OBSTETRICS

The OdonAssist inflatable device for assisted vaginal birth—the ASSIST II study (United Kingdom)

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BACKGROUND: Decreasing rates of assisted vaginal birth have been paralleled with increasing rates of cesarean deliveries over the last 40 years. The OdonAssist is a novel device for assisted vaginal birth. Iterative changes to clinical parameters, device design, and technique have been made to improve device efficacy and usability.

OBJECTIVE: This study aimed to determine if the feasibility, safety, and efficacy of the OdonAssist device were sufficient to justify conducting a future randomized controlled trial.

STUDY DESIGN: An open-label nonrandomized study of 104 participants having a clinically indicated assisted vaginal birth using the OdonAssist was undertaken at Southmead Hospital, Bristol, United Kingdom. Data were also collected from participants who consented to participate in the study but for whom trained OdonAssist operators were not available, providing a nested cohort. The primary clinical outcome was the proportion of births successfully expedited with the OdonAssist. Secondary outcomes included clinical, patient-reported, operator-reported, device and health care utilization. Neonatal outcome data were reviewed at day 28, and maternal outcomes were investigated up to day 90. Given that the number of successful OdonAssist births was ≥61 out of 104, the hypothesis of a poor rate of 50% was rejected in favor of a good rate of ≥65%.

RESULTS: Between August 2019 and June 2021, 941 (64%) of the 1471 approached, eligible participants consented to participate. Of these, 104 received the OdonAssist intervention. Birth was assisted in all cephalic vertex fetal positions, at all stations ≥1 cm below the ischial spines (with or without regional analgesia). The OdonAssist was effective in 69 of the 104 (66%) cases, consistent with the hypothesis of a good efficacy rate. There were no serious device-related maternal or neonatal adverse reactions, and there were no serious adverse device effects. Only 4% of neonatal soft tissue bruising in the successful OdonAssist group was considered device-related, as opposed to 20% and 23% in the unsuccessful OdonAssist group and the nested cohort, respectively. Participants reported high birth perception scores. All practitioners found the device use to be straightforward.

CONCLUSION: Recruitment to an interventional study of a new device for assisted vaginal birth is feasible; 64% of eligible participants were willing to participate. The success rate of the OdonAssist was comparable to that of the Kiwi OmniCup when introduced in the same unit in 2002, meeting the threshold for a randomized controlled trial to compare the OdonAssist with current standard practice. There were no disadvantages of study participation in terms of maternal and neonatal outcomes. There were potential advantages of using the OdonAssist, particularly reduced neonatal soft tissue injury. The same application technique is used for all fetal positions, with all operators deeming the device straightforward to use. This study provides important data to inform future study design.

Key words: assisted vaginal birth, BD Odon Device, feasibility, intrapartum research, management of second stage of labor, medical device, obstetrical forceps, OdonAssist, operative vaginal delivery, perineal laceration, safety, vacuum, ventouse

Introduction

Rates of assisted vaginal birth have declined across the world in recent years, in parallel with an increase in cesarean deliveries in the second stage of labor.[1,2] This has important consequences for avoidable maternal and neonatal morbidity[2–4] and contradicts the reported preferences of participants in both high- and low-income settings for assisted vaginal birth over emergency cesarean delivery.[5,6] Precise reasons underpinning the decline are unclear, with drivers that likely vary among settings, but may include lack of functioning equipment, lack of staff training, suboptimal supervision or support, and fear of litigation.[7]

The findings of the ASSIST (Assisted Vaginal Birth) study, the first Stage 2a feasibility study of the OdonAssist inflatable device for assisted vaginal birth (illustrated in Figures 1 and 2), were published in 2021.[8,9] The OdonAssist was previously called the BD Odon Device; its name was changed when a new manufacturer took on the development of the device. A Stage 2a medical study is defined as a small-scale exploratory study investigating device feasibility and technique on the basis of the IDEAL (Idea, Development, Exploration, Assessment, Long-term study) framework that has been established to evaluate and provide methodology for robust medical device research.[9,10] This framework emphasizes the importance of early development and exploratory studies to assess safety, efficacy, and learning curve evaluation.[9,10] It is anticipated that there may be iterative changes to the device during this stage. There is an expectation that this will lead to Stage 2b research, which usually involves larger-scale exploratory research focusing on quality control, outcome expectations, and learning curve.[9,10] Following this, Stage 3 research can safely be undertaken, involving a randomized controlled trial (RCT) of the investigational medical device against the standard alternatives.[9]

The initial ASSIST study was undertaken in Southmead Hospital, Bristol, United Kingdom between 2018 and 2019, and reported the feasibility of recruiting to intrapartum assisted

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AJOG at a Glance

Why was this study conducted?

This study aimed to investigate whether the safety and efficacy of the OdonAssist were sufficient to conduct a future randomized controlled trial of the device.

Key findings

In this study involving 104 participants who clinically required assisted vaginal birth for standard UK indications, the success rates of the OdonAssist device increased from 48% (19/40) in a previous study to 66% (69/104) in the current study. Maternal and neonatal outcomes indicated that adverse effects associated with the use of the OdonAssist device were relatively low. There were potential advantages for neonatal outcomes, with only 4% (3/69) of the successful OdonAssist group experiencing any device-related adverse effects in the form of neonatal soft tissue bruising, as opposed to 20% (7/35) and 23% (5/22) of the unsuccessful OdonAssist group and the nested cohort, respectively. However, further research is needed to fully understand the risks and potential adverse effects associated with the use of the device.

What does this add to what is known?

The study demonstrated that increased device understanding and improvements in technique were associated with significantly higher success rates of the OdonAssist device for assisted vaginal birth (P=.382, 2-sided). The increased success rates provide a basis for future randomized controlled trials to evaluate the safety and efficacy of the device.

vaginal birth research with initial data for efficacy, safety, and acceptability[11] of the OdonAssist in 40 births expedited for standard indications.[8] The device was used following UK guidance for all cephalic vertex presentations at station spines or below. None of the assisted births at station spines were successful. The success rate of the OdonAssist was 48% (19/40), which was lower than the reported success rates of both vacuum (88%) and forceps (93%).[12,13] This low success rate was not unexpected given that it was the first time that the device was used to expedite birth for clinical indications. As expected, there were important findings for optimal device use, device design, and clinical parameters.[14] Notably, 10% (4/40) of the devices were ineffective because of a manufacturing fault in the bulb pump mechanism for inflating the air-cuff.[8]

The aim of the current ASSIST II study was to investigate whether the safety and efficacy of the OdonAssist and feasibility of data collection were sufficient for a future RCT.[15] The objectives were to: (1) investigate the safety profile of the OdonAssist, (2) evaluate the success of the OdonAssist to inform the sample size and feasibility of future research, (3) determine participation rates and reasons for nonparticipation, (4) determine participants' satisfaction with the OdonAssist, and (3) assess the feasibility of collecting outcome data from a control group.

Materials and Methods

Study design

A single-arm feasibility observational study (Stage 2b)[9] of the OdonAssist for 104 participants who required an assisted vaginal birth for a recognized clinical indication was undertaken. Data were also collected from a nested cohort of participants who had consented to participate in the ASSIST II study but whose delivery was expedited using forceps or ventouse because of unavailability of an OdonAssist operator (Figure 3). Evaluation of these data will inform the development of protocols for future research, including RCTs comparing the OdonAssist with current alternative devices.

The ASSIST II study protocol has been published,[15] and includes qualitative work to explore best practice for information provision, and consent for intrapartum research.[16] The published protocol summarizes the protocol submitted to the ethics committee before the commencement of the study. During the study, 2 substantial and 6 nonsubstantial protocol amendments were made. These amendments were related to change in recruitment methodology because of the COVID-19 pandemic, adding COVID-19 as an exclusion criterion, including additional data collection on perineal protection, and the change of device from V4.1 to V4.2. These changes did not significantly alter the overall methodology of the study and are included in the methodology section.

