room during the second stage of delivery.

The perineum protection programme consisted of four components during the last part of second stage of delivery, when the baby's head is crowning: slowing the delivery of the baby's head with one hand, supporting perineum with the other hand and squeezing with fingers (first and second) from the perineum lateral parts towards the middle in order to lower the pressure in middle posterior perineum, and asking the delivering woman not to push. The fourth part of the intervention was education in correct performing of episiotomy. At our department, episiotomy is performed only when indicated, for example due to fetal distress or imminent severe perineal tear. The main focus of this intervention step was to avoid median cuts of episiotomy technique, when performed, due to the augmented risk of OASIS associated with median episiotomies,[20].

Comparison of groups

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

Table 1 Clinical characteristics and obstetric interventions for the whole study population. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women		**Multiparous women**	
Time period	**2003-05**	**2008-10**	**2003-05**	**2008-10**
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
Risk factors				
Age, years	*P*<0.001		*P*<0.001	
15-29	48.3 (n=3885)	43.8 (n=3872)	27.4 (n=1849)	21.4 (n=1730)
30-34	39.3 (n=3164)	40.8 (n=3604)	42 (n=2823)	40.7 (n=3287)
35-51	12.4 (n=1002)	15.4 (n=1361)	30.6 (n=2064)	37.9 (n=3068)

Birthweight, grams	*P*=0.003		*P*=0.60	
720-2999	16.4 (n=1321)	16.4 (n=1446)	11.8 (n=794)	11.6 (n=938)
3000-3499	37.9 (n=3050)	39.2 (n=3470)	32.5 (n=2191)	32.0 (n=2591)
3500-3999	33.2 (n=2670)	33.8 (n=2983)	36.3 (n=2447)	37.5 (n=3029)
4000-4499	11.0 (n=885)	9.3 (n=821)	15.6 (n=1049)	15.4 (n=1247)
4500-5850	1.5 (n=125)	1.3 (n=117)	3.8 (n=255)	3.5 (n=280)
Delivery method	*P*<0.001		*P*=0.45	
Spontaneous	81.5 (n=6558)	78.3 (n=6918)	96.2 (n=6479)	96.4 (n=7793)
Ventouse	16.5 (n=1331)	20.4 (n=1802)	3.5 (n=234)	3.4 (n=273)
Forceps	2.0 (n=162)	1.3 (n=117)	0.3 (n=23)	0.2 (n=19)
Episiotomy, all vaginal	*P*<0.001		*P*=0.066	
deliveries	31.4 (n=2528)	36.2 (n=3203)	7.3 (n=492)	8.1 (n=656)
Episiotomy, spontaneous	*P*=0.006		*P*=0.98	
deliveries	24.7 (n=1620)	22.7 (n=1569)	6.1 (n=396)	6.1 (n=477)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	60.8 (n=908)	85.1 (n=1634)	37.4 (n=96)	61.3 (n=179)
Duration 2nd stage, min	*P*=0.057		*P*=0.45	
0-29	34.1 (n=2736)	32.5 (n=2864)	84.9 (n=5696)	85.4 (n=6895)
30-59	41.0 (n=3290)	41.6 (n=3673)	12.5 (n=839)	11.9 (n=957)
60-205	24.9 (n=1994)	25.9 (n=2288)	2.6 (n=174)	2.7 (n=219)

Statistical analysis

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

The risk factors for OASIS were calculated and presented separately for the two cohorts. Continuous data were categorised and the independent variables are presented as frequencies. Univariate analysis was performed to explore the significant risk factors. Variables with $P \leq 0.10$ were included in the multivariate analysis. Univariate analyses were performed by Chi-square test. A significance level of 5% was chosen in all analyses. Adjusted odds ratios (aORs) for OASIS with 95% CI are reported from multivariate logistic regression analyses. The data were analyzed by using PASW (Predictive Analytics SoftWare, SPSS Inc., version 19.0, Chicago, IL).

Results

Overall incidence of anal sphincter injury in vaginal deliveries was significantly reduced by 50%, from 4.0% (591/14787) in the first time period (2003-5) to 1.9% (316/16922) in the second time period (2008-10). The reduction of the incidence of OASIS was of similar magnitude across all studied subgroups defined by risk factors, for both primi- and multiparous women (Table 2).

Table 2 Incidence of OASIS in different subgroups of women. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women			**Multiparous women**		
Time period	**2003-05**	**2008-10**		**2003-05**	**2008-10**	
OASIS	6.1 (489/8051)	3.0 (263/8837)		1.5 (102/6736)	0.7 (53/8085)	
Risk factors						
Age, years			*P*			*P*
15-29	5.5 (212/3885)	2.8 (107/3872)	<0.001	1.4 (25/1849)	0.5 (9/1730)	0.01
30-34	6.7 (212/3164)	3.3 (118/3604)	<0.001	1.6 (45/2823)	0.7 (22/3287)	0.001
35-51	6.5 (65/1002)	2.8 (38/1361)	<0.001	1.6 (32/2064)	0.7 (22/3068)	0.004

Birthweight, grams						
720-2999	3.0 (39/1321)	1.6 (23/1446))	0.016	0.4 (3/794)	0.5 (5/938)	0.63
3000-3499	4.4 (135/3050)	2.6 (90/3470)	<0.001	0.8 (18/2191)	0.4 (10/2591)	0.049
3500-3999	7.2 (192/2670)	3.4 (101/2983)	<0.001	1.3 (33/2447)	0.6 (19/3029)	0.006
4000-4499	11.2 (99/885)	4.8 (39/821)	<0.001	3.2 (34/1049)	0.7 (9/1247)	<0.001
4500-5850	19.2 (24/125)	8.5 (10/117)	0.017	5.5 (14/255)	3.6 (10/280)	0.28
Delivery method						
Spontaneous	4.8 (318/6558)	2.5 (170/6918)	<0.001	1.4 (91/6479)	0.6 (45/7793)	<0.001
Ventouse	10.8 (144/1331)	5.0 (90/1802)	<0.001	3.4 (8/234)	2.9 (8/273)	0.75
Forceps	16.7 (27/162)	2.6 (3/117)	<0.001	13.0 (3/23)	0 (0/19)	0.10
Episiotomy, all deliveries						
Yes	6.6 (166/2528)	3.0 (96/3203)	<0.001	2.0 (10/492)	1.8 (12/656)	0.80
No	5.8 (323/5523)	3.0 (167/5634)	<0.001	1.5 (92/6244)	0.6 (41/7429)	<0.001
Episiotomy, spontaneous deliveries						
Yes	4.0 (65/1620)	2.2 (34/1569)	<0.003	1.3 (5/396)	1.3 (6/477)	1.00
No	5.1 (253/4938)	2.5 (136/5349)	<0.001	1.4 (86/6083)	0.5 (39/7316)	<0.001
Episiotomy, instrumental deliveries						
Yes	11.1 (101/908)	3.8 (62/1634)	<0.001	5.2 (5/96)	3.4 (6/179)	0.45
No	12.0 (70/585)	10.9 (31/285)	0.64	3.7 (6/161)	1.8 (2/113)	0.34
Duration 2nd stage, min						
0-09	4.6 (13/281)	3.3 (9/273)	0.42	0.9 (20/2335)	0.4 (10/2390)	0.058
10-29	4.0 (99/2455)	2.9 (74/2591)	0.02	1.5 (50/3361)	0.5 (21/4505)	<0.001
30-59	5.5 (180/3290)	2.5 (93/3673)	<0.001	2.9 (24/839)	1.7 (16/957)	0.09
60-205	9.7 (193/1994)	3.8 (87/2288)	<0.001	4.0 (7/174)	2.3 (5/219)	0.32
Epidural						

