



# Does water birth affect the risk of obstetric anal sphincter injury? Development of a prognostic model

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## Abstract

**Introduction and hypothesis** Obstetric anal sphincter injury (OASI) is a significant complication of vaginal delivery. Water birth has become a popular preference for women giving birth in the UK, however, there is limited data on the risk of OASI following water birth. Our aim was to assess OASI risk in low-risk women giving birth in water without medical intervention compared with on land and to create a prognostic model for OASI prediction.

**Methods** This was a retrospective study of 15,734 low-risk women giving birth by spontaneous vaginal delivery between January 2008 and October 2014 in a midwifery-led unit (MLU). Patient factors and delivery data were analysed to identify differences between water and land births. Univariate analysis determined factors that statistically predicted OASI and was then used to create multivariate analysis. Significant multivariate factors were used to create a prognostic model to predict likelihood of OASI.

**Results** OASI rates were 1.6% on land and 3.3% in water [odds ratio (OR) 2.10, 95% confidence interval (CI) 1.5–2.94]. Multivariate analysis confirmed water birth, ethnicity and parity as independent risk factors for OASI (adjusted OR water birth: 1.77 (CI 1.25–2.51)). Our prognostic model showed Black and Asian primigravidae following water birth had the highest risk of OASI and white multiparae on land the lowest.

**Conclusion** This study of comparable low-risk women shows an increased risk of OASI following water birth compared with land birth. Use of this prognostic model will help women determine their risk of OASI following birth in water or on land.

**Keywords** Water birth · Obstetric anal sphincter injury

## Introduction

Over the last 20 years, water immersion during labour has become increasingly popular amongst women who desire an intervention-free, patient-controlled birth. Evidence has shown that water immersion during the first stage of labour is an effective form of pain relief [1], reducing the need for regional analgesia [2]. Labouring in water does not affect

labour duration or operative delivery rates [2]. Furthermore, it is safe for the newborn during labour and at birth [2]. Whilst some studies suggest that conducting the second stage of labour in water is associated with increased maternal satisfaction [2], there is little established evidence relating to maternal outcomes, including the risk of perineal trauma and obstetric anal sphincter injury (OASI) [2]. For the purpose of simplicity, births not in water are described as on land in this manuscript.

OASI is defined as injury to the perineum involving the anal sphincter complex [3]. It is a significant complication of vaginal birth and the leading cause of faecal incontinence in women [4]. Between 2000 and 2012, the rate of OASI tripled in the UK from 1.8 to 5.9% in primiparous women [5]. Correct OASI identification and repair results in 70% of women being asymptomatic at 6 month postnatal follow-up [6]; however, a large number of women remain symptomatic, reporting both faecal and flatus incontinence, faecal urgency and perineal and sexual problems. To avoid these potentially life-changing symptoms, it is important to prevent OASI whenever possible.

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Recent studies have suggested that perineal protection at birth reduces the risk of OASI [7, 8]. The Royal College of Obstetricians and Gynaecologists (RCOG) recommends perineal protection [3], and indeed, the OASI Care Bundle Project has been launched to promote hands-on protection of the perineum [9]. Whilst hands-on perineal protection is possible on land, it is difficult to perform during birth in water. Clinicians supporting women during water birth will therefore typically adopt the “hands-off the perineum” approach.

Two studies have reported a reduced risk of perineal trauma when giving birth in water compared with on land [10, 11]. However, these studies included episiotomies in their criteria for perineal trauma. Episiotomy is not possible during water birth, and the inclusion leads to difficulty in accurate interpretation of the results of these studies. Two studies have identified water birth as a risk factor for OASI [12, 13]. McPherson et al. [12], studying a large heterogeneous group of women, found water immersion and birth to be independent risk factors for OASI. Cortes et al. [13] demonstrated an increased risk following water birth in a group of low-risk women but did not correct for other significant variables. There is currently no published literature comparing low-risk, homogenous women with few modifiable risk factors for OASI. We hypothesised that giving birth in water increases the risk of OASI. The primary aim of this study was to determine whether water birth is an independent risk factor for OASI. We created a prognostic model to quantify OASI risk in low-risk women giving birth vaginally in order to establish any additional risk associated with giving birth in water.

