Manual protection of the perineum reduces the risk of obstetric anal sphincter ruptures

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ABSTRACT
INTRODUCTION: During vaginal delivery, the risk of obstetric anal sphincter injuries (OASIS) is well-known. Despite sufficient repair, 30-50% of women will experience anal incontinence. Recent studies from Norway have shown a reduction in the incidence of OASIS when the perineum is supported manually. In Denmark, the frequency of OASIS is the highest in Scandinavia and it is increasing. The aim of this study was to reduce the incidence of OASIS through an interventional programme.

METHODS: We conducted a study inspired by the Norwegian intervention. Our focus was on four points: 1) good communication between the delivering woman and the birth assistant, 2) visualisation of the perineum in the last stages of delivery, 3) support of the perineum during the final minutes of pushing and 4) episiotomy only on indication. A total of 768 primiparous and 1,175 multiparous women were enrolled in this quality improvement cohort study. Data were analysed for association with the occurrence of OASIS.

RESULTS: The proportions of parturients with anal sphincter ruptures decreased significantly during the first year of the study from 4.4% to 1.7% (p < 0.001). The decrease was more pronounced for primiparous women: from 7.2% to 2.9% (p = 0.006). A similar decrease was observed for instrumental deliveries although this was not significant for primiparous women, probably due to the size of the study population. Episiotomies increased significantly from 4.4% to 7.1% for all deliveries.

CONCLUSION: After the first year of intervention, our results demonstrate that manual protection of the perineum reduces the overall risk of OASIS significantly.

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Obstetric anal sphincter injury (OASIS) is a well-known complication following vaginal delivery. Even though the damage is diagnosed and sutured immediately after delivery, 30-50% of the patients will experience faecal or urinary incontinence, pain or sexual dysfunction at some point [1-3]. These complications can have important consequences for the woman’s quality of life [4]. OASIS is associated with several obstetric risk factors: First-time delivery, high birth weight, the use of forceps or vacuum and previous OASIS are the best documented risk factors [5, 6]. Other factors have been correlated with an increased risk of OASIS, though data are contradictory [6-8].

The incidence of OASIS has increased in past decades in Scandinavia. Denmark currently has the highest incidence of OASIS [9]. According to the Danish birth registry, 4.2% of all women who gave birth in 2012 had OASIS. In comparison, the incidence of OASIS was 2.3% in Norway and 1.0% in Finland. The reason for the lower risk of OASIS in Finland is believed to be the use of a better technique during delivery to support the perineum. In a retrospective study, a 13-fold increased risk of OASIS at low-risk births in Malmö compared with Turku in Finland was established. It was concluded that the technique used in Finland to support the perineum reduced the risk of OASIS [10].

In Norway in 2004, the National Health Control Agency (Helsetilsynet) along with the Department of Health and Social Affairs set up a National Advisory Committee for Childbirth (Nasjonalt Råd for Fødselsomsorg) to create a national plan: “Damage to the anal sphincter at birth should be reduced in Norway”. The goal was to reduce the incidence of OASIS to 2% within a limited number of years. Initiatives were taken by the National Advisory Committee for Childbirth and the Finnish obstetrician Professor Jouko Pirhonen and midwife Tiina Pirhonen to implement an intervention project with the intention of reducing the number of OASIS. The four focus points in the intervention projects are presented in Table 1. Five hospitals in Norway participated, and the results from these projects showed a significant reduction in the number of OASIS from 4.3% to 1.17% and 4-5%, respectively, to 1-2% [11, 12].

The aim of the present project was to assess if an intervention project similar to the Norwegian projects would yield an equivalent decrease in the incidence of OASIS in a maternity ward in Denmark.

METHODS
As a first step in this project, a sphincter group was created in February 2012 consisting of four midwives and three doctors. The group contacted Professor Jouko Pirhonen and midwife Tiina Pirhonen, who initiated several of the Norwegian intervention projects. After having
corresponded during 2012, the project was organised much in line with the previous Norwegian intervention projects. Midwives and doctors were continuously informed by emails, and a maternity ward meeting was held to present and discuss the project. The four focus points of the quality improvement project are presented in Table 1.