Yes	6.5 (228/3494)	3.0 (128/4267)	<0.001	2.0 (20/1008)	0.8 (12/1419)	0.015
No	5.7 (261/4557)	3.0 (135/4570)	<0.001	1.4 (82/5728)	0.6 (41/6666)	<0.001
Shoulder dystocia						
Yes	15.8 (12/76))	14.1 (9/64)	0.78	5.7 (5/87)	4.1 (3/73)	0.64
No	6.0 (477/7975)	2.9 (254/8773)	<0.001	1.5 (97/6649)	0.6 (50/8012)	<0.001
Occiput posterior presentation						
Yes	11.4 (20/176)	6.9 (17/245)	0.11	0.7 (1/150)	1.7 (4/237)	0.39
No	6.0 (469/7875)	2.9 (246/8592)	<0.001	1.5 (101/6586)	0.6 (49/7848)	<0.001
Induced labour						
Yes	5.5 (75/1365)	3.0 (50/1650)	0.001	1.3 (12/903)	0.7 (9/1269)	0.18
No	6.2 (414/6686)	3.0 (213/7187)	<0.001	1.5 (90/5833)	0.6 (44/6816)	<0.001

The incidence of OASIS over the study years is displayed in Figure 1, demonstrating a reduced incidence of OASIS, which in time follows the implementation of the perineum support program for the staff. Figure 1 also demonstrates a similar reduction of OASIS incidence for the different delivery methods (operative and spontaneous vaginal delivery) between the two study periods: in spontaneous deliveries the OASIS incidence was reduced from 3.1% (409/13037) to 1.5% (215/14711) and in ventouse from 9.7% (152/1565) to 4.7% (98/2075). Forceps is less used in our department, but a significant OASIS reduction was also observed in forceps deliveries from 16.2% (30/185) to 2.2% (3/136).

Population characteristics across the study years

Overall changes in population characteristics between the two time periods were small, but the prevalence of older women (>35 years) was significantly higher in the second period (2008-10), and use of ventouse delivery, episiotomy, epidural and induction of labour was

more frequent (Table 1). Primiparous women comprised 85% of the women with OASIS, but represented only 53.3 % of the overall study population.

Primiparous women

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

Table 3 Clinical characteristics and obstetric interventions among primiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Primiparous women	**2003-05**		**2008-10**	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
n deliveries	n=489	n=7562	n=263	n=8574
Incidence OASIS	6.1 (489/7562)		3.0 (263/8574)	
Risk factors	%		%	
Age, years	*P*=0.08		*P*=0.39	
15-29	43.4 (n=212)	48.6 (n=3673)	40.7 (n=107)	43.9 (n=3765)
30-34	43.4 (n=212)	39 (n=2952)	44.9 (n=118)	40.7 (n=3486)
35-51	13.3 (n=65)	12.4 (n=937)	14.4 (n=38)	15.4 (n=1323)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	8.0 (n=39)	17.0 (n=1282)	8.7 (n=23)	16.6 (n=1423)
3000-3499	27.6 (n=135)	38.5 (n=2915)	34.2 (n=90)	39.4 (n=3380)
3500-3999	39.3 (n=192)	32.8 (n=2478)	38.4 (n=101)	33.6 (n=2882)
4000-4499	20.2 (n=99)	10.4 (n=786)	14.8 (n=39)	9.1 (n=782)

4500-5850	4.9 (n=24)	1.3 (n=101)	3.8 (n=10)	1.2 (n=107)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	65.0 (n=318)	82.5 (n=6240)	64.6 (n=170)	78.7 (n=6748)
Ventouse	29.4 (n=144)	15.7 (n=1187)	34.2 (n=90)	20.0 (n=1712)
Forceps	5.5 (n=27)	1.8 (n=135)	1.1(n=3)	1.3(n=114)
Episiotomy, all vaginal deliveries	*P*=0.21		*P*=0.93	
	33.9 (n=166)	31.2 (n=2362)	36.5 (n=96)	36.2 (n=3107)
Episiotomy, spontaneous deliveries	*P*=0.07		*P*=0.40	
	20.4 (n=65)	24.9 (n=1555)	20.0 (n=34)	22.7 (n=1535)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	59.1 (n=101)	61.0 (n=807)	66.7 (n=62)	86.1 (n=1572)
Duration 2nd stage, min	*P*<0.001		*P*=0.07	
0-09	2.7 (n=13)	3.5 (n=268)	3.4 (n=9)	3.1 (n=264)
10-29	20.2 (n=99)	31.2 (n=2356)	28.1 (n=74)	29.4 (n=2517)
30-59	36.8 (n=180)	41.1 (n=3110)	35.4 (n=93)	41.8 (n=3580)
60-205	39.5 (n=193)	23.8 (n=1801)	33.1 (n=87)	25.7 (n=2201)
Missing data (n=4/n=27)	0.8 (n=4)	0.4 (n=27)	0 (n=0)	0.1 (n=12)
Epidural	*P*=0.14		*P*=0.90	
	46.6 (n=228)	43.2 (n=3266)	48.7 (n=128)	48.3 (n=4139)
Shoulder dystocia	*P*<0.001		*P*<0.001	
	2.5 (n=12)	0.8 (n=64)	3.4 (n=9)	0.6 (n=55)
Occiput posterior presentation	*P*=0.003		*P*<0.001	
	4.1 (n=20)	2.1 (n=156)	6.5 (n=17)	2.7 (n=228)
Induced labour	*P*=0.32		*P*=0.89	
	15.3 (n=75)	17.1 (n=1290)	19.0 (n=50)	18.7 (n=18.7)

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

In a multivariate regression analysis (Table 4), large infant birth weight, instrumental delivery, prolonged second stage and occiput posterior presentation were significant risk factors for OASIS in the first study period. In the second study period, when the incidence of OASIS was reduced, only instrumental delivery and fetal occiput posterior presentation remained significant risk factors for OASIS.

Table 4 Risk factors for OASIS in the multivariate regression model (adjusted odds ratio (aOR) and 95% confidence intervals).

	Primiparous women		**Multiparous women**	
Time period	**2003-05**	**2008-10**	**2003-05**	**2008-10**
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
n OASIS	489	263	102	53
Incidence OASIS	6.0 %	3.0%	1.5%	0.7%
Risk factors	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Age, years				
15-29	0.90 (0.72 to 1.08)	0.90 (0.67 to 1.15)	0.99 (0.60 to 1.64)	0.86 (0.40 to 1.90)
30-34	1	1	1	1
35-51	0.96 (0.71 to 1.28)	0.84 (0.58 to 1.22)	0.91 (0.57 to 1.44)	0.95 (0.52 to 1.75)
Birthweight, grams				

720-3499	0.70 (0.55 to 0.87)	0.80 (0.60 to 1.08)	0.46 (0.25 to 0.82)	0.93 (0.44 to 1.94)
3500-3999	1	1	1	1
4000-5850	1.50 (1.16 to 1.92)	1.26 (0.87 to 1.83)	2.81 (1.73 to 4.58)	1.19 (0.58 to 2.45)
Delivery method				
Spontaneous	1	1	1	1
Instrumental	2.10 (1.71 to 2.68)	2.46 (1.74 to 3.47)	2.19 (1.02 to 4.73)	1.72 (0.64 to 4.66)
Episiotomy				
No	1	1	1	1
Yes	0.72 (0.58 to 0.90)	0.52 (0.38 to 0.73)	0.92 (0.46 to 1.87)	1.57 (0.71 to 3.49)
Duration 2nd stage, min				
0-29	0.80 (0.62 to 1.02)	1.18 (0.87 to 1.60)	0.50 (0.31 to 0.82)	0.34 (0.18 to 0.64)
30-59	1	1	1	1
60-205	1.40 (1.15 to 1.79)	1.29 (0.95 to 1.75)	1.03 (0.41 to 2.58)	0.83 (0.28 to 2.48)
Epidural				
No	1	1	1	1
Yes	0.95 (0.78 to 1.15)	0.86 (0.67 to 1.12)	1.15 (0.69 to 1.93)	0.88 (0.44 to 1.76)
Shoulder dystocia				
No	1	1	1	1
Yes	1.58 (0.83 to 1.39)	3.73 (1.76 to 7.90)	1.58 (0.60 to 4.16)	2.25 (0.50 to 10.10)
Occiput posterior presentation				
No	1	1	1	1
Yes	1.72 (1.04 to 2.82)	2.40 (1.42 to 4.06)	0.24 (0.03 to 1.78)	1.95 (0.66 to 5.73)
Induced labour				
No	1	1	1	1
Yes	0.77 (0.60 to 1.00)	0.92 (0.66 to 1.27)	0.86 (0.46 to 1.60)	0.81 (0.37 to 1.77)

Frequency of episiotomy use in spontaneous deliveries of primiparous women was reduced from the first time period to the second, and increased in instrumental deliveries (Table 1). When adjusted for risk factors in the multivariate analysis, episiotomy appeared as a protective factor for OASIS in both time periods for primiparous women (Table 4).