Population

Potential participants were approached during any antenatal visit to Southmead Hospital, North Bristol NHS Trust, Bristol, United Kingdom. Figure 4 outlines eligibility criteria for initial consent and allocation to the intervention, consistent with standard UK criteria for assisted vaginal birth.[12] To provide consent, participants needed to be at ≥28+0 weeks' gestation and <4 cm of cervical dilation without any regional analgesia in place. One important difference between this protocol and our previous study was that births were only assisted if at station +1 and below, as opposed to at or below the spines.[15,17] Participants were provided with study information using an information leaflet and video-based information, including a demonstration of the OdonAssist.[16]

FIGURE 1
The OdonAssist

A 3D figure of the complete OdonAssist when it is ready for use. 2023 Maternal Newborn Health Innovations, PBC. Permission for publication granted by Maternal Newborn Health Innovations, PBC.

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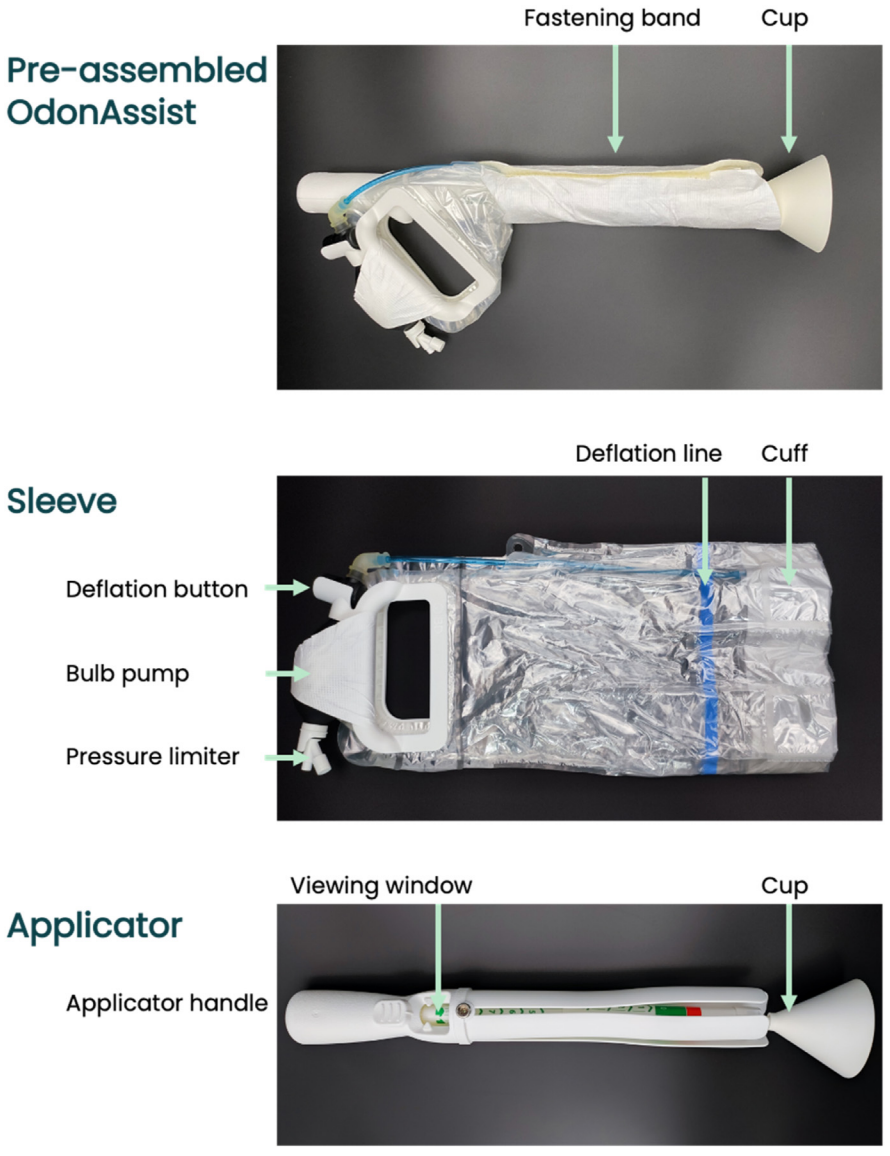
FIGURE 2
Components of the OdonAssist



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Intervention

OdonAssist births were conducted by 13 obstetricians who had undergone specialized training on high-fidelity mannequins.[8,15] If OdonAssist was unsuccessful, the obstetricians used their clinical judgment to complete the birth (using a second OdonAssist device, ventouse, forceps, or cesarean delivery). All OdonAssist devices were immediately systematically examined after use for faults by a member of the research team and then later by a member of the manufacturing team.

Outcomes

The primary outcome was the proportion of births successfully assisted with OdonAssist. A birth was defined as successful if it was expedited only with OdonAssist and there were no serious maternal or neonatal adverse reactions[18] related to the use of the device. Secondary outcomes included metrics related to study feasibility and maternal, neonatal, and device safety (Figure 5). Neonates were followed up until day 28 and mothers until day 90. All neonatal injury was assessed by consultant neonatologists to determine whether it was related to the device.