## Methods

This was a retrospective study of low-risk women giving birth in a midwifery-led unit (MLU) in a large teaching hospital in the UK. Ethical approval was not required for this study. Data was collected from an electronic maternity database (Meditech) in which data was entered by midwives between January 2008 and October 2014. In 2015, there was local recognition of a possible increase in OASI after birth in water, and a national recognition of increased OASI rates for all births. To avoid capturing temporary changes in practice or unconscious bias, we analysed data prior to these changes in understanding.

The MLU was chosen to ensure that all women in the study were low risk in the antenatal and intrapartum periods. Eligibility for the MLU was determined prior to and on admission using locally set exclusion criteria. Exclusion criteria included all women with a significant medical condition, who developed problems during the antenatal period or deemed to be high risk in labour. All women were >37 weeks' gestation and laboured spontaneously. A full list of exclusion criteria can be found in Supplement 1.

All women in the MLU are offered the option of labouring in the pool when available. Progress in labour is assessed by midwives using a partogram, with stages and delays in progress determined as per National Institute for Health and Care (NICE) guidelines for labour [14]. If there were maternal or foetal concerns during labour, then women were advised to leave the pool. Women who required medical intervention and were transferred to the delivery suite were excluded, which included augmentation of labour, assisted delivery and episiotomy. Perineal trauma was assessed by the midwife following birth for women in the land group and  $\geq 1$  h following water birth. OASI included all 3A, 3B, 3C and fourth degree tears and was defined as per RCOG definitions [3]. OASI was confirmed by the attending doctor, with repair performed as per RCOG guidelines. Only women with OASI confirmed in the operating theatre were included in the study.

Patient factors and delivery data were collected and analysed to assess differences between birth in water and on land. Patient factors included age, ethnicity, booking, body mass index (BMI) and parity. Ethnicity was defined as white, black, Asian and other. Delivery data assessed birth weight in kilogrammes; length of first, second and active second stages of labour, use of opiate analgesia and shoulder dystocia. Data was analysed using independent *t* and Mann–Whitney *U* tests for continuous and a chi-squared test for categorical variables.

OASI rates on land and in water were calculated, and patient and delivery data were summarised and compared between women with and without OASI. A logistic regression model was constructed to determine whether water birth is an independent risk factor for OASI. All patient factors and delivery data were tested independently in a univariate analysis to determine whether they were significantly ( $p < 0.05$ ) related to the outcome variable.

Univariate analysis (Table 2) identified eight variables that were significantly different in women who experienced OASI compared with those who had not. Active pushing was categorised into 15-min intervals, which is more in keeping with our clinical practice. A multivariate model was constructed using one variable at a time in a step-wise manner. Variables were retained if  $p < 0.05$ . Previously retained variables were excluded if their new *p* value was  $> 0.1$ .

## Prognostic model

Two prognostic models were created for predicting the risk of OASI, including only variables that remained significant. The first model included variables that could be determined antenatally; in the second model, time of active pushing was included. Regression coefficients of these variables were used to create the models by which the risk of OASI for each individual woman was estimated.

## Results

Analysis was carried out on data of 15,734 eligible, low-risk term women having a spontaneous vaginal birth without medical intervention in the MLU. Of these women 14,490 (92.1%) gave birth on land, and 1244 (7.9%) in water. There were no clinically important differences in age, BMI and duration of labour, including active pushing, between women choosing to give birth in water and on land (Table 1). Each group had an average BMI of 24.7 and average age of 29.6 years in the land group and 29.7 years in the water group.

Women labouring for the first time were more likely to give birth in water (10.5%) compared with multiparous women (6.1%) ( $p < 0.001$ ). Asian and black women were less likely to choose to give birth in water compared with white women (3.6 vs 8.5%;  $p < 0.001$ ). Women giving birth in water were significantly less likely to require opiate analgesia than those giving birth on land. Only 12.1% of women required opiates during labour in water, compared with 44.7% of women labouring on land ( $p < 0.001$ ). Birth weight of babies born in water was somewhat higher than those born on land, with mean birth weights of 3521 and 3427 g, respectively.

### Primary outcome

The overall risk of OASI in the MLU was 1.76%. Initial analysis showed a 3.3% rate of OASI when giving birth in water

compared with 1.6% on land [odds ratio (OR) 2.10, 95% confidence interval (CI) 1.5–2.94]. Results of univariate analysis are shown in Table 2. A number of significant variables increased the risk of OASI, including place of birth, ethnicity, parity, opiate analgesia use, birth weight and length of all stages of labour.