Primiparous women with a previous caesarean section only, and no previous vaginal delivery (n=440), had an increased OASIS risk compared to women with no previous delivery OR=2.2 (95% CI 1.6 to 3.1), both in the first time period (11.5% and 5.9%, respectively, *P*=0.001) and in the second (6.7% and 2.9%, respectively, *P*=0.001). Also in this subgroup, the OASIS incidence was reduced with 50% after implementation of the perineal protection programme. When the various study analyses were performed without this small subgroup of vaginal primiparous women with one previous caesarean only, the study conclusions remained unaltered, as expected due to the small number of women in this subgroup.

Multiparous women

In a univariate analysis for multiparous women (Table 5), instrumental delivery, prolonged second stage of delivery, shoulder dystocia, large infant head circumference (data not shown) and birth weight were significant risk factors for OASIS in both time periods. The risk of OASIS was markedly reduced from the first to the second time period and the time period for the delivery was one of the most important "risk factors"; OR for OASIS in the logistic regression analysis for the first time period as compared to the second was 2.31 (95% CI 1.65 to 3.25).

Table 5 Clinical characteristics and obstetric interventions among multiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Multiparous women	**2003-05**	**2008-10**

	OASIS	Non-OASIS	OASIS	Non-OASIS
n deliveries	n=102	n=6634	n=53	n=8032
Incidence OASIS	1.5 (102/6634)		0.7 (53/8032)	
Risk factors	%		%	
Age, years	*P*=0.79		*P*=0.71	
15-29	24.5 (n=25)	27.5 (n=1824)	17.0 (n=9)	21.4 (n=1721)
30-34	44.1 (n=45)	41.9 (n=2778)	41.5 (n=22)	40.6 (n=3265)
35-51	31.4 (n=32)	30.6 (n=2032)	41.5 (n=22)	37.9 (n=3046)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	2.9 (n=3)	11.9 (n=791)	9.4 (n=5)	11.6 (n=933)
3000-3499	17.6 (n=18)	32.8 (n=2173)	18.9 (n=10)	32.1 (n=2581)
3500-3999	32.4 (n=33)	36.4 (n=2414)	35.8 (n=19)	37.5 (n=3010)
4000-4499	33.3 (n=34)	15.3 (n=1015)	17.0 (n=9)	15.4 (n=1238)
4500-5850	13.7 (n=14)	3.6 (n=241)	18.9 (n=10)	3.4 (n=270)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	89.2 (n=91)	96.3 (n=6388)	84.9 (n=45)	96.5 (n=7748)
Ventouse	7.8 (n=8)	3.4 (n=226)	15.1 (n=8)	3.3 (n=265)
Forceps	2.9 (n=3)	0.3 (n=20)	0 (n=0)	0.2 (n=19)
Episiotomy, all vaginal deliveries	*P*=0.33		*P*<0.001	
	9.8 (n=10)	7.3 (n=482)	22.6 (n=12)	8.0 (n=644)
Episiotomy, spontaneous deliveries	*P*=0.80		*P*=0.43	
	5.5 (n=5)	6.1 (n=391)	13.3 (n=6)	6.1 (n=471)
Episiotomy, instrumental	*P*=0.57		*P*=0.42	
deliveries	45.5 (n=5)	37.0 (n=91)	75 (n=6)	60.9 (n=173)
Duration 2nd stage, min	*P*<0.001		*P*<0.001	
0-09	19.6 (n=20)	34.9 (n=2315)	18.9 (n=10)	29.6 (n=2380)
10-29	49.0 (n=50)	49.9 (n=3311)	39.6 (n=21)	55.8 (n=4484)

30-59	23.5 (n=24)	12.3 (n=815)	30.2 (n=16)	11.7 (n=941)
60-205	6.9 (n=7)	2.5 (n=167)	9.4 (n=5)	2.7 (n=214)
Missing data (n=4/n=27)	1.0 (n=1)	0.4 (n=26)	1.9 (n=1)	0.2 (n=13)
Epidural	*P*=0.21		*P*=0.36	
	19.6 (n=20)	14.9 (n=988)	22.6 (n=12)	17.5 (n=1407)
Shoulder dystocia	*P*=0.001		*P*<0.001	
	4.9 (n=5)	1.2 (n=82)	5.7 (n=3)	0.9 (n=70)
Occiput posterior presentation	*P*=0.39		*P*=0.046	
	1.0 (n=1)	2.2 (n=149)	7.5 (n=4)	2.9 (n=233)
Induced labour	*P*=0.62		*P*=0.80	
	11.8 (n=12)	13.4 (n=891)	17.0 (n=9)	15.7 (n=1260)

In the multivariate regression analysis (Table 4), macrosomia and instrumental delivery significantly increased the OASIS risk for multiparous women in the first time period, but not in the second. In the second time period, none of the identified risk factors for OASIS were significant for multiparous women. However, OASIS cases were few (n=53) in this subgroup of women. In the multivariate analysis the effect of episiotomy was non-significant in both time periods (Table 4). However, multiparous women with episiotomy were very few in this study and interpretation of the results should be undertaken cautiously (Table 2 and 5).

Discussion

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

Similar reduction in OASIS following alteration in clinical routines and intervention programmes during the second stage of delivery have been presented previously, both in Norway,[17, 18] and in the US ,[21], but we are not aware of other publications exploring the reduced incidence of OASIS in different subgroups defined by risk factors.

Strengths and limitations of the study

Strengths of this hospital-based large observational study includes a very low risk of diagnostic misclassification of the OASIS outcome as all OASIS diagnoses were validated for study purposes in addition to primarily being diagnosed by at least two accoucheurs, and always by an obstetrician or gynecologist. This is in contrast to studies based on registries that are not primarily created for research, but are established for other purposes for the health care providers. In our study, the medical records of all patients registered with an OASIS were carefully reviewed by one senior consultant (KL). In addition, diagnosis of OASIS cases were cross-checked between several available sources (individual patient records, delivery unit protocols and hospital discharge lists, including ICD-10 diagnose codes and surgical codes for OASIS repair) for the study years. Another strength is that the study was carried out at in a single large hospital focusing on improved quality of primary diagnosis and repair of OASIS, and this also reduces the risk of misclassification in registration. Strength of the study is also the unselected population of delivering women and a large number of deliveries.

A randomized controlled trial (RCT) would be the optimal design for evaluating a OASIS reducing effect of manual perineum protection, but carrying out such an RCT is challenging during delivery, due to contamination of methods in different study arms and problems with blinding of patients or staff. We did not conduct an RCT because in Norway, several hospitals already had managed to reduce the incidence of OASIS with implementation of improved manual perineal protection, and we consider randomizing women to hands-off

delivering techniques as unethical in the light of these recent historical clinical results. Previous RCTs have not shown a beneficial effect on OASIS by hands-on perineal protection, but the published RCTs have not described a structured training of the staff, such as the intervention programme of our study,[22]. These trials had problems with bias caused by contamination of compared methods and different use of medial episiotomy in the study arms,[23, 24], were under-powered to explore OASIS, or were not designed to assess OASIS, but perineal pain or perineal injury in general (including 1st and 2nd degree tears and episiotomy),[23-25]. The marked 50% reduction in the OASIS incidence obtained in our delivery unit appeared simultaneously with the introduction of a manual perineal protection during second stage of labour. The main difference for our study population between the two time periods was the perineum protection training programme, the patient characteristics remained almost unaltered between the time periods and could not explain the reduction of incidence of OASIS. Thus, our study indicates that such a perineal protection programme has a beneficial effect in reducing the incidence of OASIS, both for primiparous and multiparous women, despite the lack of an RCT supporting this conclusion.