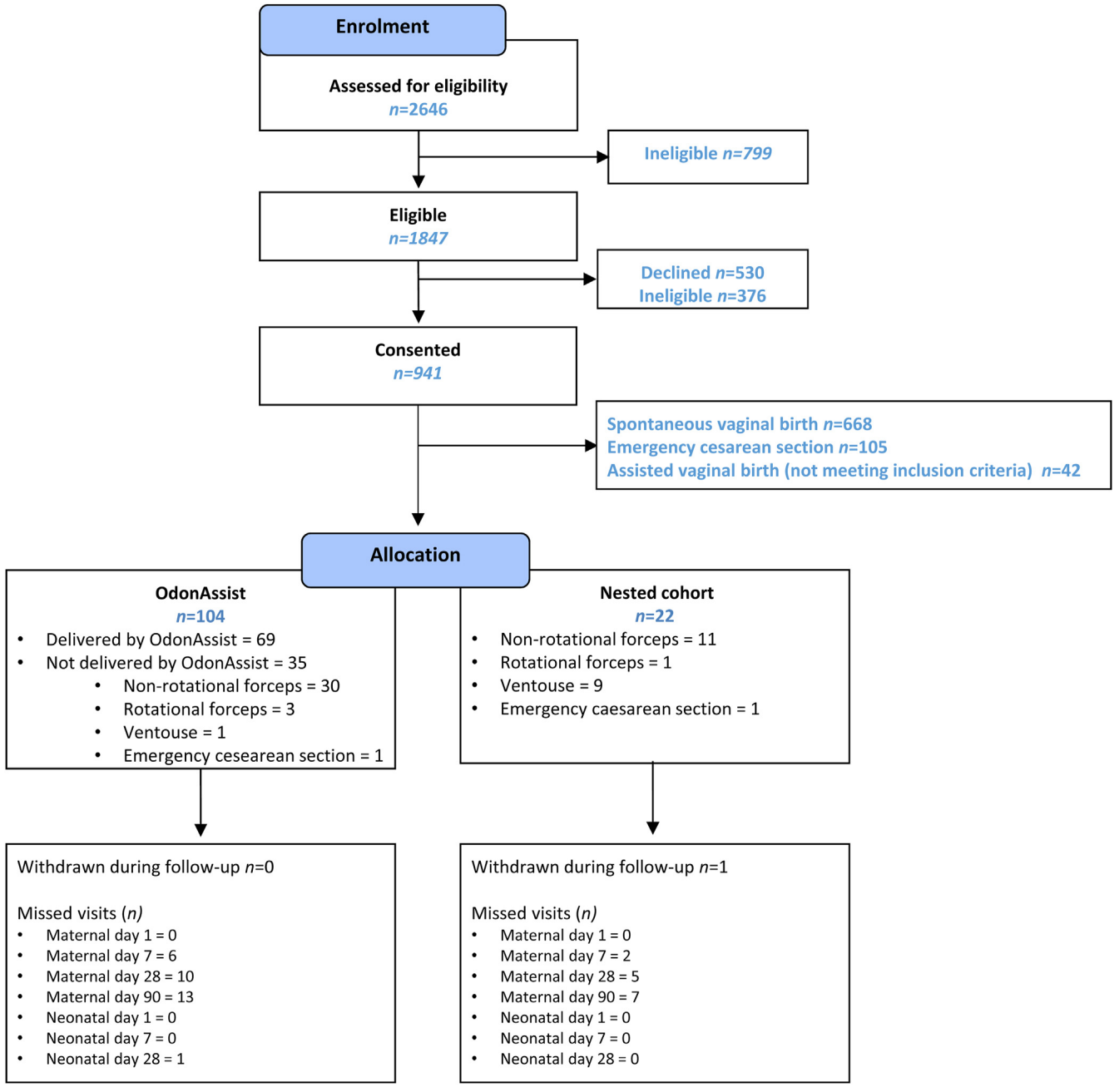
Sample size

The A'Hern approach[19] for sample size calculation was applied in PASS 15 Power Analysis and Sample Size software (NCSS, LLC, Kaysville, UT; URL: www.ncss.com/software/pass). Assuming that a poor success rate of an assisted vaginal birth device would be ≤50% and a good success rate would be ≥65%, with 1-sided alpha risk of 5% and power of 90%, a study with 104 participants would be required. If the number of successful OdonAssist births is ≥61 out of 104, the hypothesis of a poor rate of ≤50% is rejected in favor of a good rate of ≥65%. The 65% threshold was based on a previous study of a new ventouse device in the same unit.[20] The A'Hern approach is a robust and directional statistical method for differentiating between a null hypothesis of a poor success rate and a good success rate,[19] which are assumed to be ≤50% and ≥65%, respectively. In our study, the prospective A'Hern decision rule is on the basis of these parameters, and accomplishing ≥61 successful births out of 104 would indicate that the poor rate of ≤50% is not readily plausible and an assumed good rate is more likely to be tenable. Given that 69 (66%) attempts were successful, the poor rate of ≤50% was excluded.

Statistical analysis

Data were entered and stored on a bespoke study database (GeneSYS) designed and managed by the Clinical Trial and Evaluation Unit, University of Bristol, United Kingdom. Data were analyzed using Stata, version 15.1 (StataCorp, College Station, TX). Continuous variables are reported as mean and standard deviation, or median and

FIGURE 3
Patient flow diagram



Patient flow diagram for the ASSIST II study including enrollment, allocation, and follow-up.

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interquartile range; categorical variables are reported as frequency and percentages. Relationships between characteristics that affect the success of the OdonAssist were explored using modified Poisson regression and Fisher exact test. Given that this is a feasibility study, these comparisons are exploratory.

Ethics

The study was approved by South Central—Berkshire Research Ethics Committee, United Kingdom on May 29, 2019 (19/SC/0226), the Medicines and Healthcare products Regulatory Agency on June 12, 2019, and the Health Research Authority on June 19, 2019.

Results

Recruitment

Participants were recruited between August 9, 2019 and June 7, 2021. Recruitment was paused between March 23, 2020 and September 16, 2020 because of the COVID-19 pandemic. Pregnancy notes of 2646 participants

FIGURE 4
Eligibility criteria

Key inclusion criteria for consent • ≥18 years of age • May require an assisted vaginal birth • Live, singleton pregnancy >28 weeks' gestation • Negative antenatal screen for HIV and Hepatitis B	**Key exclusion criteria for consent** • Maternal-reported fetal skull abnormality, fetal osteogenesis imperfecta or fetal bleeding disorder • Intrauterine fetal death in the current pregnancy • The woman is currently serving a prison sentence • The woman lacks capacity to consent • The woman has a lack of ability to read or understand English • Sensitivity to latex
Key inclusion criteria for allocation to intervention • Informed consent has previously been given • An AVB is required for a clinical indication • The vertex is 1cm or more below ischial spines • The Royal College of Obstetricians and Gynaecologists (RCOG) requirements for AVB are fulfilled* and there are no contraindications to AVB (i.e., macrocephaly, osteogenesis imperfecta or a suspicion of a fetal bleeding disorder such as von Willebrand's disease, ITP, haemophilia	**Key exclusion criteria for allocation to intervention** • Informed consent is withdrawn • There is an ongoing fetal bradycardia • No Odon trained practitioner available to assist the birth • Current confirmed or clinically suspected Covid-19 infection • Woman is shielding from Covid-19 due to a medical condition or medication as per current PHE guidance

Details of the criteria for patient consent and for allocation to the device once recruited.
AVB, assisted vaginal birth; *ITP*, immune thrombocytopenia; *PHE*, Public Health England.
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were screened, and 68% (1847/2646) of participants were initially deemed eligible and approached. Of those approached, 21% (376/1793) were subsequently deemed ineligible. Of the 1471 participants who were approached and eligible, 64% (941/1471) consented to participate in the case of requiring an assisted vaginal birth (Figure 3).

Of the 941 participants who consented, 87% (815/941) became ineligible intrapartum: 82% (668/815) had a spontaneous vaginal birth, 13% (105/815) had a cesarean delivery, and 5% (42/815) had an assisted vaginal birth but did not meet the eligibility criteria of the study. Overall, 126 participants who had provided consent required an assisted vaginal birth; the OdonAssist was used in 83% (104/126), and 17% (22/126) of participants were in the nested cohort. Four participants withdrew from the study before allocation to the OdonAssist. No participants allocated to receive the OdonAssist withdrew from the study. One participant withdrew from the nested cohort before 90-day follow-up.

Devices

Initially, OdonAssist version 4.1 was used for the first 46 births, followed by version 4.2 for births 47 to 104. The device changes between versions were fully published,[14] including modifications aimed at improving operator usability. These modifications included strengthening the sleeve seal lines, creating a wider opening between the sleeve handles, altering the design of the deflation button, and addressing the manufacturing fault identified in the first ASSIST study.[8,14]

Data quality

All participants were available for follow-up, but some data were incomplete. In the OdonAssist group, 6% (6/104) of participants had incomplete data at day 7, 11% (11/104) at day 28 and 13% (13/104) at day 90. One neonate (1%) was lost to follow-up at day 28. In the nested cohort, 14 participants (45%) had incomplete follow-up data. However, there were no missing data related to the primary outcome.

Demographics and characteristics

The primary clinical indication for assisted vaginal birth was presumed fetal compromise in 61% (63/104) of participants, delay in the second stage of labor (UK national guidance[12]) in 39% (40/104), and maternal exhaustion in 1% (1/104). The proportion of nulliparous participants was 89% (92/104), and 82% (85/104) of participants had their labor induced. Birth was assisted in all cephalic fetal positions, at all stations from 1 cm below the ischial spines, with and without regional analgesia (Table 1).

Primary clinical outcome

The OdonAssist was successfully used in 66% (69/104) of births (95% confidence interval [CI], 57%−75%); in 1 of these cases, a second OdonAssist device was required after failure of the first. There were no serious maternal or neonatal device-related adverse reactions,[18] and there were no serious adverse device effects.[18] Additional assistance was required to complete the birth in 34% (35/104) of cases (Figure 3). This was by nonrotational forceps in 86% (30/35) of cases, rotational forceps in 9% (3/35), ventouse in 3% (1/35), and emergency cesarean delivery in 3% (1/35). The OdonAssist devices were systematically inspected after use, and none were faulty.

FIGURE 5
Timing of the assessments

Timepoint	Enrolment	Allocation	Post- allocation					
	Pre-recruitment	Point of requiring AVB	AVB	Day 1 PN	By Day 3 PN	Day 7 PN	Day 28 PN	Day 90 PN
Baseline characteristics	X	X						
Birth characteristics			X					
Primary outcomes			X	X				
Maternal outcomes			X	X		X	X	X
Neonatal outcomes			X	X	X		X	

Details of when the key characteristics and outcomes were collected for participants and their neonates.