Primiparous women were more likely to suffer OASI (2.8%) than were multiparous women (1.0%) who had previous vaginal births. Asian (3.3%) and black women (3.1%) were more likely to suffer OASI than white women (1.6%). The length of each stage of labour was significantly longer in the OASI group. First stage of labour was an average of 20 min longer in the OASI group ( $p = 0.01$ ), total second stage was 24 min longer ( $p < 0.001$ ) and active second stage was 10 min longer ( $p < 0.001$ ). Birth weight in the OASI group was significantly less than the non-OASI group: 3434 vs 3641 g, respectively ( $p < 0.01$ ). There was no significant difference in age, BMI, need for opiate analgesia and rate of shoulder dystocia. A multivariate logistical regression model was constructed (Table 3). Eight significant variables were identified in univariate analysis (Table 2) and carried forward, but only four of these were significant and retained in the final multivariate model.

Multivariate analysis revealed an adjusted OR for OASI in water of 1.77 (CI 1.25–2.51). Multiparous women had less than half the risk of suffering OASI compared with women giving birth to their first baby (OR 0.39, CI 0.29–0.52). Asian

**Table 1** Comparison of demographic factors between land and water groups

| Variables                                       | Land<br>14,490   | Water<br>1244    | Significance     |
|---|------------------|------------------|------------------|
| Age (mean, SD)                                  | 29.57 (5.50)     | 29.69 (5.58)     | $P = 0.5$        |
| Ethnicity (%) <sup>*</sup>                      |                  |                  | $P < 0.001$ **** |
| White   | 12,246 (84.8)    | 1139 (91.7)      |                  |
| Asian   | 551 (3.7)        | 21 (1.7)         |                  |
| Black   | 502 (3.4)        | 19 (1.5)         |                  |
| Other   | 1177 (8.1)       | 63 (5.1)         |                  |
| Unknown   | 14               | 2                |                  |
| Parity (%) <sup>*</sup>                         |                  |                  | $P < 0.001$ **** |
| Primi   | 5749 (39.7)      | 675 (54.3)       |                  |
| Multi   | 8741 (60.3)      | 568 (45.7)       |                  |
| Unknown   |                  | 1                |                  |
| BMI (mean, SD) <sup>**</sup>                    | 24.7 (4.68)      | 24.7 (4.41)      | $P = 0.98$       |
| Opiate analgesia (%) <sup>*</sup>               |                  |                  | $P < 0.001$ **** |
| No  | 8019 (55.3)      | 1093 (87.9)      |                  |
| Yes   | 6471 (44.7)      | 151 (12.1)       |                  |
| Birth weight (mean, SD)                         | 3426.89 (451.62) | 3520.93 (436.02) | $P < 0.001$ **** |
| First stage (h:min) median (IQR) <sup>***</sup> | 4:00 (4:10)      | 3:55 (3:40)      | $P = 0.85$       |
| Second stage (h:min)                            | 0:20 (0:43)      | 0:21 (0:35)      | $P = 0.84$       |
| Median (IQR) <sup>***</sup>                     |                  |                  |                  |
| Active pushing (h:min)                          | 0:15 (0:27)      | 0:15 (0:24)      | $P = 0.08$ ****  |
| Median (IQR) <sup>***</sup>                     |                  |                  |                  |
| Shoulder dystocia (%) <sup>*</sup>              |                  |                  | $P = 0.65$       |
| No  | 14,403 (99.4)    | 1236 (99.5)      |                  |
| Yes   | 87 (0.6)         | 8 (0.5)          |                  |

Primi primiparous, Multi multiparous, SD standard deviation, BMI body mass index, IQR interquartile range

<sup>\*</sup>Chi-squared test, <sup>\*\*</sup>independent sample *t* test, <sup>\*\*\*</sup>Mann–Whitney *U* test, <sup>\*\*\*\*</sup>statistical significance