The intervention started with lectures for all midwives and physicians held by Tiina and Jouko Pirhonen in the beginning of January 2013. Expert midwife Tiina Pirhonen worked seven weeks at the delivery ward where she trained all midwives in the pelvic model followed by hands-on work and supervision in the delivery room. The expert midwife first had her hand on the midwife’s hand to teach the proper technique, and when the midwife mastered the technique, she was further supervised, typically during 3-4 deliveries, before she was considered fully qualified.

Experiences from Norway have shown that one of the main objectives in the intervention projects should be the establishment of a local team of midwives and doctors capable of continuing the intervention after the expert midwife has left. The four midwives in the sphincter group handled more supervised births during the expert midwives stay than anyone else. These new experts have subsequently handled the training of the remaining midwives and have maintained a focus on the project. Professor Pirhonen trained the department’s doctors in perineum support during vacuum delivery using a pelvic model, and a consultant and member of the sphincter group also received training. Emails updated all midwives and doctors with information on the effect of the intervention project.

Diagnosis and suturing of OASIS were done immediately after the obstetric trauma according to the department’s standard procedure. If the midwife had suspicion of OASIS during delivery, she called a specialist in obstetrics and gynaecology for evaluation and suturing. OASIS was classified according to national guidelines (Table 2). A summary was prepared with data on the birth to evaluate and describe the cause of the OASIS and to learn from experiences.

Data from all deliveries at Hospital Vendsyssel (1 January 2012 to 31 December 2013) were included in this quality improvement cohort project and extracted from the regional delivery database. To confirm the right graduation of OASIS, all patient records were evaluated in the two periods. In total, 1943 vaginal deliveries were included. In pregnancy week 29, all women were given oral and written information about the intervention project by a midwife, and they provided written and oral consent at the time of delivery. If the woman had a very fast delivery, she was not included as there was no time for enrolment. Twin births were excluded. There were no cases of OASIS in this specific group either in 2012 or 2013. For statistical analysis, the statistical programme STATA was used. The rate of vaginal deliveries with OASIS (International Classification of Diseases, 10 revision, codes O702 and O703) was established per 100 singleton vaginal deliveries.

A subdivision between instrumental and non-instrumental delivery was made. Similarly, a subdivision was made between primiparous (P0) and multiparous (MP) births. The period before the intervention (2012) was compared with the period after the intervention (2013) via statistical models, the chi-squared test and the t-test. A p-value < 0.05 was considered statistically significant. The project was classified as a quality-improving project and was therefore approved by the local ethical committee.

Trial registration: not relevant.

RESULTS

The characteristics of the study population before and after the intervention project are presented in Table 3.
No statistical difference was found in the demographic data between the two periods.

The rate of vacuum deliveries increased from 7.6% in 2012 to 8.6% in 2013 (relative risk (RR) = 1.13 (95% confidence interval (CI): 0.84-1.53)). The rate of episiotomies increased from 4.3% to 7.1% for all vaginal deliveries (RR = 1.65 (95% CI: 1.14-2.39)) and from 9.3% to 13.7% for P0 (RR = 1.47 (95% CI: 0.99-2.20)). Among women with episiotomies, two P0 and three multiparous (MP) had an OASIS in 2012 and one OASIS occurred in a P0 in 2013. All 6 women had an instrumental delivery.

No statistical difference was found in infant birth weight and head circumference in 2013 compared with 2012. Nor was neonatal outcome affected by the intervention as Apgar score and umbilical artery pH were unchanged.

The total amount of OASIS decreased significantly for all vaginal deliveries from 2012 to 2013, mainly P0 (Table 4). For non-instrumental deliveries in P0, the incidence of OASIS decreased from 6.0% to 2.2% (RR = 0.38 (95% CI: 0.16-0.86)), whereas for MP it decreased from 2.0% to 0.96% (RR = 0.49 (95% CI: 0.17-1.38)). The relative risk of OASIS for instrumental deliveries for P0 decreased to 0.44 (95% CI: 0.14-1.40) in 2013, but due to a low number of included patients, significance was not achieved. Significance was found for MP with instrumental delivery (22.7% to 0%, p = 0.047). The total number of spontaneous ruptures was reduced from 44.9% to 39.8% (RR = 0.63 (95% CI: 0.58-0.70)).