AVB, assisted vaginal birth; *PN*, postnatal.

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Secondary outcomes

Characteristics that affect the success of the OdonAssist

Table 2 summarizes the characteristics of labor and birth of the successful (69/104) and unsuccessful (35/104) cases, and presents data from the nested cohort (n=22). Exploratory analyses show that parameters associated with a successful birth with the OdonAssist were clinically plausible: (1) participants with a longer active second stage (>90 minutes) were at greater risk of an unsuccessful outcome (relative risk [RR], 1.99; CI, 1.11−3.57); (2) participants with a longer total second stage (>135 minutes) were at greater risk of an unsuccessful outcome (RR, 1.94; CI, 1.07−3.55); (3) participants with a delay in second stage were at greater risk of an unsuccessful outcome compared with participants whose indication was fetal compromise (RR, 1.87; CI, 1.10−3.19); and (4) fetuses at station +1 were at greater risk of an unsuccessful outcome compared with those at station +2 and +3 (RR, 3.46; CI, 1.48−8.07). In these descriptive analyses, there was no marked difference in success by degree of caput, molding, asynclitism, median birthweight, or median head circumference.

Neonatal clinical outcomes

Table 3 summarizes the immediate neonatal outcomes. Two infants (both unsuccessful OdonAssist births delivered for "presumed fetal compromise") had an Apgar score of <7 at 5 minutes of life. One of these had an umbilical artery pH of <7.05. The proportion of infants

TABLE 1
Demographics and characteristics of participants

		Attempted OdonAssist birth			Nested cohort
Demographic		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
Maternal age (y), mean (SD)		30.2 (4.8)	29.7 (5.0)	31.2 (4.2)	29.2 (4.5)
Body mass index at booking, mean (SD)		26.3 (6.3)	26.8 (6.8)	25.3 (5.1)	27.0 (6.1)
Body mass index at 34−38 wk, mean (SD)		30.1 (6.4)	30.5 (6.9)	29.4 (5.2)	31.5 (5.8)
Ethnicity, n (%)	White British	88 (84.6)	57 (82.6)	31 (88.6)	18 (81.8)
	Any other White	6 (5.8)	4 (5.8)	2 (5.7)	2 (9.1)
	Indian	2 (1.9)	1 (1.5)	1 (2.9)	0 (0.0)
	Chinese	3 (2.9)	2 (2.9)	1 (2.9)	0 (0.0)
	Any other Asian	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
	Mixed background	4 (3.9)	4 (5.8)	0 (0.0)	2 (9.1)
Gravidity, n (%)	1	74 (71.2)	47 (68.1)	27 (77.1)	12 (54.6)
	≥2	30 (28.9)	22 (31.9)	8 (22.9)	10 (45.4)
Parity, n (%)	0	92 (88.5)	59 (85.5)	33 (94.3)	18 (81.8)
	≥1	12 (11.5)	10 (14.5)	2 (5.7)	4 (18.2)
Previous cesarean delivery, n (%)		4 (3.9)	4 (5.8)	0 (0.0)	1 (4.6)

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TABLE 2
Labor and birth characteristics

Labor and birth characteristic		Attempted OdonAssist birth			Nested cohort
		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
First stage (min) Mean (SD) (min–max)		358 (248) (40–1085)	329 (244) (40–1085)	416 (250) (90–1030)	348 (281) (0–914)
Duration of active second stage (min) Mean (SD) (min–max)		90 (52) (2–290)	82 (48) (18–290)	106 (56) (2–235)	82 (58) (15–238)
Duration of passive second stage (min) Mean (SD) (min–max)		45 (41) (0–151)	42 (41) (0–151)	49 (39) (0–130)	37 (51) (0–191)
Total duration of second stage (min) Mean (SD) (min–max)		135 (71) (16–291)	124 (69) (18–291)	155 (70) (16–270)	118 (101) (19–429)
Total duration of second stage <90 min, n (%)		53 (51.0)	41 (59.4)	12 (34.3)	
Total duration of second stage ≥90 min, n (%)		51 (49.0)	28 (40.6)	23 (65.7)	
Total duration of second stage <135 min, n (%)		49 (47.1)	38 (55.1)	11 (31.4)	
Total duration of second stage ≥135 min, n (%)		55 (52.9)	31 (44.9)	24 (68.6)	
Labor onset	Induced	85 (81.7)	58 (84.1)	27 (77.1)	21 (95.4)
	Spontaneous	19 (18.3)	11 (15.9)	8 (22.9)	1 (4.6)
Primary indication for assisted vaginal birth, n (%)	Presumed fetal compromise	63 (60.6)	47 (68.1)	16 (45.7)	16 (72.7)
	Delay in 2nd stage	40 (38.5)	21 (30.4)	19 (54.3)	6 (27.3)
	Maternal exhaustion	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
Fetal position, n (%)	OA	47 (45.2)	34 (49.3)	13 (37.1)	9 (40.9)
	LOA / ROA	36 (34.6)	25 (36.2)	11 (31.4)	6 (27.3)
	OT	10 (9.6)	5 (7.3)	5 (14.3)	4 (18.2)
	LOP / ROP	3 (2.9)	1 (1.5)	2 (5.7)	0 (0.0)
	OP	8 (7.7)	4 (5.8)	4 (11.4)	3 (13.6)
Head palpable per abdomen	0/5ths	98 (94.2)	67 (97.1)	31 (88.6)	21 (95.4)
	1/5ths	5 (4.8)	2 (2.9)	3 (8.6)	1 (4.6)
Station of fetal head, n (%)	+1	59 (56.7)	29 (42.0)	30 (85.7)	15 (68.2)
	+2	34 (32.7)	29 (42.0)	5 (14.3)	7 (31.8)
	+3	11 (10.6)	11 (15.9)	0 (0.0)	0 (0.0)
Molding	None	37 (35.6)	28 (40.6)	9 (25.7)	12 (54.5)
	+	59 (56.7)	37 (53.6)	22 (62.9)	7 (31.8)
	++	8 (7.7)	4 (5.8)	4 (11.4)	2 (9.1)
	+++	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.5)
Caput (cm)	None	17 (16.3)	12 (17.4)	5 (14.3)	3 (13.6)
	1	46 (44.3)	32 (46.4)	14 (40.0)	10 (45.4)
	2	36 (34.6)	23 (33.3)	13 (37.1)	5 (22.7)
	3	5 (4.8)	2 (2.9)	3 (8.6)	4 (18.2)
Asynclitic presentation, n (%)		12 (11.5)	5 (7.3)	7 (20.0)	6 (27.3)
Analgesia (>1 type of analgesia can be used)	None	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Epidural	79 (76.0)	50 (72.5)	29 (82.9)	17 (77.3)

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(continued)

TABLE 2
Labor and birth characteristics *(continued)*

Labor and birth characteristic		Attempted OdonAssist birth			Nested cohort
		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
	Spinal	10 (9.6)	6 (8.7)	4 (11.4)	3 (13.6)
	Pudendal	3 (2.9)	2 (2.9)	1 (2.9)	0 (0.0)
	Perineal Infiltration	12 (11.5)	11 (15.9)	1 (2.9)	2 (9.1)
	General Anesthesia	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Grade of operator	ST1-ST2	0 (0.0)	0 (0.0)	0 (0.0)	4 (18.2)
	ST3-ST5	9 (8.7)	6 (8.7)	3 (8.6)	12 (54.5)
	ST6-ST7	61 (58.7)	45 (65.2)	16 (45.7)	4 (18.2)
	Consultant	34 (32.7)	18 (26.1)	16 (45.7)	2 (9.1)
Time between decision and birth (min), median (Q1−Q3)		22 (16−41)	20 (14−31)	40 (20−50)	22.5 (14−43)
Time between first application and birth (min), median (Q1−Q3)		7 (5−10)	5 (4−7)	10 (7−13)	4.5 (3−8)
Location of birth, n (%)	Delivery suite room	67 (64.4)	51 (73.9)	16 (45.7)	10 (45.4)
	Operating theatre	37 (35.6)	18 (26.1)	19 (54.3)	12 (54.6)
Number of applications of first device	1	100 (96.1)	67 (97.1)	33 (94.3)	20 (90.9)
	2 or more	4 (3.8)	2 (2.9)	2 (5.7)	2 (9.1)
Number of pulls with first device	0	2 (1.9)	0 (0.0)	2 (5.7)	0 (0.0)
	1	36 (34.6)	19 (27.5)	17 (48.6)	8 (36.4)
	2	45 (43.3)	36 (52.2)	9 (25.7)	10 (45.4)
	3-5	21 (20.2)	14 (20.3)	7 (20.0)	4 (18.2)
Episiotomy with first device		66 (63.5)	64 (92.8)	2 (5.7)	17 (77.3)