**Table 2** Comparison between obstetric anal sphincter injury (OASI) and non-OASI groups

| Variables                             |         | OASI ( <i>n</i> 273) | No OASI ( <i>n</i> 15,461) | Significance        |
|---------------------------------------|---------|----------------------|----------------------------|---------------------|
| Water Birth (%)                       | No      | 232 (85)             | 14,258 (92.2)              | <i>P</i> < 0.001*** |
|                                       | Yes     | 41 (15)              | 1203 (7.8)                 |                     |
| Age (Mean SD)                         |         | 29.56 (5.22)         | 29.58 (5.51)               | <i>P</i> = 0.94     |
| Ethnicity (%)*                        | White   | 218 (79.9)           | 13,167 (85.3)              | <i>P</i> < 0.002*** |
|                                       | Asian   | 19 (7.0)             | 553 (3.6)                  |                     |
|                                       | Black   | 16 (5.9)             | 505 (3.3)                  |                     |
|                                       | Other   | 20 (7.3)             | 1220 (7.9)                 |                     |
|                                       | Unknown |                      | 16                         |                     |
| Parity (%)*                           | None    | 183 (67.3)           | 6241 (40.4)                | <i>P</i> < 0.001*** |
|                                       | None    | 89 (32.7)            | 9220 (59.6)                |                     |
|                                       | Missing | 1                    |                            |                     |
| BMI (mean; SD)                        |         | 24.76 (4.20)         | 24.70 (4.67)               | <i>P</i> = 0.84     |
| Pain relief (%)                       | No      | 141 (51.6)           | 8971 (58)                  | <i>P</i> = 0.03***  |
|                                       | Yes     | 132 (48.4)           | 6490 (42)                  |                     |
| Birth Weight (mean; SD)               |         | 3434.21 (451.12)     | 3641.60 (457.87)           | <i>P</i> < 0.001*** |
| First stage (h:min) Median (IQR)**    |         | 4:20 (4:30)          | 4:00 (4:05)                | <i>P</i> = 0.01***  |
| Second stage (h:min) Median (IQR)**   |         | 0:44 (1:01)          | 0:20 (0:42)                | <i>P</i> < 0.001*** |
| Active pushing (h:min) Median (IQR)** |         | 0:25 (0:35)          | 0:15 (0:27)                | <i>P</i> < 0.001*** |
| Shoulder dystocia (%)*                | No      | 272 (99.6)           | 15,369 (99.4)              | <i>P</i> = 0.63     |
|                                       | Yes     | 1 (0.4)              | 92 (0.6)                   |                     |

*SD* standard deviation, *BMI* body mass index, *IQR* interquartile range

\*Chi-squared test, \*\*Mann–Whitney *U* test, \*\*\*statistical significance

and black women were more likely to experience OASI than white women (Asian: OR 2.29, CI 1.42–3.71; black: OR 2.38, CI 1.41–4.01). We found that an active second stage of between 15 and 60 min significantly increased the risk of OASI. Women with an active second stage of between 60 and 75 min demonstrated the highest risk of OASI (OR 2.63, CI 1.64–4.21). Four variables, birth weight, pain relief and length of first and second stages of labour lost significance and were excluded from the models.

### Prognostic model

Antenatal risk factors were used to develop the first model (Table 4). Two significant variables from multivariate analysis, parity and ethnicity, were used to predict OASI risk for water vs land birth. This model found white multiparous women to have the lowest risk for OASI and black primiparae the highest. OASI risk for all groups was higher in births in water compared with on land.

The highest risk group, black primiparae giving birth in water, had a 9.7% OASI risk compared with 6.0% on land. Black multiparae had a 3.6% risk in water compared with 2.2% on land. The lowest risk group was white multiparous women giving birth on land, with a 0.8% risk of OASI compared with 1.3% following water birth. The OASI risk in our most prevalent group of women, white primiparae, was 3.8%

in water compared with 2.3% on land. Asian women had an increased OASI risk compared with white women, with a 2.6% risk in multiparous women in water compared with 1.6% on land. This risk increased in Asian primiparous women, with rates of 7.2% in water and 4.4% on land.

Our second model used the original multivariate analysis and included active second stage (Table 3). OASI risk increased with increasing length of active second stage for all groups, with the highest increase after 60–75 min of active pushing. A second stage of between 45 and 60 min increased OASI risk in white primiparae giving birth in water from 3.8% to 5.0%, rising to 7.8% after 60 to 75 min. In black primiparae giving birth in water, the risk of OASI increased from 9.7% to 11.2% after 45 to 60 min, increasing further to 16.8% after 60–75 min. In white multiparae, the risk following birth in water rose from 1.3% to 2% after 45–60 min and 3.2% after 60–75 min.