A weakness of our study is that the use of perineum support method, if used during second stage of delivery, was not registered in the medical records, and therefore, use of perineum support could not be assessed directly in our retrospective study. However, if this method was not used in some deliveries during the second time period or was used in some deliveries during the first time period, our study would tend to underestimate the OASIS incidence reducing effect of the perineum protection intervention program, and hence, our efficacy estimates on reduction of OASIS from the intervention are minimum estimates.

Meaning of the study

The observed reduction of incidence of OASIS came rapidly after the introduction of the perineal protection programme and the low incidence of OASIS has lasted over the last years. The changes in clinical characteristics of the study population were very modest between the two time periods, and cannot explain the rapid reduction of the incidence of OASIS. Without the intervention programme, we could have expected an increase of the incidence of OASIS in the second time period, as one of the most important OASIS risk factors, instrumental delivery, became more frequent in the study population (Table 1) over the study years. In our study the reduction of incidence of OASIS was surprisingly consistent in all subgroups defined by OASIS risk factors (Table 2). The decrease of the incidence of OASIS was similar in spontaneous and operative deliveries and in parity groups (primiparous and multiparous), again surprising, as primiparity is one of the most important risk factors for OASIS, as is operative delivery,[5, 10, 15]. Interestingly, as shown in Figure 1, the 2010 incidence of OASIS in women delivered by ventouse delivery is of similar magnitude as the incidence of OASIS in the spontaneous deliveries was back in 2005 (3.6 and 3.8%, respectively).

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

Comparison with other studies

Traditionally, there has been a focus on OASIS risk factors with high OR. However, such risk factors may not necessarily represent the most frequent events in a delivery unit. Shoulder dystocia and occiput posterior presentation are examples of risk factors with high OR and a very low incidence,[5, 15]. In numbers, most of the OASIS occurs during deliveries with low

risk; during spontaneous deliveries with an infant of normal size. In our study, the number of women with OASIS illustrates the major groups of women that will suffer this obstetric complication; of the 752 primiparous women with OASIS in our study, 488 delivered spontaneously, only 21 after shoulder dystocia, 39 from an infant in occiput posterior presentation. In total 77% (580/752) of the primiparous women with OASIS delivered an infant that was not macrosomic (>4000g). Actually, 38% of the women with OASIS delivered an infant smaller than the mean infant birth weight (3500 g) in our study population.

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

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

Research and policy implications

We expected a more notable reduction of the incidences of OASIS in the subgroups with lower risk (low or normal infant birth weight), as compared to women with higher risk (large

infant), if the perineal support program had been followed consistently in all deliveries. We believe that a non-consistent use of perineum support in deliveries with lower risk for OASIS could account for the results; the main clinical focus was on women with high risk for OASIS, based on publications focusing on such risk factors. Previous studies have shown that antenatal scoring systems based on patient risk factors could not predict OASIS [29-31], therefore methods that reduce risk for OASIS should be offered to all delivering women, not only for women in high risk for OASIS.

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

Conclusions

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

risk of OASIS across all groups of delivering women, not only in high risk groups.

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Contributorship Statement: All the authors' contributed to create the manuscript:

KL: Had the study idea and initiated the study. Planned the study. Performed data retrieval from hospital systems and records. Performed all data analyses. Wrote first draft of manuscript, prepared the manuscript and submitted last version.

FES: Participated in study planning, data analysis and manuscript prepare. Accepted last manuscript that was submitted.

LS: Participated in data analysis and manuscript prepare. Accepted last manuscript that was submitted

ACS: Supervised the planning of the study and all data analyses. Contributed to writing first draft of manuscript, revised the manuscript and accepted last manuscript that was submitted. PhD supervisor of first author (KL).

Data Sharing Statement: The dataset that has been used in this paper is available to all coauthors.

First author has done all statistical analyses, and all of these have been supervised and checked by the senior coauthors that are epidemiologists/statisticians (LV and FES).

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Introduction

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

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

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

In 2004 the Norwegian National Board of Health criticized the delivery units for a high incidence of OASIS, at that time being 4.5% of vaginal deliveries, and required that hospitals should implement programs to reduce the OASIS incidence. Programs to introduce manual perineal protection in the second stage of delivery were implemented in many Norwegian hospitals, and a reduction in OASIS incidence was achieved ,[17, 18]. In the

Obstetric Department at Oslo University Hospital, Ullevål, attempts to reduce the incidence of OASIS were developed in steps, starting in 2006 with more focus on the OASIS issue in clinical meetings, whereas practical training to improve protection of perineum during second stage of delivery started in 2008. Such training programmes have previously been described in two studies ,[17, 18].

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

Methods

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

Databases and participants

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

Women with obstetric anal sphincter injuries were identified from the labour protocols at the delivery unit and validated against individual electronic and paper-based medical charts (by the first author: KL). Surgery notes for the perineum repair in the medical record for each case were carefully read, and false positive cases were excluded (n=22). In addition, patients

with the diagnosis OASIS (ICD-10 code O70.2 or O70.3) were identified from the electronic hospital discharge register and 13 additional patients with OASIS were identified. After excluding women delivered with caesarean section, preterm deliveries (< week 32), triplets and quadruplets, the study population comprised 31 709 deliveries, of which 907 women with OASIS.

Definition and diagnostics of OASIS

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

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

Risk factors for OASIS

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

The intervention programme

The need to reduce the incidence of OASIS was discussed among delivery personnel in clinical meetings from 2006. An intervention programme was implemented from 2008, including both midwives and physicians at the Department of Obstetrics and Gynaecology. An external midwife was hired in from another hospital (where a similar programme was previously successfully implemented) to educate a group of trainer-midwives, who then further educated the entire midwife-staff. Physicians (both registrars and specialists) were educated in the perineal supporting technique and supervised by the first author (KL). First part of the training included a practical hands-on training on a pelvic delivery model and the second part included hands-on supervision in labour room during the second stage of delivery. The perineum protection programme consisted of four components during the last part of second stage of delivery, when the baby's head is crowning: slowing the delivery of the baby's head with one hand, supporting perineum with the other hand and squeezing with fingers (first and second) from the perineum lateral parts towards the middle in order to lower the pressure in middle posterior perineum, and asking the delivering woman not to push. The fourth part of the intervention was education in correct performing of episiotomy. At our department, episiotomy is performed only when indicated, for example due to fetal distress or imminent severe perineal tear. The main focus of this intervention step was to avoid median cuts of episiotomy technique, when performed, due to the augmented risk of OASIS associated with median episiotomies,[20].