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admitted to the neonatal intensive care unit (NICU) following birth was 7% (7/104). Two of these infants were in the successful OdonAssist group; one was born preterm (36+5 weeks of gestation) and required support for hypoglycemia and hypothermia, and the other required initial respiratory support and a septic screen. Four of the 5 infants who were admitted from the unsuccessful OdonAssist group required respiratory support, and 1 required support for hypoglycemia secondary to maternal gestational diabetes mellitus. Infant distress was assessed using the Neonatal Infant Pain Score (NIPS), a unidimensional scale measuring 6 behavioral patterns; a score of ≥4 has been shown to indicate pain.[21] Four infants had a NIPS ≥4; of these, 2 had a successful OdonAssist birth and neither was admitted to the NICU, whereas the other 2 were in the nested cohort and 1 of them was admitted to the NICU for respiratory support.

The proportion of neonates with a recorded adverse event was 49% (51/104), and all of these cases were attributed to soft tissue trauma (bruise, graze, scalp injury, or facial injury) (Table 4). There were no reported cases of pressure necrosis. There were no reported grazes or lacerations ≥50 mm. In the OdonAssist group, there was 1 reported case of clinically significant cephalohematoma, which was determined to be unrelated to the device given its location on the neonatal head.

There was less soft tissue trauma of any size (predominantly superficial bruising) in successful OdonAssist births; 39% (27/69) of neonates whose birth was successfully assisted with the OdonAssist had evidence of any soft tissue trauma, as opposed to 69% (24/35) of neonates where the device was unsuccessful (P=.007). There was a higher rate of soft tissue trauma in the nested cohort (73%; 16/22) than in the successful OdonAssist group (P=.007). There was a lower rate of bruising and injury in the successful OdonAssist group than in the unsuccessful OdonAssist group or in the nested cohort (all bruising: 28% [19/69] vs 69% [24/35] and 68% [15/22]; device-related bruising: 4% [3/69] vs 20% [7/35] and 23% [5/22]; clinically significant bruising: 7% [5/69] vs 26% [9/35] and 27% [6/22]).

Six infants received phototherapy for jaundice (3 successful and 3 unsuccessful OdonAssist births). Three of these cases were related to bruising (1 successful and

TABLE 3
Immediate neonatal outcomes

Neonatal outcome		Attempted OdonAssist birth			Nested cohort
		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
Birthweight (g) Mean (SD)		3344 (390)	3315 (402)	3402 (363)	3498 (372)
Head circumference (cm) Mean (SD)		34.6 (1.5)	34.6 (1.5)	34.6 (1.5)[a]	34.7 (1.3)
Sex, n (%)	Male	47 (45.2)	27 (39.1)	20 (57.1)	11 (50.0)
	Female	57 (54.8)	42 (60.9)	15 (42.9)	11 (50.0)
Gestation at birth (wk^{+d})					
Mean (SD)		39^{+5} (1^{+1})	39^{+4} (1^{+2})	39^{+6} (1^{+0})	39^{+6} (1^{+3})
(min–max)		(36^{+5}–42^{+1})	(36^{+5}–42^{+1})	(37^{+4}–42^{+0})	(32^{+3}–42^{+0})
Umbilical artery pH	Unable to obtain, n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)
	Not taken, n (%)	26 (25.0)	21 (30.4)	5 (14.3)	4 (18.2)
	Mean (SD)	7.19 (0.08)	7.21 (0.08)	7.17 (0.09)	7.22 (0.07)
	<7.10, n (%)	11 (10.6)	4 (5.8)	7 (20.0)	0 (0.0)
	<7.05, n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)
	<7.00, n (%)	1 (0.9)	0 (0.0)	1 (2.9)	0 (0.0)
Umbilical artery base excess	Unable to obtain, n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)
	Not taken, n (%)	27 (26.0)	22 (31.9)	5 (14.3)	4 (18.2)
	Mean (SD)	−7.3 (3.3)	−6.6 (3.2)	−8.3 (3.2)	−6.4 (2.8)
	≤−10, n (%)	14 (18.7)	7 (15.2)	7 (24.1)	2 (11.1)
	≤−15, n (%)	1 (1.3)	0 (0.0)	1 (3.4)	0 (0.0)
Umbilical vein pH	Unable to obtain, n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)
	Not taken, n (%)	6 (5.8)	4 (5.8)	2 (5.7)	4 (18.2)
	Mean (SD)	7.32 (0.06)	7.32 (0.06)	7.30 (0.07)	7.33 (0.07)
Umbilical vein base excess	Unable to obtain, n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)
	Not taken, n (%)	7 (6.7)	5 (7.2)	2 (5.7)	4 (18.2)
	Mean (SD)	−5.3 (2.3)	−4.9 (1.9)	−6.1 (2.7)	−5.1 (2.4)
Shoulder dystocia, n (%)		5 (4.8)	1 (1.5)	4 (11.4)	1 (4.5)
Apgar scores <7, n (%)	1 min	11 (10.6)	5 (7.3)	6 (17.1)	3 (13.6)
	5 min	2 (1.9)	0 (0.0)	2 (5.7)	1 (4.5)
	10 min	1 (1.0)	0 (0.0)	1 (2.9)	0 (0.0)
Neonatal Infant Pain Score >4, n (%)	2 h postnatal	0 (0.0)[b]	0 (0.0)[c]	0 (0.0)[a]	0 (0.0)[c]
	6 h postnatal	2 (1.9)[d]	2 (3.0)[c]	0 (0.0)[e]	1 (4.5)[c]

[a] Missing data n=1; [b] Missing data n=3; [c] Missing data n=2; [d] Missing data n=7; [e] Missing data n=5.

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2 unsuccessful OdonAssist births), and 3 were diagnosed as physiological jaundice (Table 5).

Maternal clinical outcomes

Tables 6 and 7 summarize the maternal outcomes; 27% (28/104) of participants experienced 49 serious adverse events. Eight participants sustained a third-degree tear (9% [6/69] successful and 6% [2/35] unsuccessful OdonAssist births, respectively), 2 participants a fourth-degree perineal tear (2% [1/69] successful and 3% [1/35] unsuccessful OdonAssist births), and 2 participants a buttonhole tear (a tear involving the rectal mucosa with an intact anal sphincter complex) (2% [1/69] successful and 3% [1/35] unsuccessful OdonAssist births). There were no cervical tears or tears into the ischial rectal fossa in any groups.