Both risk models can be found in Supplement 2.

### Discussion

This is the first study of a large number of low-risk, homogeneous women, giving birth vaginally without medical intervention and by a similar group of midwives. The overall risk for OASI of 1.76% in this study was less than the UK average

**Table 3** Multivariate prognostic model

| Variable                 | Regression Coefficient | Significance | OR (95% CI)      |
|--------------------------|------------------------|--------------|------------------|
| Constant                 | −4.01                  |              |                  |
| Parity                   | Reference              |              |                  |
| Primi                    | −0.95                  | P < 0.001    | 0.39 (0.29–0.52) |
| Multi                    |                        |              |                  |
| Place                    | Reference              |              |                  |
| MLU                      | 0.57                   | P = 0.001    | 1.77 (1.25–2.51) |
| MLU pool                 |                        |              |                  |
| Ethnicity                | Reference              |              |                  |
| White                    | 0.83                   | P = 0.001    | 2.29 (1.42–3.71) |
| Asian                    | 0.87                   | P = 0.001    | 2.38 (1.41–4.01) |
| Black                    | 0.07                   | P = 0.77     | 1.07 (0.67–1.71) |
| Other                    |                        |              |                  |
| Active pushing (min) <15 | Reference              |              |                  |
| 15–29                    | 0.53                   | P < 0.001    | 1.70 (1.23–2.36) |
| 30–44                    | 0.41                   | P = 0.045    | 1.52 (1.01–2.29) |
| 45–59                    | 0.50                   | P = 0.041    | 1.65 (1.02–2.66) |
| 60–75                    | 0.97                   | P < 0.001    | 2.63 (1.64–4.21) |
| 75+                      | −0.30                  | P = 0.27     | 0.74 (0.44–1.26) |

*Primi* primiparous, *Multi* multiparous, *SD* standard deviation, *BMI* body mass index, *IQR* interquartile range, *MLU* midwifery-led unit, *OR* odds ratio, *CI* confidence interval

\*Chi-squared test, \*\*independent sample *t* test, \*\*\*Mann–Whitney *U* test, \*\*\*\*statistical significance

of 2.9% [15]. The risk in water was higher, at 3.3%. The low OASI rate is expected in this low-risk group of women due to the absence of medical intervention.

Secondary outcomes have, in general, supported previously published literature and identified known risk factors for OASI. An increased risk of perineal tears in Asian women has been well documented in a number of studies. It is thought that this may be due to anatomical differences, with a shorter perineum being associated with an increased risk of OASI [5]. An increased OASI risk in black women has been noted in three previous studies [12, 16, 17]; however, the link between

this ethnic group and OASI is not yet established. Studies on the incidence of perineal trauma have consistently found an increased risk of trauma in primiparous women, regardless of method of vaginal birth [5, 18].

### Strengths and limitations

The main strength of this study is the inclusion of only low-risk women delivering without medical interventions, which have been shown to increase the risk of OASI. This ensured minimal variables between groups that may have influenced primary outcome. Secondly, our MLU is staffed by a small number of midwives who support low-risk women opting for water or land birth. There is little variation in clinical practice that could influence the rate of OASI. Finally, this is the first study to describe a prognostic model for use by healthcare workers and low-risk women to determine individual OASI risk for giving birth on land or water birth, enabling an informed choice when preparing for labour and birth.

Our main limitation is a lack of data regarding the duration of time spent in water and on women who exited the pool to give birth on land. This information would be useful to understand the aetiology of OASI in water birth and whether water immersion is associated with a change in perineal tissues, which then may increase the risk of perineal injury and OASI. Whilst our prognostic model can help women decide on whether to give birth on land

**Table 4** Multivariate analysis for model 1 (antenatal prediction)

| Variable  | Regression Coefficient | Significance | OR (95% CI)       |
|-----------|------------------------|--------------|-------------------|
| Constant  | −3.69                  |              |                   |
| Parity    | Reference              |              |                   |
| Primi     | −1.105                 | P < 0.001    | 0.33 (0.26, 0.43) |
| Multi     |                        |              |                   |
| Place     | Reference              |              |                   |
| MLU       | 0.61                   | P = 0.001    | 1.84 (1.30, 2.51) |
| MLU pool  |                        |              |                   |
| Ethnicity | Reference              |              |                   |
| White     | 0.84                   | P = 0.001    | 2.32 (1.43, 3.74) |
| Asian     | 0.84                   | P = 0.002    | 2.32 (1.38, 3.89) |
| Black     | 0.08                   | P = 0.74     | 1.08 (0.68, 1.72) |
| Other     |                        |              |                   |