Comparison of groups

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

Table 1 Clinical characteristics and obstetric interventions for the whole study population. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women		Multiparous women	
Time period	**2003-05**	**2008-10**	**2003-05**	**2008-10**
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
Risk factors				
Age, years	*P*<0.001		*P*<0.001	
15-29	48.3 (n=3885)	43.8 (n=3872)	27.4 (n=1849)	21.4 (n=1730)
30-34	39.3 (n=3164)	40.8 (n=3604)	42 (n=2823)	40.7 (n=3287)
35-51	12.4 (n=1002)	15.4 (n=1361)	30.6 (n=2064)	37.9 (n=3068)
Birthweight, grams	*P*=0.003		*P*=0.60	
720-2999	16.4 (n=1321)	16.4 (n=1446)	11.8 (n=794)	11.6 (n=938)
3000-3499	37.9 (n=3050)	39.2 (n=3470)	32.5 (n=2191)	32.0 (n=2591)
3500-3999	33.2 (n=2670)	33.8 (n=2983)	36.3 (n=2447)	37.5 (n=3029)
4000-4499	11.0 (n=885)	9.3 (n=821)	15.6 (n=1049)	15.4 (n=1247)
4500-5850	1.5 (n=125)	1.3 (n=117)	3.8 (n=255)	3.5 (n=280)
Delivery method	*P*<0.001		*P*=0.45	
Spontaneous	81.5 (n=6558)	78.3 (n=6918)	96.2 (n=6479)	96.4 (n=7793)
Ventouse	16.5 (n=1331)	20.4 (n=1802)	3.5 (n=234)	3.4 (n=273)
Forceps	2.0 (n=162)	1.3 (n=117)	0.3 (n=23)	0.2 (n=19)
Episiotomy, all vaginal	*P*<0.001		*P*=0.066	
deliveries	31.4 (n=2528)	36.2 (n=3203)	7.3 (n=492)	8.1 (n=656)
Episiotomy, spontaneous	*P*=0.006		*P*=0.98	
deliveries	24.7 (n=1620)	22.7 (n=1569)	6.1 (n=396)	6.1 (n=477)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	60.8 (n=908)	85.1 (n=1634)	37.4 (n=96)	61.3 (n=179)

Duration 2nd stage, min	*P*=0.057		*P*=0.45	
0-29	34.1 (n=2736)	32.5 (n=2864)	84.9 (n=5696)	85.4 (n=6895)
30-59	41.0 (n=3290)	41.6 (n=3673)	12.5 (n=839)	11.9 (n=957)
60-205	24.9 (n=1994)	25.9 (n=2288)	2.6 (n=174)	2.7 (n=219)

Statistical analysis

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

The risk factors for OASIS were calculated and presented separately for the two cohorts. Continuous data were categorised and the independent variables are presented as frequencies. Univariate analysis was performed to explore the significant risk factors. Variables with $P \leq 0.10$ were included in the multivariate analysis. Univariate analyses were performed by Chi-square test. A significance level of 5% was chosen in all analyses. Adjusted odds ratios (aORs) for OASIS with 95% CI are reported from multivariate logistic regression analyses. The data were analyzed by using PASW (Predictive Analytics SoftWare, SPSS Inc., version 19.0, Chicago, IL).

Results

Overall incidence of anal sphincter injury in vaginal deliveries was significantly reduced by 50%, from 4.0% (591/14787) in the first time period (2003-5) to 1.9% (316/16922) in the second time period (2008-10). The reduction of the incidence of OASIS was of similar magnitude across all studied subgroups defined by risk factors, for both primi- and multiparous women (Table 2).

Table 2 Incidence of OASIS in different subgroups of women. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

	Primiparous women			Multiparous women		
Time period	**2003-05**	**2008-10**		**2003-05**	**2008-10**	
OASIS	6.1 (489/8051)	3.0 (263/8837)		1.5 (102/6736)	0.7 (53/8085)	
Risk factors						
Age, years			*P*			*P*
15-29	5.5 (212/3885)	2.8 (107/3872)	<0.001	1.4 (25/1849)	0.5 (9/1730)	0.01
30-34	6.7 (212/3164)	3.3 (118/3604)	<0.001	1.6 (45/2823)	0.7 (22/3287)	0.001
35-51	6.5 (65/1002)	2.8 (38/1361)	<0.001	1.6 (32/2064)	0.7 (22/3068)	0.004
Birthweight, grams						
720-2999	3.0 (39/1321)	1.6 (23/1446))	0.016	0.4 (3/794)	0.5 (5/938)	0.63
3000-3499	4.4 (135/3050)	2.6 (90/3470)	<0.001	0.8 (18/2191)	0.4 (10/2591)	0.049
3500-3999	7.2 (192/2670)	3.4 (101/2983)	<0.001	1.3 (33/2447)	0.6 (19/3029)	0.006
4000-4499	11.2 (99/885)	4.8 (39/821)	<0.001	3.2 (34/1049)	0.7 (9/1247)	<0.001
4500-5850	19.2 (24/125)	8.5 (10/117)	0.017	5.5 (14/255)	3.6 (10/280)	0.28
Delivery method						
Spontaneous	4.8 (318/6558)	2.5 (170/6918)	<0.001	1.4 (91/6479)	0.6 (45/7793)	<0.001
Ventouse	10.8 (144/1331)	5.0 (90/1802)	<0.001	3.4 (8/234)	2.9 (8/273)	0.75
Forceps	16.7 (27/162)	2.6 (3/117)	<0.001	13.0 (3/23)	0 (0/19)	0.10
Episiotomy, all deliveries						
Yes	6.6 (166/2528)	3.0 (96/3203)	<0.001	2.0 (10/492)	1.8 (12/656)	0.80
No	5.8 (323/5523)	3.0 (167/5634)	<0.001	1.5 (92/6244)	0.6 (41/7429)	<0.001
Episiotomy, spontaneous deliveries						
Yes	4.0 (65/1620)	2.2 (34/1569)	<0.003	1.3 (5/396)	1.3 (6/477)	1.00

No	5.1 (253/4938)	2.5 (136/5349)	<0.001	1.4 (86/6083)	0.5 (39/7316)	<0.001
Episiotomy, instrumental deliveries						
Yes	11.1 (101/908)	3.8 (62/1634)	<0.001	5.2 (5/96)	3.4 (6/179)	0.45
No	12.0 (70/585)	10.9 (31/285)	0.64	3.7 (6/161)	1.8 (2/113)	0.34
Duration 2nd stage, min						
0-09	4.6 (13/281)	3.3 (9/273)	0.42	0.9 (20/2335)	0.4 (10/2390)	0.058
10-29	4.0 (99/2455)	2.9 (74/2591)	0.02	1.5 (50/3361)	0.5 (21/4505)	<0.001
30-59	5.5 (180/3290)	2.5 (93/3673)	<0.001	2.9 (24/839)	1.7 (16/957)	0.09
60-205	9.7 (193/1994)	3.8 (87/2288)	<0.001	4.0 (7/174)	2.3 (5/219)	0.32
Epidural						
Yes	6.5 (228/3494)	3.0 (128/4267)	<0.001	2.0 (20/1008)	0.8 (12/1419)	0.015
No	5.7 (261/4557)	3.0 (135/4570)	<0.001	1.4 (82/5728)	0.6 (41/6666)	<0.001
Shoulder dystocia						
Yes	15.8 (12/76))	14.1 (9/64)	0.78	5.7 (5/87)	4.1 (3/73)	0.64
No	6.0 (477/7975)	2.9 (254/8773)	<0.001	1.5 (97/6649)	0.6 (50/8012)	<0.001
Occiput posterior presentation						
Yes	11.4 (20/176)	6.9 (17/245)	0.11	0.7 (1/150)	1.7 (4/237)	0.39
No	6.0 (469/7875)	2.9 (246/8592)	<0.001	1.5 (101/6586)	0.6 (49/7848)	<0.001
Induced labour						
Yes	5.5 (75/1365)	3.0 (50/1650)	0.001	1.3 (12/903)	0.7 (9/1269)	0.18
No	6.2 (414/6686)	3.0 (213/7187)	<0.001	1.5 (90/5833)	0.6 (44/6816)	<0.001

The incidence of OASIS over the study years is displayed in Figure 1, demonstrating a reduced incidence of OASIS, which in time follows the implementation of the perineum support program for the staff. Figure 1 also demonstrates a similar reduction of OASIS

incidence for the different delivery methods (operative and spontaneous vaginal delivery) between the two study periods: in spontaneous deliveries the OASIS incidence was reduced from 3.1% (409/13037) to 1.5% (215/14711) and in ventouse from 9.7% (152/1565) to 4.7% (98/2075). Forceps is less used in our department, but a significant OASIS reduction was also observed in forceps deliveries from 16.2% (30/185) to 2.2% (3/136).