TABLE 4
Neonatal soft tissue injury

Soft tissue injury		Attempted OdonAssist birth			Nested cohort
		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
Cephalohematoma	Number of infants with confirmed, n (%)	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
	Number with cephalohematoma ≥50 mm, n (%)	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
	Of whom had a clinically significant injury, n (%)	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
	Of whom had a device-related injury, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Bruise	Number with confirmed bruises, n (%)	43 (41.3)	19 (27.5)	24 (69.0)	15 (68.2)
	On face, n (%)	33 (31.7)	10 (14.5)	23 (65.7)	11 (50.0)
	On scalp, n (%)	25 (24.0)	15 (21.7)	10 (28.6)	10 (45.5)
	Number of infants with bruise ≥50 mm, n (%)	21 (20.2)	10 (14.5)	11 (31.4)	7 (31.8)
	On face, n (%)	8 (7.7)	1 (1.4)	7 (20.0)	4 (18.2)
	On scalp, n (%)	16 (14.4)	10 (14.5)	6 (17.1)	4 (18.2)
	Of whom had a clinically significant injury, n (%)	14 (13.5)	5 (7.2)	9 (25.7)	6 (27.3)
	Of whom had a device-related injury, n (%)	10 (9.6)	3 (4.3)	7 (20.0)	5 (22.7)
Graze	Number of infants with confirmed, n (%)	15 (14.4)	7 (10.1)	8 (22.9)	3 (13.6)
	On face, n (%)	8 (7.7)	3 (4.3)	5 (14.9)	3 (13.6)
	On scalp, n (%)	7 (6.7)	4 (5.8)	3 (8.6)	1 (4.5)
	Number of confirmed grazes, n (%)	34 (32.7)	17 (24.6)	17 (48.6)	11 (50.0)
	On face, n (%)	20 (19.2)	10 (14.5)	10 (28.6)	8 (36.4)
	On scalp, n (%)	14 (13.5)	7 (10.1)	7 (20.0)	3 (13.6)
	Number of infants with graze ≥50 mm, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Laceration	Number of infants with confirmed, n (%)	3 (2.9)	3 (4.3)	0 (0.0)	1 (4.5)
	On face, n (%)	1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
	On scalp, n (%)	2 (1.9)	2 (2.9)	0 (0.0)	1 (4.5)
	Number of confirmed lacerations, n (%)	13 (12.5)	13 (18.8)	0 (0.0)	1 (4.5)
	On face, n (%)	3 (2.9)	3 (4.3)	0 (0.0)	0 (0.0)
	On scalp, n (%)	10 (9.6)	10 (14.5)	0 (0.0)	1 (4.5)
	Number of infants with laceration ≥50 mm, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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The median weighed blood loss was 659 mL (interquartile range, 406−1032 mL) in the attempted OdonAssist group. Seven participants (7%; 7/104) had a weighed blood loss ≥1500 mL. Eight participants received a postnatal red blood cell transfusion, of whom 6% (4/69) were in the successful and 11% (4/35) in the unsuccessful OdonAssist group. One participant in the successful OdonAssist group did not have excessive blood loss but was anemic before birth and required a transfusion for symptom control postnatally. Two participants had urinary retention requiring catheterization (intermittent or indwelling) after postnatal day 7; both were in the unsuccessful OdonAssist group (6%; 2/35). One participant in the successful OdonAssist group had fecal urgency persisting at postnatal day 90 (2%; 1/69).

All participants reported a better health-related quality of life score (standardized EQ-5D-5L health-related quality of life questionnaire) at postnatal day 28 (mean, 83.3; SD, 13.1) compared with the antenatal score (mean, 77.0; SD, 15.2) and the postnatal day 1 score (mean, 66.0; SD, 18.0). Scores were slightly higher in the successful than in the unsuccessful OdonAssist group and the nested cohort at all time points (Supplemental File 1). Participants' birth perception was positive, with a median of 15 in all groups at postnatal days 1, 7, and 28 (15 being the highest achievable positive score and 3 the lowest possible negative score). Postnatal scores for maternal perception of pain were low,

TABLE 5
Neonatal serious adverse events

Neonatal amber/red outcome	Attempted OdonAssist birth			Nested cohort
	Overall n=104, n (%)	Successful n=69, n (%)	Unsuccessful n=35, n (%)	n=22, n (%)
Prolonged hospital stay (>4 d)	10 events affecting 10 (9.6) neonates	5 events affecting 5 (7.2) neonates	5 events affecting 5 (14.3) neonates	3 events affecting 3 (13.6) neonates
Unplanned readmission	8 events affecting 8 (7.7) neonates	5 events affecting 5 (7.2) neonates	3 events affecting 3 (8.6) neonates	0 (0)
Apgar <7 at 5 minutes	2 (1.9)	0 (0.0)	2 (5.7)	1 (4.5)
Jaundice requiring phototherapy (related to bruising)	3 (2.9)	1 (1.4)	2 (5.7)	0 (0.0)
Admission to neonatal intensive care unit	7 (6.7)	2 (2.9)	5 (14.3)	2 (9.1)
Pressure necrosis of skin or fat	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Neonatal death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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TABLE 6
Maternal outcomes

Outcome		Attempted OdonAssist birth			Nested cohort
		Overall n=104	Successful n=69	Unsuccessful n=35	Overall n=22
Weighed estimated blood loss (mL), mean (SD)		803 (600)	800 (608)	811 (590)	831 (415)
Weighed blood loss of ≥1500 mL, n (%)		7 (6.7)	3 (4.3)	4 (11.4)	1 (4.6)
Participants requiring a blood transfusion, n (%)		8 (7.7)	4 (5.8)	4 (11.4)	0 (0.0)
Perineal tears, n (%)	None	1 (1.0)	1 (1.5)	0 (0.0)	1 (4.6)
	Labial tear requiring suturing	9 (8.6)	5 (7.2)	4 (11.4)	2 (9.1)
	1st degree	10 (9.6)	4 (5.8)	6 (17.1)	2 (9.1)
	2nd degree	22 (21.1)	13 (18.8)	9 (25.7)	8 (36.4)
	Episiotomy	93 (89.4)	64 (92.7)	29 (82.9)	18 (81.3)
	3rd degree	8 (7.7)	6 (8.7)	2 (5.7)	0 (0.0)
	4th degree	2 (1.9)	1[a] (1.5)	1 (2.9)	0 (0.0)
	Buttonhole	2 (1.9)	1[a] (1.5)	1 (2.9)	0 (0.0)
Tear into ischiorectal fossa, n (%)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Cervical tear, n (%)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention requiring catheterization (intermittent or indwelling) after postnatal day 7, n (%)		2 (1.9)	0 (0.0)	2 (5.7)	0 (0.0)
Fecal urgency/incontinence persisting at postnatal day 90, n (%)		1 (1.0)	1 (1.5)	0 (0.0)	1 (4.6)
Thromboembolism within 42 postnatal days, n (%)		1 (1.0)	1 (1.5)	0 (0.0)	0 (0.0)
Dural puncture (with >1 readmission to hospital), n (%)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Maternal death, n (%)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[a] 1 participant sustained a combined injury (fourth-degree tear and buttonhole tear).

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TABLE 7
Maternal serious adverse events

Maternal amber/red outcomes		OdonAssist Overall n=104, N (%)	OdonAssist Successful n=69, N (%)	OdonAssist Unsuccessful n=35, N (%)	Nested cohort n=22, N (%)
Prolonged hospital stay (>4 d)		5 events affecting 5 (4.8) participants	2 events affecting 2 (2.9) participants	3 events affecting 3 (13.6) participants	2 events affecting 2 (9.1) participants
Unplanned readmission		14 events affecting 10 (9.6) participants	9 events affecting 6 (8.7) participants	5 events affecting 4 (11.4) participants	3 events affecting 3 (13.6) participants
PPH >1500 mL		7 (6.7)	3 (4.3)	4 (11.4)	1 (4.5)
Postnatal blood transfusion		8 (7.7)	4 (5.8)	4 (11.4)	0 (0.0)
Cervical tear requiring suturing		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
3rd or 4th degree tear	Any type	11 (10.6)	7 (10.1)	4 (11.4)	0 (0.0)
	3rd degree	8 (7.7)	6 (8.7)	2 (5.7)	0 (0.0)
	4th degree	2 (1.9)	1[a] (1.4)	1 (2.9)	0 (0.0)
	Buttonhole[b]	2 (1.9)	1[a] (1.4)	1 (2.9)	0 (0.0)
Ischiorectal fossa defect		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary retention requiring catheterization (intermittent or indwelling) after postnatal day 7		2 (1.9)	0 (0.0)	2 (5.7)	0 (0.0)
Fecal urgency/incontinence persisting at postnatal day 90		1 (1.0)	1 (1.4)	0 (0.0)	1 (4.5)
Thromboembolism within 42 postnatal days		1 (1.0)	1 (1.4)	0 (0.0)	0 (0.0)
Dural puncture (>1 readmission to hospital)		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Maternal death		0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

PPH, postpartum hemorrhage.