*Primi* primiparous, *Multi* multiparous, *MLU* midwifery-led unit, *OR* odds ratio, *CI* confidence interval

or in water, it cannot determine the risk of OASI when labouring in water and exiting for land birth. There were no data regarding the position in which women gave birth, either on land or in water. One study comparing the risk of perineal trauma at birth in various maternal positions found that squatting and kneeling positions increased the risk of perineal tears compared with birth positions on the bed and in water [19]. It is possible that positions chosen on land differ from those in the water, therefore potentially influencing results.

## Interpretation

Previous studies have identified water birth as a risk factor for OASI [12, 13]. In contrast with our own, these studies did not control for potentially interacting variables. Ours is the first to identify water birth as an independent risk factor for OASI in a homogenous, low-risk group of women giving birth vaginally and without medical intervention. Although an increased risk of OASI for women giving birth in water has been demonstrated, the mechanism behind this remains unclear. There are two main hypotheses as to the aetiology of this increased risk: perineal support and perineal oedema. A number of studies have shown a strong relationship between perineal protection techniques and reduced rates of OASI [7, 8]. A Norwegian study of four obstetric units showed a significant reduction in OASI rates following the introduction of an intervention programme involving control of the foetal head with the left hand and protection of the perineum under the neonate's chin with the right hand [7].

The pool design in our unit does not allow for the midwife to perform hands-on protection of the perineum at birth. Whilst the woman can be encouraged to provide their own perineal protection, this was not documented in delivery notes. Furthermore, hands-on or hands-off protection during birth on land was not routinely documented. At the time of data collection, there was no guidance as to whether to use hands on or off techniques at birth, and therefore, midwives would perform their preferred technique. There is, therefore, no objective evidence to support the assumption that hands-on protection was more likely to be carried out on land.

It is possible that prolonged labour in water may result in perineal oedema, weakening perineal tissue and increasing risk of tear. There is, however, very little literature available on the potential effects of water immersion on these possibilities. One study investigating risk factors for OASI found that in women giving birth on land, severe perineal oedema was associated with a sixfold increase in OASI [20]. The cause of perineal oedema is likely due to prolonged labour, and it cannot be assumed that oedema caused by water immersion would have similar results. It has been proposed that labouring in water may reduce the risk of perineal injury by increasing elasticity of the birth canal and perineum [13]. However, two

randomised controlled trials (RCT) [21, 22] comparing land and water labours, where both groups gave birth on land, found no significant difference in perineal tear rates. Based on these studies, we cannot draw conclusions regarding the risk of perineal trauma in women who labour in water and give birth on land.

Several studies have attempted to create a prognostic model for OASI [12, 23, 24]. These models, which could not be used clinically due to low predictive values, used heterogeneous groups of women requiring medical intervention, such as induction of labour, episiotomy and instrumental delivery. Our models are based on a large homogeneous group of low-risk women giving birth without medical intervention. Our antenatal model can be used to calculate personal risk for OASI when giving birth on land or in water. This will allow women to make an informed choice regarding their preferred birthing method based on their individual risk factors. The second model included calculation of risk as active second stage lengthens. Whilst our model can quantify the added OASI risk of longer active second stage, we have insufficient data to conclude that exiting the pool will alter this risk and therefore cannot be used in clinical practice. Future research should prospectively test different interventions and timings of the same in women at high risk of OASI who wish to give birth in water. Interventions include leaving the pool at certain points to continue active pushing on land with or without episiotomy or instrumental delivery.

## Conclusion

This study has shown an increased rate of OASI in low-risk women giving birth vaginally following water birth compared with on land. Our prognostic model can be used to inform low-risk women giving birth in MLU on their individual risk of OASI, allowing them to make their own informed decision on whether to give birth in water or on land. Further studies should research the relationship between labouring in water and the risk of OASI and explore interventions that may be offered when the risk of OASI in water becomes unacceptably high.

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## Compliance with ethical standards

**Conflicts of interest** None.

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