Population characteristics across the study years

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

Primiparous women

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

Table 3 Clinical characteristics and obstetric interventions among primiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Primiparous women	**2003-05**		**2008-10**	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
n deliveries	n=489	n=7562	n=263	n=8574

Incidence OASIS	6.1 (489/7562)		3.0 (263/8574)	
Risk factors	%		%	
Age, years	*P*=0.08		*P*=0.39	
15-29	43.4 (n=212)	48.6 (n=3673)	40.7 (n=107)	43.9 (n=3765)
30-34	43.4 (n=212)	39 (n=2952)	44.9 (n=118)	40.7 (n=3486)
35-51	13.3 (n=65)	12.4 (n=937)	14.4 (n=38)	15.4 (n=1323)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	8.0 (n=39)	17.0 (n=1282)	8.7 (n=23)	16.6 (n=1423)
3000-3499	27.6 (n=135)	38.5 (n=2915)	34.2 (n=90)	39.4 (n=3380)
3500-3999	39.3 (n=192)	32.8 (n=2478)	38.4 (n=101)	33.6 (n=2882)
4000-4499	20.2 (n=99)	10.4 (n=786)	14.8 (n=39)	9.1 (n=782)
4500-5850	4.9 (n=24)	1.3 (n=101)	3.8 (n=10)	1.2 (n=107)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	65.0 (n=318)	82.5 (n=6240)	64.6 (n=170)	78.7 (n=6748)
Ventouse	29.4 (n=144)	15.7 (n=1187)	34.2 (n=90)	20.0 (n=1712)
Forceps	5.5 (n=27)	1.8 (n=135)	1.1(n=3)	1.3(n=114)
Episiotomy, all vaginal deliveries	*P*=0.21		*P*=0.93	
	33.9 (n=166)	31.2 (n=2362)	36.5 (n=96)	36.2 (n=3107)
Episiotomy, spontaneous deliveries	*P*=0.07		*P*=0.40	
	20.4 (n=65)	24.9 (n=1555)	20.0 (n=34)	22.7 (n=1535)
Episiotomy, instrumental	*P*<0.001		*P*<0.001	
deliveries	59.1 (n=101)	61.0 (n=807)	66.7 (n=62)	86.1 (n=1572)
Duration 2nd stage, min	*P*<0.001		*P*=0.07	
0-09	2.7 (n=13)	3.5 (n=268)	3.4 (n=9)	3.1 (n=264)
10-29	20.2 (n=99)	31.2 (n=2356)	28.1 (n=74)	29.4 (n=2517)
30-59	36.8 (n=180)	41.1 (n=3110)	35.4 (n=93)	41.8 (n=3580)
60-205	39.5 (n=193)	23.8 (n=1801)	33.1 (n=87)	25.7 (n=2201)

Missing data (n=4/n=27)	0.8 (n=4)	0.4 (n=27)	0 (n=0)	0.1 (n=12)
Epidural	*P*=0.14		*P*=0.90	
	46.6 (n=228)	43.2 (n=3266)	48.7 (n=128)	48.3 (n=4139)
Shoulder dystocia	*P*<0.001		*P*<0.001	
	2.5 (n=12)	0.8 (n=64)	3.4 (n=9)	0.6 (n=55)
Occiput posterior presentation	*P*=0.003		*P*<0.001	
	4.1 (n=20)	2.1 (n=156)	6.5 (n=17)	2.7 (n=228)
Induced labour	*P*=0.32		*P*=0.89	
	15.3 (n=75)	17.1 (n=1290)	19.0 (n=50)	18.7 (n=18.7)

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

In a multivariate regression analysis (Table 4), large infant birth weight, instrumental delivery, prolonged second stage and occiput posterior presentation were significant risk factors for OASIS in the first study period. In the second study period, when the incidence of OASIS was reduced, only instrumental delivery and fetal occiput posterior presentation remained significant risk factors for OASIS.

Table 4 Risk factors for OASIS in the multivariate regression model (adjusted odds ratio (aOR) and 95% confidence intervals).

	Primiparous women	**Multiparous women**

Time period	2003-05	2008-10	2003-05	2008-10
n vaginal deliveries	n=8051	n=8837	n=6736	n=8085
n OASIS	489	263	102	53
Incidence OASIS	6.0 %	3.0%	1.5%	0.7%
Risk factors	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)	aOR (95% CI)
Age, years				
15-29	0.90 (0.72 to 1.08)	0.90 (0.67 to 1.15)	0.99 (0.60 to 1.64)	0.86 (0.40 to 1.90)
30-34	1	1	1	1
35-51	0.96 (0.71 to 1.28)	0.84 (0.58 to 1.22)	0.91 (0.57 to 1.44)	0.95 (0.52 to 1.75)
Birthweight, grams				
720-3499	0.70 (0.55 to 0.87)	0.80 (0.60 to 1.08)	0.46 (0.25 to 0.82)	0.93 (0.44 to 1.94)
3500-3999	1	1	1	1
4000-5850	1.50 (1.16 to 1.92)	1.26 (0.87 to 1.83)	2.81 (1.73 to 4.58)	1.19 (0.58 to 2.45)
Delivery method				
Spontaneous	1	1	1	1
Instrumental	2.10 (1.71 to 2.68)	2.46 (1.74 to 3.47)	2.19 (1.02 to 4.73)	1.72 (0.64 to 4.66)
Episiotomy				
No	1	1	1	1
Yes	0.72 (0.58 to 0.90)	0.52 (0.38 to 0.73)	0.92 (0.46 to 1.87)	1.57 (0.71 to 3.49)
Duration 2nd stage, min				
0-29	0.80 (0.62 to 1.02)	1.18 (0.87 to 1.60)	0.50 (0.31 to 0.82)	0.34 (0.18 to 0.64)
30-59	1	1	1	1
60-205	1.40 (1.15 to 1.79)	1.29 (0.95 to 1.75)	1.03 (0.41 to 2.58)	0.83 (0.28 to 2.48)
Epidural				
No	1	1	1	1
Yes	0.95 (0.78 to 1.15)	0.86 (0.67 to 1.12)	1.15 (0.69 to 1.93)	0.88 (0.44 to 1.76)
Shoulder dystocia				

No	1	1	1	1
Yes	1.58 (0.83 to 1.39)	3.73 (1.76 to 7.90)	1.58 (0.60 to 4.16)	2.25 (0.50 to 10.10)
Occiput posterior presentation				
No	1	1	1	1
Yes	1.72 (1.04 to 2.82)	2.40 (1.42 to 4.06)	0.24 (0.03 to 1.78)	1.95 (0.66 to 5.73)
Induced labour				
No	1	1	1	1
Yes	0.77 (0.60 to 1.00)	0.92 (0.66 to 1.27)	0.86 (0.46 to 1.60)	0.81 (0.37 to 1.77)

Frequency of episiotomy use in spontaneous deliveries of primiparous women was reduced from the first time period to the second, and increased in instrumental deliveries (Table 1). When adjusted for risk factors in the multivariate analysis, episiotomy appeared as a protective factor for OASIS in both time periods for primiparous women (Table 4).

Primiparous women with a previous caesarean section only, and no previous vaginal delivery (n=440), had an increased OASIS risk compared to women with no previous delivery OR=2.2 (95% CI 1.6 to 3.1), both in the first time period (11.5% and 5.9%, respectively, *P*=0.001) and in the second (6.7% and 2.9%, respectively, *P*=0.001). Also in this subgroup, the OASIS incidence was reduced with 50% after implementation of the perineal protection programme. When the various study analyses were performed without this small subgroup of vaginal primiparous women with one previous caesarean only, the study conclusions remained unaltered, as expected due to the small number of women in this subgroup.