[a] 1 participant sustained a combined injury (fourth-degree tear and buttonhole tear); [b] A buttonhole tear is not a 3rd or 4th degree tear but a tear involving the rectal mucosa with an intact anal sphincter complex.

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with a median of 4 on postnatal day 1, median of 5 on postnatal day 7, and median of 1 on postnatal day 28 (Supplemental File 2).

Use of device and device outcomes

The seniority of the operator was not associated with higher success rates. Junior obstetricians (3−5 years of obstetrical experience) had a 67% (6/9) success rate, senior obstetricians (6−7 years of experience) had a 74% (45/61) success rate, and attendings (>7 years of experience) had a 53% (18/34) success rate.

All operators reported that the device was "easy" or "very easy" to use apart from the withdrawal of the applicator, with initial reports of this being "difficult." After birth, 35 spatula channels were lubricated before the device was applied to the fetal head, after which the withdrawal of the applicator was reported to be "easy." The spatula channels are the 4 pockets that the applicators sit in to allow the positioning of the cuff around the fetal head during the insertion of the device.

Comment

Principal findings

The recruitment rate of pregnant participants to this study for investigating a novel device was 64% (941/1471). Given that it is difficult to antenatally predict participants who require an assisted vaginal birth, 941 participants were recruited to achieve the sample size of 104 assisted vaginal births. Follow-up data collection for participants up to day 90 and for neonates up to day 28 was excellent. There was a 66% (69/104) success rate for the OdonAssist (95% CI, 57%−75%), indicating good efficacy and passing the a priori threshold for continuing research on the OdonAssist.

Results in the context of what is known

The success rate of the OdonAssist was 66% (69/104), which was significantly higher than the 48% (19/40)[8] rate found in the first clinical study of the device (P=.038, 2-sided).[8] This increase can be attributed to: (1) change in clinical parameters (excluding fetuses with a presenting part at the level of the ischial spines), (2) device technique

improvements on the basis of learning from the first clinical trial,[14] (3) operator learning curve, and (4) using an updated device (Version 4.2). The current success rate of the OdonAssist is very similar to the 66% success rate reported for the Kiwi OmniCup when it was introduced in the same hospital (Southmead Hospital, Bristol, United Kingdom) in 2002.[20] A review of all 1704 assisted vaginal births performed at Southmead Hospital during the ASSIST II study period demonstrated that the Kiwi OmniCup was successful in 84% (211/251) of births. It is plausible that OdonAssist success rates will increase with experience, as observed with the Kiwi OmniCup. The small numbers in the nested cohort make it difficult to draw firm conclusions, particularly in direct comparisons.

It is widely appreciated that there is a substantial learning curve when an operator is introduced to a novel device, with steepness varying considerably.[22] Operator expertise or experience may also affect the results of a medical device trial,[23,24] with the chance that outcomes for a novel device (such as efficacy or safety) could be negatively affected by lack of experience.[25] During the development and introduction of a novel medical device, operator training and learning must be considered. The operator learning curve should be studied when assessing trial results, and where possible, statistical analysis or adjustment can be contemplated. The traditional method of assessing the learning curve is by using the volume—outcome relationship, which has demonstrated that the increased number of procedures is inversely related to poor outcomes.[26,27] In this study, a higher average success rate was observed when operators had performed ≥5 procedures. There were 6 operators who had experience of ≥10 births within the 2 trials[8,15] in Bristol.

Globally, the management of the second stage varies drastically, with all guidelines/societies recommending assisted vaginal birth for delay in second stage, but questions remain regarding optimal timing. The second stage has 2 components: passive (when there is no urge to push or active pushing) and active (when there is an urge to push or active pushing). Many recommend a passive second stage of 60 to 120 minutes to lower rotational and mid-cavity interventions.[12,28,29] We found a significantly increased OdonAssist success rate when the total second stage was <135 minutes. Accounting for passive second stage recommendations, this would indicate an optimal active second stage duration of 15 to 75 minutes. There is great disparity in timing of diagnosing delay in the second stage: in France, this is after 30 minutes of active labor,[30] whereas UK and US guidance does not specify length of the active second stage but focuses on the total length of the second stage (180 minutes for nulliparous participants with regional analgesia, 120 minutes for nulliparous participants without regional analgesia or multiparous participants with regional analgesia, and 60 minutes for multiparous participants without regional analgesia).[4,12,31]

Clinical implications

There were no maternal or neonatal adverse reactions with use of the device; however, the number of births was small. There seemed to be some neonatal benefits associated with the use of the device, consistent with findings from the first ASSIST study.[8] The number of severe perineal injuries is important, and these should be reduced wherever possible[32]; there was no clear difference between the 3 groups, and the rate of perineal injury is consistent with other studies of assisted vaginal birth.[32−34]

It is difficult to compare the proportion of participants requiring a blood transfusion between assisted vaginal delivery performed in this study and routine practice. There are very little data published on rates of blood transfusion associated with assisted vaginal birth; blood transfusion is not included in the recent Cochrane review of assisted vaginal birth.[35] However, we believe it is an important metric that should be included in a core outcomes set for assisted vaginal birth. Other maternal outcomes were consistent with other studies, and there were no disadvantages for participants included in the study. Maternal birth perception should be an essential outcome measure of assisted vaginal birth,[36] and measurement is feasible in intrapartum research.[15] Success rates of the device were associated with station, indication, and position, which is consistent with the current literature.[37]

Research implications

An RCT is required to objectively compare outcomes between the OdonAssist and the alternatives. The rates and safety profile in this study confirm that developments in both the device and technique have met the threshold for further research, including an RCT. It should be acknowledged that there will be methodological challenges for an RCT, particularly the likely superior experience and/or greater success rate in a standard care arm, and we consider that a noninferiority RCT study design would be optimal, using a standard clinical definition for delay in the second stage of labor.

The availability of experienced operators will be a key component to the success of an RCT. With 13 operators, 83% (104 of 126 consenting participants who required an assisted vaginal birth) of births were attended in this study. The optimal number of experienced operators to ensure ubiquitous availability of the intervention needs to be considered in any future RCT design.

A useful study innovation was the use of body maps by research midwives to document the birth injuries on the neonates postnatally. These body maps were reviewed by neonatologists to categorize any injury and to determine if they were device related. Neonatal injury was consistently lower in the successful OdonAssist group when compared with the unsuccessful group and the nested cohort. In contrast to findings regarding forceps and ventouse,[35] no typical pattern of neonatal injury was observed with the OdonAssist. Standardized neonatal photographs in the immediate postnatal period have the potential to be more informative and objective than a body map. It may be possible for parents to provide follow-up photographs of their neonate to enable longer-term

evaluation of soft tissue trauma injury, as done previously in wound studies.[38] The use of body maps or standardized neonatal photographs would enable the researchers categorizing neonatal injuries to be blinded to the intervention in an RCT.

Strengths and limitations

This was the second study using the OdonAssist to expedite birth for standard UK indications. The study used a holistic approach to evaluation, with comprehensive data for participants, infants, clinicians, midwives, and postnatal device analysis. The methodology used followed international recommendations from the IDEAL framework,[9] which highlights the importance of robust feasibility work before a definitive RCT. Key limitations include the small sample size and a limited follow-up period of 90 days. We also acknowledge that this research was undertaken at a single site where most of the participants were White British.

Conclusions

Recruitment for OdonAssist trials is feasible, and the predefined success threshold for further research was met. There was no disadvantage for study participants with regard to maternal and neonatal outcomes compared with outcomes found in other assisted vaginal birth studies. There were potential benefits with the OdonAssist, particularly for the neonate. The same application technique can be used for all fetal positions. Finally, participants were extremely positive about their participation in the study, their birth perception, and the device.

