

The Odon Device for assisted vaginal birth – the ASSIST II study

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Objective

Assisted vaginal birth (AVB) is recognised by the WHO as a critical component of basic emergency care. However, worldwide AVB rates have declined. Complications, public perception, insufficient training in device use and device availability may have all contributed to this decline.

The Odon Device (OD) is a novel device for AVB undergoing clinical feasibility testing that may provide a new method for AVB.

Design

Single-arm feasibility study in a single UK Maternity Unit. OD was used in 104 women who required an AVB for a recognised clinical indication. Outcomes for a 'nested cohort' of women who had consented to participate and needed an AVB but were unable to have an OD assisted birth due to operator unavailability were collected.

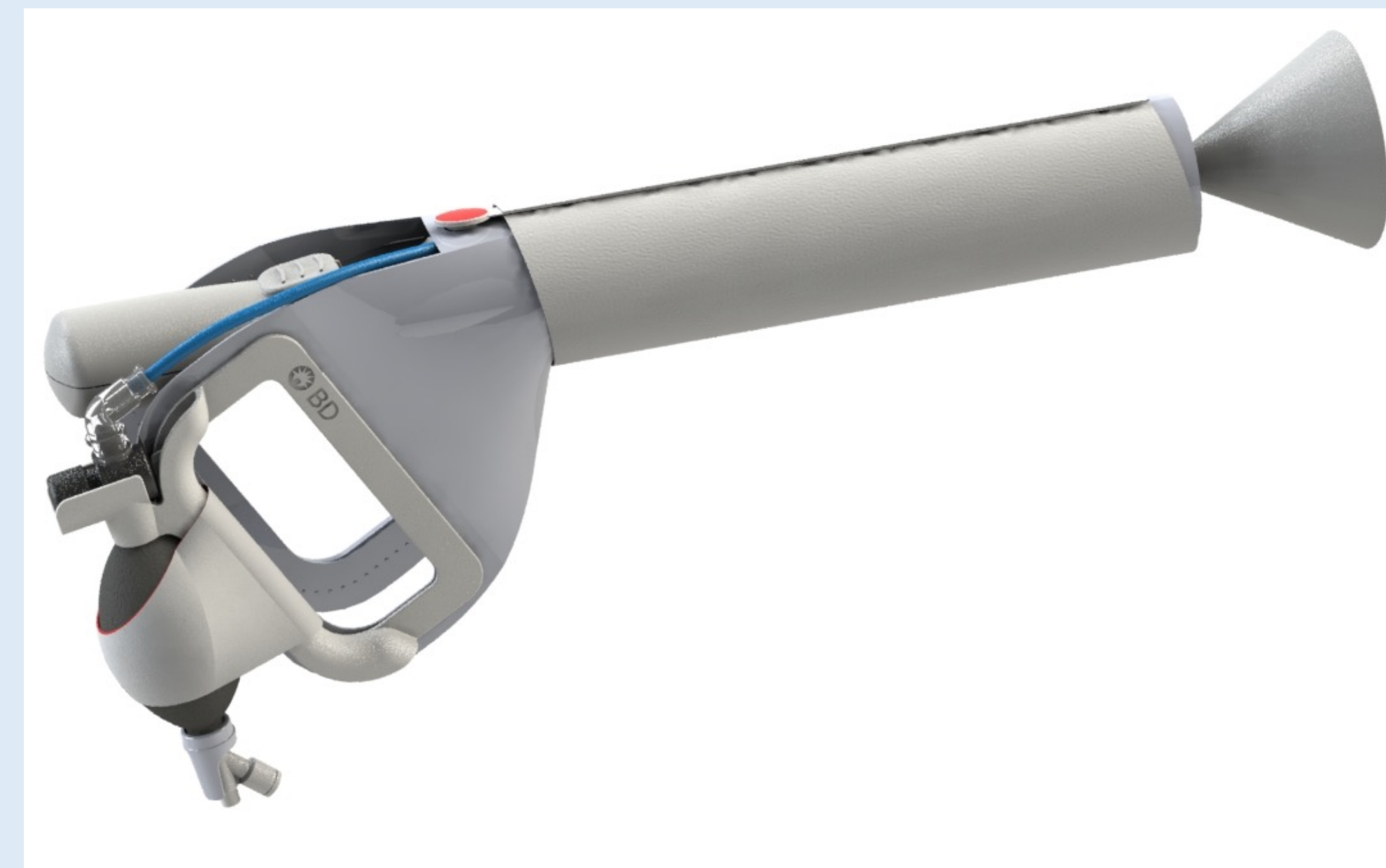
Method

Women were approached antenatally or intrapartum and consented using an innovative video method. If a potential participant required an AVB, the birth was assisted with the OD by one of 12 trained obstetricians.

Primary clinical outcome: proportion of births successfully assisted with the OD.

'Successful' was a vaginal birth expedited with the OD with no serious maternal or neonatal adverse reactions related to device use.

Secondary outcomes: metrics related to study feasibility and maternal, neonatal and device safety. Neonates were followed up to day 28 and mothers to day 90-post birth.



Results

Between 9th August 2019-7th June 2021, 2646 women were screened to participate, the OD was used in 104 cases with 22 nested cohort cases. 69/104 (66%) of births were successfully assisted with the OD.

Birth: Fetal position at time of AVB with OD was: 83 OA, 11 OP, 10 OT with 59 at station +1, 34 at station +2 and 11 at station +3. Forty births were assisted for prolonged stage and 63 for presumed fetal compromise. Median decision to delivery interval was 22 minutes (20 successful, 40 unsuccessful, 22 nested).

Maternal: Median blood loss was 803ml (800 successful, 811 unsuccessful, 831 nested).

There were 93 (89%) episiotomies, 22 (21%) second, eight (8%) third and two (2%) fourth degree tears.

Neonatal: Two babies had an Apgar score <7 at 5 mins, and there was one umbilical artery pH <7.0. Seven babies were admitted to NICU (2 successful, 5 unsuccessful). Ten babies had a cephalohaematoma (5 successful, 5 unsuccessful).

Conclusion

It is feasible recruit women to a study using a novel device for AVB. The OD can be used, and outcomes collected from women, their babies and the device. There is now a need to evaluate its efficacy against currently used devices in a randomised controlled trial. Further exploration of the device in low- and middle-income settings is also warranted.