Multiparous women

In a univariate analysis for multiparous women (Table 5), instrumental delivery, prolonged second stage of delivery, shoulder dystocia, large infant head circumference (data not shown)

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

Table 5 Clinical characteristics and obstetric interventions among multiparous women with OASIS and women without OASIS. Data are presented in frequencies (and numbers). *P*-values from Chi-square test.

Multiparous women	**2003-05**		**2008-10**	
	OASIS	**Non-OASIS**	**OASIS**	**Non-OASIS**
n deliveries	n=102	n=6634	n=53	n=8032
Incidence OASIS	1.5 (102/6634)		0.7 (53/8032)	
Risk factors	%		%	
Age, years	*P*=0.79		*P*=0.71	
15-29	24.5 (n=25)	27.5 (n=1824)	17.0 (n=9)	21.4 (n=1721)
30-34	44.1 (n=45)	41.9 (n=2778)	41.5 (n=22)	40.6 (n=3265)
35-51	31.4 (n=32)	30.6 (n=2032)	41.5 (n=22)	37.9 (n=3046)
Birthweight, grams	*P*<0.001		*P*<0.001	
720-2999	2.9 (n=3)	11.9 (n=791)	9.4 (n=5)	11.6 (n=933)
3000-3499	17.6 (n=18)	32.8 (n=2173)	18.9 (n=10)	32.1 (n=2581)
3500-3999	32.4 (n=33)	36.4 (n=2414)	35.8 (n=19)	37.5 (n=3010)
4000-4499	33.3 (n=34)	15.3 (n=1015)	17.0 (n=9)	15.4 (n=1238)
4500-5850	13.7 (n=14)	3.6 (n=241)	18.9 (n=10)	3.4 (n=270)
Delivery method	*P*<0.001		*P*<0.001	
Spontaneous	89.2 (n=91)	96.3 (n=6388)	84.9 (n=45)	96.5 (n=7748)
Ventouse	7.8 (n=8)	3.4 (n=226)	15.1 (n=8)	3.3 (n=265)

Forceps	2.9 (n=3)	0.3 (n=20)	0 (n=0)	0.2 (n=19)
Episiotomy, all vaginal deliveries	*P*=0.33		*P*<0.001	
	9.8 (n=10)	7.3 (n=482)	22.6 (n=12)	8.0 (n=644)
Episiotomy, spontaneous deliveries	*P*=0.80		*P*=0.43	
	5.5 (n=5)	6.1 (n=391)	13.3 (n=6)	6.1 (n=471)
Episiotomy, instrumental	*P*=0.57		*P*=0.42	
deliveries	45.5 (n=5)	37.0 (n=91)	75 (n=6)	60.9 (n=173)
Duration 2nd stage, min	*P*<0.001		*P*<0.001	
0-09	19.6 (n=20)	34.9 (n=2315)	18.9 (n=10)	29.6 (n=2380)
10-29	49.0 (n=50)	49.9 (n=3311)	39.6 (n=21)	55.8 (n=4484)
30-59	23.5 (n=24)	12.3 (n=815)	30.2 (n=16)	11.7 (n=941)
60-205	6.9 (n=7)	2.5 (n=167)	9.4 (n=5)	2.7 (n=214)
Missing data (n=4/n=27)	1.0 (n=1)	0.4 (n=26)	1.9 (n=1)	0.2 (n=13)
Epidural	*P*=0.21		*P*=0.36	
	19.6 (n=20)	14.9 (n=988)	22.6 (n=12)	17.5 (n=1407)
Shoulder dystocia	*P*=0.001		*P*<0.001	
	4.9 (n=5)	1.2 (n=82)	5.7 (n=3)	0.9 (n=70)
Occiput posterior presentation	*P*=0.39		*P*=0.046	
	1.0 (n=1)	2.2 (n=149)	7.5 (n=4)	2.9 (n=233)
Induced labour	*P*=0.62		*P*=0.80	
	11.8 (n=12)	13.4 (n=891)	17.0 (n=9)	15.7 (n=1260)

In the multivariate regression analysis (Table 4), macrosomia and instrumental delivery significantly increased the OASIS risk for multiparous women in the first time period, but not in the second. In the second time period, none of the identified risk factors for OASIS were significant for multiparous women. However, OASIS cases were few (n=53) in this subgroup of women. In the multivariate analysis the effect of episiotomy was non-

significant in both time periods (Table 4). However, multiparous women with episiotomy were very few in this study and interpretation of the results should be undertaken cautiously (Table 2 and 5).

Discussion

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

Similar reduction in OASIS following alteration in clinical routines and intervention programmes during the second stage of delivery have been presented previously, both in Norway,[17, 18] and in the US ,[21], but we are not aware of other publications exploring the reduced incidence of OASIS in different subgroups defined by risk factors.

Strengths and limitations of the study

Strengths of this hospital-based large observational study includes a very low risk of diagnostic misclassification of the OASIS outcome as all OASIS diagnoses were validated for study purposes in addition to primarily being diagnosed by at least two accoucheurs, and always by an obstetrician or gynecologist. This is in contrast to studies based on registries that are not primarily created for research, but are established for other purposes for the health care providers. In our study, the medical records of all patients registered with an OASIS were carefully reviewed by one senior consultant (KL). In addition, diagnosis of OASIS cases were cross-checked between several available sources (individual patient records, delivery unit protocols and hospital discharge lists, including ICD-10 diagnose codes and surgical codes for OASIS repair) for the study years. Another strength is that the study was carried out at in a

single large hospital focusing on improved quality of primary diagnosis and repair of OASIS, and this also reduces the risk of misclassification in registration. Strength of the study is also the unselected population of delivering women and a large number of deliveries.

A randomized controlled trial (RCT) would be the optimal design for evaluating a OASIS reducing effect of manual perineum protection, but carrying out such an RCT is challenging during delivery, due to contamination of methods in different study arms and problems with blinding of patients or staff. We did not conduct an RCT because in Norway, several hospitals already had managed to reduce the incidence of OASIS with implementation of improved manual perineal protection, and we consider randomizing women to hands-off delivering techniques as unethical in the light of these recent historical clinical results. Previous RCTs have not shown a beneficial effect on OASIS by hands-on perineal protection, but the published RCTs have not described a structured training of the staff, such as the intervention programme of our study,[22]. These trials had problems with bias caused by contamination of compared methods and different use of medial episiotomy in the study arms,[23, 24], were under-powered to explore OASIS, or were not designed to assess OASIS, but perineal pain or perineal injury in general (including 1st and 2nd degree tears and episiotomy),[23-25]. The marked 50% reduction in the OASIS incidence obtained in our delivery unit appeared simultaneously with the introduction of a manual perineal protection during second stage of labour. The main difference for our study population between the two time periods was the perineum protection training programme, the patient characteristics remained almost unaltered between the time periods and could not explain the reduction of incidence of OASIS. Thus, our study indicates that such a perineal protection programme has a beneficial effect in reducing the incidence of OASIS, both for primiparous and multiparous women, despite the lack of an RCT supporting this conclusion.

A weakness of our study is that the use of perineum support method, if used during second stage of delivery, was not registered in the medical records, and therefore, use of perineum support could not be assessed directly in our retrospective study. However, if this method was not used in some deliveries during the second time period or was used in some deliveries during the first time period, our study would tend to underestimate the OASIS incidence reducing effect of the perineum protection intervention program, and hence, our efficacy estimates on reduction of OASIS from the intervention are minimum estimates.