More research is required to investigate the OdonAssist further and understand its potential benefits for expediting birth; this study provides important data to demonstrate that further work is feasible and to inform future research design. ■

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The views expressed are solely those of the authors and not necessarily those of the UK National Health Service. The authors are responsible for the design of the protocol and the planning, conducting, and analysis of the study.

OdonAssist is a trademark of Maternal Newborn Health Innovations, PBC. The OdonAssist is a product under development by Maternal Newborn Health Innovations, PBC, and was not available for sale at the time of submission of this article.

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SUPPLEMENTAL FILE 1

Health-related quality of life

Health-related quality of life data (EQ-5D-5L)			Antenatal				Day 1 postnatal				Day 28 postnatal			
			Overall n=104	Successful Odon n=69	Unsuccessful Odon n=35	Nested cohort n=22	Overall n=104	Successful Odon n=69	Unsuccessful Odon n=35	Nested cohort n=22	Overall n=104	*Successful Odon n=69*	*Unsuccessful Odon n=35*	*Nested cohort n=22*
Health score out of 100		Mean (SD)	77.0 (15.2)	78.6 (14.0)	73.8 (17.0)	76.8 (17.1)	66.0 (18.0)	69.1 (16.1)	59.9 (20.1)	68.0 (18.6)	83.3 (13.1)	86.6 (9.8)	77.8 (16.1)	84.1 (17.4)
		Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (8.6)	9 (13.0)	0 (0.0)	5 (22.7)
Mobility	No problems	n (%)	68 (65.4)	45 (65.2)	23 (65.7)	14 (63.6)	15 (14.4)	9 (13.0)	6 (17.1)	4 (18.2)	73 (70.2)	48 (69.6)	25 (71.4)	14 (63.6)
	Slight	n (%)	15 (14.4)	13 (18.8)	2 (5.7)	6 (27.3)	50 (48.1)	40 (58.0)	10 (28.6)	10 (45.4)	19 (18.3)	10 (14.5)	9 (25.7)	3 (13.6)
	Moderate	n (%)	8 (7.7)	5 (7.2)	3 (8.6)	1 (4.5)	25 (24.0)	14 (20.3)	11 (31.4)	7 (31.8)	3 (2.9)	2 (2.9)	1 (2.9)	0 (0.0)
	Severe	n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)	7 (6.7)	5 (7.2)	2 (5.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Extreme	n (%)	11 (10.6)	5 (7.2)	6 (17.1)	1 (4.5)	7 (6.7)	1 (1.4)	6 (17.1)	1 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Self-care	No problems	n (%)	73 (70.2)	51 (73.9)	22 (62.9)	15 (68.2)	35 (33.6)	25 (36.2)	10 (28.6)	10 (45.4)	95 (91.3)	60 (87.0)	35 (100.0)	16 (72.7)
	Slight	n (%)	18 (17.3)	11 (15.9)	7 (20.0)	5 (22.7)	47 (45.2)	37 (53.6)	10 (28.6)	10 (45.4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.6)
	Moderate	n (%)	4 (3.8)	3 (4.3)	1 (2.9)	1 (4.5)	15 (14.4)	4 (5.8)	11 (31.4)	2 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Severe	n (%)	2 (1.9)	2 (2.9)	0 (0.0)	1 (4.5)	2 (1.9)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Extreme	n (%)	7 (6.7)	2 (2.9)	5 (14.3)	0 (0.0)	5 (4.8)	1 (1.4)	4 (11.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Usual activities	No problems	n (%)	52 (50.0)	35 (50.7)	17 (48.6)	9 (40.9)	19 (18.3)	13 (18.8)	6 (17.1)	2 (9.1)	71 (68.3)	44 (63.8)	27 (77.1)	12 (54.5)
	Slight	n (%)	30 (28.8)	20 (29.0)	10 (28.6)	8 (36.4)	35 (33.6)	29 (42.0)	6 (17.1)	5 (22.7)	19 (18.3)	13 (18.8)	6 (17.1)	5 (22.7)
	Moderate	n (%)	12 (11.5)	10 (14.5)	2 (5.7)	4 (18.2)	23 (22.1)	14 (20.3)	9 (25.7)	9 (40.9)	5 (4.8)	3 (4.3)	2 (5.7)	0 (0.0)
	Severe	n (%)	2 (1.9)	1 (1.4)	1 (2.9)	0 (0.0)	11 (10.6)	6 (8.7)	5 (14.3)	2 (9.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Extreme	n (%)	8 (7.7)	3 (4.3)	5 (14.3)	1 (4.6)	16 (15.4)	7 (10.1)	9 (25.7)	4 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Pain/ discomfort	No problems	n (%)	29 (27.9)	18 (26.1)	11 (31.4)	5 (22.7)	5 (4.8)	3 (4.3)	2 (5.7)	0 (0.0)	56 (53.8)	37 (53.6)	19 (54.3)	8 (36.4)
	Slight	n (%)	50 (48.1)	36 (52.2)	14 (40.0)	12 (54.5)	43 (41.3)	30 (43.5)	13 (37.1)	10 (45.4)	34 (32.7)	21 (30.4)	13 (37.1)	8 (36.4)
	Moderate	n (%)	22 (21.1)	14 (20.3)	8 (22.9)	4 (18.2)	47 (45.2)	32 (46.4)	15 (42.9)	12 (54.5)	5 (4.8)	2 (2.9)	3 (8.6)	1 (4.6)
	Severe	n (%)	3 (2.9)	1 (1.4)	2 (5.7)	1 (4.6)	7 (6.7)	2 (2.9)	5 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Extreme	n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (1.9)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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(continued)

SUPPLEMENTAL FILE 1

Health-related quality of life *(continued)*

Health-related quality of life data (EQ-5D-5L)			Antenatal				Day 1 postnatal				Day 28 postnatal			
			Overall n=104	Successful Odon n=69	Unsuccessful Odon n=35	Nested cohort n=22	Overall n=104	Successful Odon n=69	Unsuccessful Odon n=35	Nested cohort n=22	Overall n=104	*Successful Odon n=69*	*Unsuccessful Odon n=35*	*Nested cohort n=22*
Anxiety/ depression	No problems	n (%)	60 (67.7)	42 (60.9)	17 (51.4)	12 (54.5)	61 (58.6)	44 (63.8)	17 (48.6)	17 (77.3)	71 (68.3)	46 (66.7)	25 (71.4)	10 (45.4)
	Slight	N (%)	34 (22.7)	21 (30.4)	13 (37.1)	8 (36.4)	37 (35.6)	21 (30.4)	16 (45.7)	5 (22.7)	19 (18.3)	11 (15.9)	8 (22.9)	6 (27.3)
	Moderate	N (%)	8 (7.7)	4 (5.8)	4 (11.4)	2 (9.1)	6 (5.8)	4 (5.8)	2 (5.7)	0 (0.0)	5 (4.8)	3 (4.3)	2 (5.7)	0 (0.0)
	Severe	N (%)	2 (1.9)	2 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (4.6)
	Extreme	N (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

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SUPPLEMENTAL FILE 2

Maternal perception of pain

Score out of 11 (11=the most pain, 1=the least pain) Median (Q1–Q3) Min–max		Postnatal day 1	Postnatal day 7	Postnatal day 28
	Overall n=104	4 (3–6) 1–11	5 (5–5) 2–5	1 (1–2) 1–7
	Missing data	0	6	10
	Successful Odon n=69	4 (3–6) 1–9	5 (5–5) 3–5	1 (1–2) 1–7
	Missing data	0	6	10
	Unsuccessful Odon n=35	4 (3–7) 1–11	5 (4–5) 2–5	1 (1–2) 1–4
	Missing data	0	0	0
	Nested cohort n=22	4 (2–5) 1–6	5 (4–5) 3–5	2 (1–3) 1–5
	Missing data	0	3	5

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