**DISCUSSION**

This project demonstrates that effort implemented in relation to four particular aspects of delivery techniques dramatically decreased the incidence of OASIS. In 2013, 29 women avoided OASIS and its potential consequences which could otherwise have affected their quality of life [4]. The results of this project are in line with those of the intervention projects from Norway. A continuous, low incidence of OASIS has been obtained also after a longer period of time. At 9 years after the intervention, one of the Norwegian intervention hospitals (Ålesund) has an incidence of 0.85%, the lowest incidence of OASIS in Norway [11, 12]. In 2014, the incidence of OASIS at Hospital Vendsyssel remained low (2.2%). We believe that the quality improvement project explains this decrease.

The study design reduces the evidence level of this project. The influence of time course effects on the results cannot be calculated. However, the results from Norway and Finland were so convincing that we felt it would be ethically incorrect to divide women into groups receiving support and others not receiving support. We have no descriptions of how the perineum was supported in our controls; i.e. the women who gave birth before the intervention project. In a Cochrane review, no difference was observed in the incidence of OASIS between “hands on” and “hands poised”. The

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**TABLE 3**

| Characteristics of the delivering before and after the intervention. |
|---------------------------------|-----------------|-----------------|-----------------|
| Deliveries, total, n            | 2012            | 1,291           | 2013            | 1,174           |
| Vaginal deliveries, total, n/N (%) | 1,025/1,291 (79.4) | 918/1,174 (78.2) | 2013            | 0.99 (0.95-1.03) | NS |
| Instrumental delivery, n/N (%)  | 78/1,025 (7.6)  | 79/918 (8.6)    | 2013            | 1.13 (0.84-1.53) | NS |
| Vaginal deliveries, P0, n/N (%)  | 388/1,025 (37.9) | 380/918 (41.4)  | 2013            | 1.09 (0.98-1.22) | 0.11 (NS) |
| Instrumental delivery, P0, n/N (%) | 56/388 (14.4)  | 64/380 (16.8)   | 2013            | 1.27 (0.90-1.80) | NS |
| Epidural, n (%)                 | 244 (23.8)      | 231 (25.2)      | 2013            | 1.06 (0.90-1.23) | NS |
| Episiotomy, n (%)               | 44 (4.3)        | 65 (7.1)        | 2013            | 1.65 (1.14-2.39) | 0.005 |
| Body mass index, kg/m², median ± SD | 25.1 ± 0.2     | 24.7 ± 0.2      | 2013            | -               | NS |
| Gestational age, weeks, median ± SD | 39.4 ± 0.1     | 39.5 ± 0.1      | 2013            | -               | NS |
| Parity, median ± SD             | 2.39 ± 0.04     | 2.36 ± 0.05     | 2013            | -               | NS |

CI = confidence interval; NS = non-significant; P0 = primiparous women; RR = relative risk; SD = standard deviation.

**TABLE 4**

The incidence of obstetric anal sphincter injuries before and after intervention.

<table>
<thead>
<tr>
<th>2012, % (n/N)</th>
<th>2013, % (n/N)</th>
<th>RR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>OASIS, total</td>
<td>4.4 (45/1,025)</td>
<td>1.7 (16/918)</td>
<td>0.40 (0.23-0.70)</td>
</tr>
<tr>
<td>OASIS, P0</td>
<td>7.2 (28/388)</td>
<td>2.9 (11/380)</td>
<td>0.40 (0.20-0.79)</td>
</tr>
<tr>
<td>OASIS, non-instrumental deliveries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P0</td>
<td>6.0 (20/332)</td>
<td>2.2 (7/316)</td>
<td>0.38 (0.16-0.86)</td>
</tr>
<tr>
<td>MP</td>
<td>2.0 (12/615)</td>
<td>0.96 (5/523)</td>
<td>0.49 (0.17-1.38)</td>
</tr>
<tr>
<td>OASIS, instrumental deliveries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P0</td>
<td>14.3 (8/56)</td>
<td>6.3 (4/64)</td>
<td>0.44 (0.14-1.40)</td>
</tr>
<tr>
<td>MP</td>
<td>22.7 (5/22)</td>
<td>0 (0/15)</td>
<td>-</td>
</tr>
</tbody>
</table>

CI = confidence interval; MP = multiparous women; NS = non-significant; OASIS = obstetric anal sphincter injuries; P0 = primiparous women; RR = relative risk.
term “hands poised” was, however, not clearly defined. Three randomised trials (RCT) were included counting a total of 6,617 women, both PO and MP [13]. However, the number of OASIS was low (1.3%) compared with the incidence in Denmark, and one of the RCTs investigated only perineal support. Furthermore, the changes in clinical practice introduced with the four focus points are so complex that they are hardly amenable to the design of an RCT.

