

Dear Dr. Papageorghiou,

We thank de Leeuw et al. for their interest in The POOL cohort study.¹ [ref letter] The primary study aim was to determine, among women without risk factors who used intrapartum water immersion in the UK, whether waterbirth was associated with increased rates of OASI or neonatal morbidity, compared to leaving the water prior to birth.

The overall rates of OASI in the POOL study among waterbirths and births out of water were 2.5% and 3.8% (aOR 0.89, 1-sided 95% CI $-\infty$ to 0.98). These were unfortunately not as remarkable as suggested. A previous UK study of spontaneous vaginal births in England during 2015-2016² reported OASI rates among women of all parity of 3.16% in births out of water and 3.56% among waterbirths, (aOR 1.00 (1-sided 95% CI 0.86 to 1.16).

The highest rate of OASI found in the POOL study was among nulliparous women giving birth out of water (5.3%). This was not dissimilar to rates found in a randomised trial³ conducted in Sweden between 2018 and 2020. The trial compared policies of two midwives or a single midwife being present during spontaneous vaginal births to nulliparous women, with rates of OASI of 3.9% and 5.7% in the intervention and control groups (adjusted OR (aOR) 0.69, 95% CI 0.49 to 0.97).

The OASI care bundle, including manual perineal protection, was implemented in 16 UK maternity units from January 2017. The programme had modest effectiveness with a non-significant reduction in OASI rates among nulliparous women 5.2% to 4.9%; (aOR 0.81, 95% CI 0.65 to 1.00), a reduction during spontaneous vaginal births overall from 2.6% to 2.2% (aOR 0.75, 95% CI 0.60 to 0.93) and no reduction in OASI during births assisted with forceps, 7.6% to 7.6% (aOR 0.88, 95% CI 0.69 to 1.14).⁴ Results of the evaluation of the UK OASI care bundle were published in 2021, six years after the commencement of data collection for the POOL study. As manual perineal protection was not recommended practice in the UK during the period of designing the POOL study in 2018, data relating to the use of manual perineal protection were not collected.

We dispute that the rate of OASI reported among births out of water suggest the study was biased and remain confident in the study's findings. The study used a no consent model ensuring a close to complete cohort of eligible women giving birth over a 7.5 year period without selection bias. The pre-determined sample size provided sufficient power for good precision around the estimate of OASI among parity sub-groups. It remains possible that there is some unexplored rationale for the absolute higher rate of OASI among nulliparous and parous women giving birth out of water, and recognising the observational, and not randomised study design, we did not conclude that birth in water was 'protective' of OASI but is 'non-inferior'.

OASI remains an important birth outcome warranting further research, including robust testing of interventions. The POOL study generated important information with accessible results already available.

https://www.cardiff.ac.uk/__data/assets/pdf_file/0007/2821489/POOL-Study-Using-a-pool-during-labour-and-birth.pdf

AUTHOR CONTRIBUTIONS

JS and BC-J wrote the first draft of the letter, all authors contributed.

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None.

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CONFLICT OF INTEREST STATEMENT

None.

ETHICS APPROVAL

Research Ethics Committee (REC) approval was granted by the REC for Wales (18/WA/0291), and the transfer and use of identifiable data was approved by the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) (18/CAG/0153).

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