Meaning of the study

The observed reduction of incidence of OASIS came rapidly after the introduction of the perineal protection programme and the low incidence of OASIS has lasted over the last years. The changes in clinical characteristics of the study population were very modest between the two time periods, and cannot explain the rapid reduction of the incidence of OASIS. Without the intervention programme, we could have expected an increase of the incidence of OASIS in the second time period, as one of the most important OASIS risk factors, instrumental delivery, became more frequent in the study population (Table 1) over the study years. In our study the reduction of incidence of OASIS was surprisingly consistent in all subgroups defined by OASIS risk factors (Table 2). The decrease of the incidence of OASIS was similar in spontaneous and operative deliveries and in parity groups (primiparous and multiparous), again surprising, as primiparity is one of the most important risk factors for OASIS, as is operative delivery,[5, 10, 15]. Interestingly, as shown in Figure 1, the 2010 incidence of OASIS in women delivered by ventouse delivery is of similar magnitude as the incidence of OASIS in the spontaneous deliveries was back in 2005 (3.6 and 3.8%, respectively).

Underreporting OASIS cases in the second time period is an unlikely cause for the registered reduction of the incidence of OASIS, as the procedure emphasizing more than one

accoucheur present at all deliveries was introduced before the second study period in form of a written procedure. Caesarean rate was unaltered between the two study periods and cannot explain the reduction of the incidence of OASIS.

Comparison with other studies

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

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

During the study period, the use of episiotomy in our hospital decreased slightly in spontaneous deliveries in primiparous women (from 24.7 to 22.7%), but increased in instrumental deliveries in primiparous women (from 60.8 to 85.1%) (Table 1), and was shown

to be a protective factor against OASIS for primiparous women in both time periods (Table 4). Differences in effect of episiotomy between different parity groups on OASIS occurrence can be explained by indication bias, a mix between cause and effect, as episiotomy is used in deliveries with high OASIS risk. Multiparous women needing episiotomy may represent a group of women with difficult delivery with many risk factors.

Research and policy implications

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

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

Conclusions

Our study shows a large and rapid reduction of the incidence of OASIS following an introduction of a perineum support programme, across all risk groups of OASIS. We suggest

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

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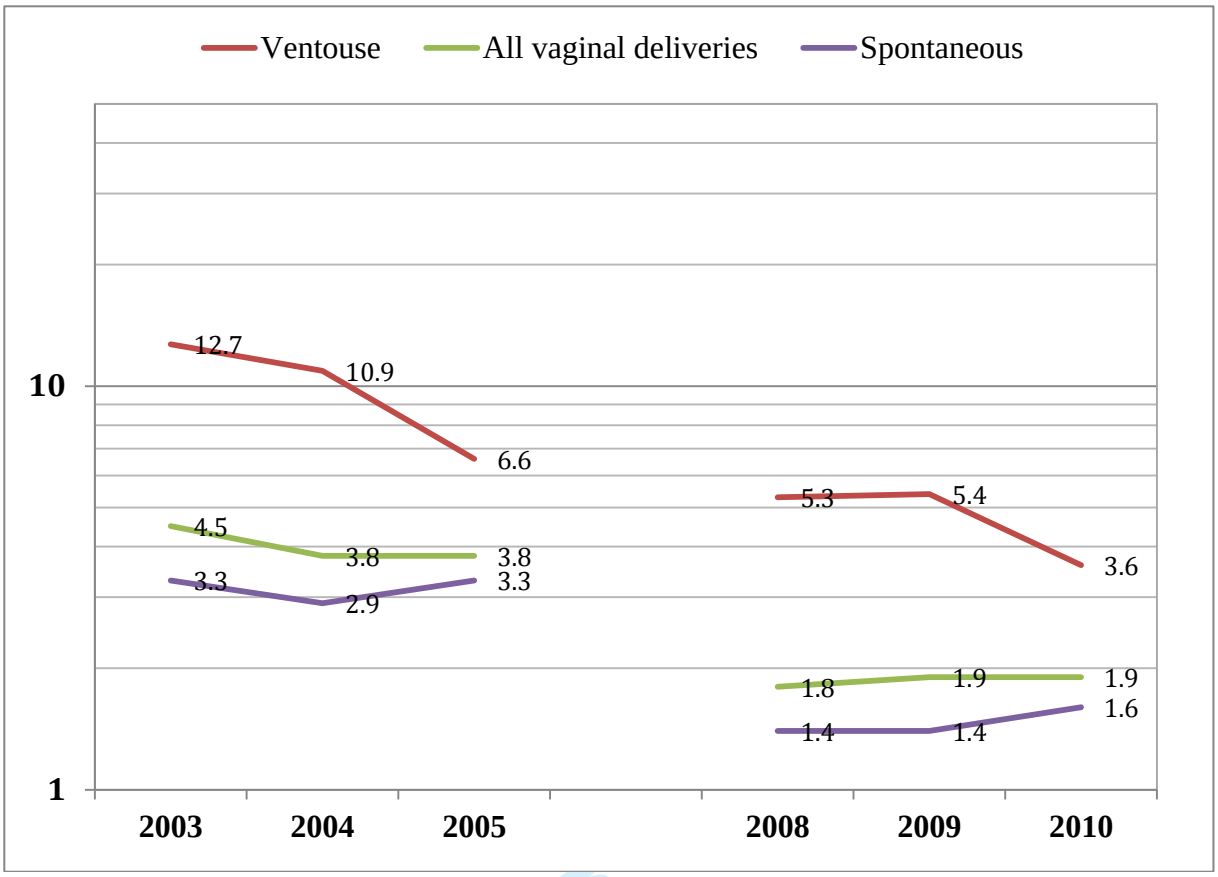

Figure 1 Frequency of OASIS (%) for different delivery methods during the study years.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1 ok	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2 ok	Explain the scientific background and rationale for the investigation being reported
Objectives	3 ok	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4 ok	Present key elements of study design early in the paper
Setting	5 ok	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6 ok	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7 ok	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*ok	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9 ok	Describe any efforts to address potential sources of bias
Study size	10 ok	Explain how the study size was arrived at
Quantitative variables	11 ok	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12 ok	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*ok	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*ok	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*ok	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16ok	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17ok	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18ok	Summarise key results with reference to study objectives
Limitations	19 ok	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20 ok	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21 ok	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22 ok	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

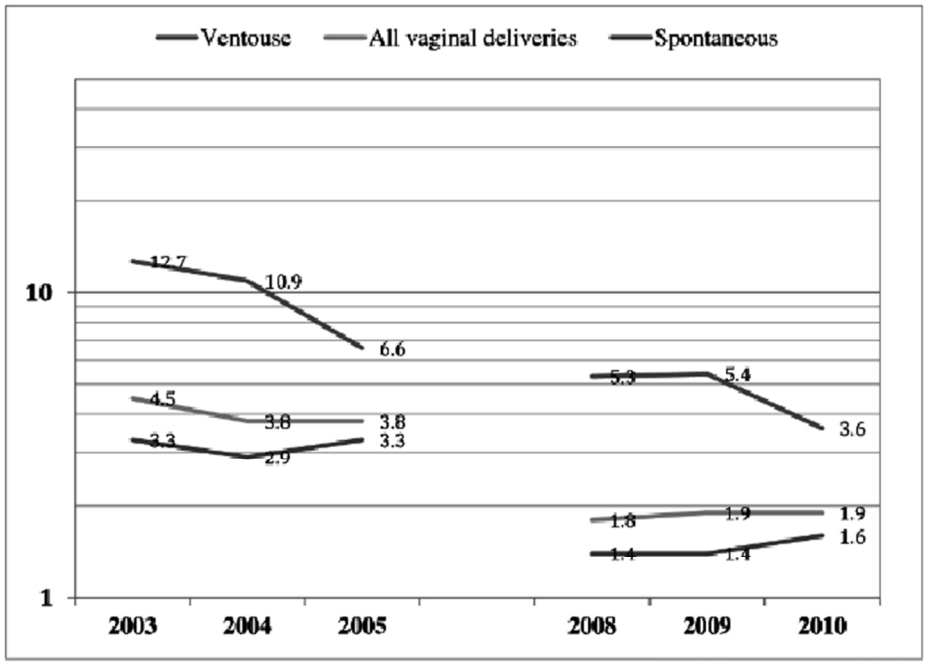

Figure 1 Frequency of OASIS (%) for different delivery methods during the study years.