The results of this and other observational studies regarding perineal support and the use of the four focus points do not allow us to decide which one of the four focus points is most important. Together they consist in slowing down the speed of the head’s passage through the vaginal introitus and in distributing force on the perineum. Previous studies have shown a relation between support of the perineum and a decrease in OASIS [7, 10]. Furthermore, a delivery position that allows visualisation of the perineum is of importance to be able to support the perineum. In a Cochrane review including five RCT, no significance difference in terms of OASIS incidence was found when a recumbent/semi-recumbent position was compared with an upright position [14]. The fourth focus in the Norwegian model is episiotomy. The existing literature presents contradictory data on this issue, some showing that episiotomy increases the risk of OASIS and others showing the opposite. The frequency of episiotomy in all vaginal deliveries in Finland in 2010 was 24.1%, and the corresponding share for Norway was 19.1%. For comparison, the frequency in Denmark was 5.0% [15]. Initially, we decided not to change the indications for episiotomy. In our department, these indications are threatening asphyxia and perineum rigidum; but the incidence of episiotomy is, nevertheless, increased significantly as the instructors considered perineal oedema and thin bloodless perineum indications of episiotomy. Few women with OASIS had an episiotomy in the two study periods (five in 2012 and one in 2013). All six women had a delivery by vacuum extraction, which is a strong risk factor for OASIS. Traditionally, Danish midwives and physicians are trained to perform the procedure as a mediolateral episiotomy. The Finnish instructors preferred lateral episiotomy and therefore an unknown rate of episiotomies performed in 2013 were undertaken laterally, which may affect the results.

A trend towards an increased number of instrumental deliveries was seen in 2013. Because instrumental delivery is a strong risk factor for OASIS, the protective effect of the intervention could be larger than presented here [16, 17]. The incidence of OASIS for all instrumental deliveries for both PO and MP were significantly reduced but due to a low number of included patients, significance was not achieved for PO. The obstetrician was trained in support of the perineum and in slowing down the head’s passage through a change of vacuum extraction technique; however, we do not have information on how often the obstetrician supported the perineum and how often they chose to pass this task on to an “approved” midwife. It is conceivable that using both hands during delivery of the head with vacuum extraction would give the doctor a better control of the speed of the head, but this needs to be investigated further.

Some have speculated that the reduction of the speed of the head’s passage could contribute to a slightly longer delivery and increase the risk for the newborn. We found no difference between the groups in terms of Apgar score and umbilical cord pH, which is in line with the Norwegian studies [12]. Few employees have questioned if the presented results will lead to a shift from third-degree to second-degree ruptures. Our results, however, show a significant decrease in the total number of all ruptures and a reduction, although insignificant, in second-degree ruptures. This seems to contradict that the decrease in OASIS is due to underdiagnosis. The total number of ruptures in our project was lower than those described in the literature, where studies show that up to 80% of women have birth tears following vaginal deliveries [18]. Even after including episiotomy in the total number of ruptures in our project, we come nowhere close to 80% in any of the project periods. The reason for this could be differences in registration practices.

The sphincter group has evaluated the project, and they agree that its implementation requires cooperation, good information and acceptance among employees in order to succeed. A persistent focus is required if other labour wards want to implement a similar project.

A descriptive questionnaire study has explored the roles and responsibilities of the expert midwives involved in teaching staff how to reduce OASIS. The 18 included expert midwives afterwards deemed themselves better and more successful professionals than before [19]. This positive effect was also seen in our group. The four expert midwives have visited other maternity wards in Denmark to educate colleagues, and other departments have initiated similar projects to reduce OASIS.

Following an increased focus on preventative actions regarding OASIS, a national guideline on “Prevention of obstetric anal sphincter injuries (OASIS) in Denmark” has just been accepted by the Danish Society of Obstetrics and Gynaecology (DSOG).

CONCLUSION
Focusing on a more gentle delivery of the head with the support of perineum reduces the incidence of OASIS (Figure 1).
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LITERATURE