Persistent occiput posterior position outcomes following manual rotation: a randomized controlled trial

Hala Phipps, PhD; Jon A. Hyett, MD; Sabrina Kuah, MBBS, FRANZCOG; John Pardey, MBBS, FRANZCOG; Geoff Matthews, MBBS, FRANZCOG; Joanne Ludlow, MM (Clin Epi); Rajit Narayan, MBBS, FRANZCOG; Stanley Santiagu, MBSS, FRANZCOG; Rachel Earl, BMBS; Chris Wilkinson, MPH, FRACOG; Andrew Bisits, MD; Wendy Carseldine, MBBS, FRANZCOG; Jane Tooher, PhD; Kevin McGeechan, PhD; Bradley de Vries, PhD

BACKGROUND: Persistent occiput posterior position in labor is associated with adverse maternal and perinatal outcomes. Prophylactic manual rotation from the occiput posterior position to the occiput anterior position in the second stage of labor is considered a safe and easy to perform procedure that in observational studies has shown promise as a method for preventing operative deliveries.

OBJECTIVE: This study aimed to determine the efficacy of prophylactic manual rotation in the management of occiput posterior position for preventing operative delivery. The hypothesis was that among women who are at least 37 weeks pregnant and whose baby is in the occiput posterior position early in the second stage of labor, manual rotation will reduce the rate of operative delivery compared with the "sham" rotation.

STUDY DESIGN: A double-blinded, parallel, superiority, multicenter, randomized controlled clinical trial in 4 tertiary hospitals was conducted in Australia. A total of 254 nulliparous and parous women with a term pregnancy and a baby in the occiput posterior position in the second stage of labor were randomly assigned to receive either a prophylactic manual rotation (n=127) or a sham rotation (n=127). The primary outcome was operative delivery (cesarean, forceps, or vacuum delivery). Secondary outcomes were cesarean delivery, combined maternal mortality and serious morbidity, and combined perinatal mortality and serious morbidity. Analysis was by intention to treat. Proportions were compared using chi-square tests adjusted for stratification variables using the Mantel-Haenszel method or the Fisher exact test. Planned subgroup analyses by operator experience and by manual rotation technique (digital or whole-hand rotation) were performed.

RESULTS: Operative delivery occurred in 79 of 127 women (62%) assigned to prophylactic manual rotation and 90 of 127 women (71%) assigned to sham rotation (common risk difference, 12; 95% confidence interval, −1.7 to 26; *P*=.09). Among more experienced operators or investigators, operative delivery occurred in 46 of 74 women (62%) assigned to manual rotation and 52 of 71 women (73%) assigned to a sham rotation (common risk difference, 18; 95% confidence interval, −0.5 to 36; *P*=.07). Cesarean delivery occurred in 22 of 127 women (17%) in both groups. Instrumental delivery (forceps or vacuum) occurred in 57 of 127 women (45%) assigned to prophylactic manual rotation and 68 of 127 women (54%) assigned to sham rotation (common risk difference, 10; 95% confidence interval, −3.1 to 22; *P*=.14). There was no significant difference in the combined maternal and perinatal outcomes.

CONCLUSION: Prophylactic manual rotation did not result in a reduction in the rate of operative delivery. Given manual rotation was associated with a nonsignificant reduction in operative delivery, more randomized trials are needed, as our trial might have been underpowered. In addition, further research is required to further explore the potential impact of operator or investigator experience.

Key words: cesarean delivery, fetal position, instrumental delivery, manual rotation, operative delivery, posterior position, prolonged labor, second stage of labor

Introduction

The occiput posterior (OP) position in the second stage of labor is associated with adverse maternal and perinatal outcomes and is present in 10% to 20% of all labors.[1−4] It is a major risk factor for cesarean delivery for slow progress in labor and for assisted vaginal delivery,[1,5−7] which in turn are associated with well-recognized serious adverse outcomes.[8,9] Rates of cesarean delivery in particular have increased markedly in recent decades.[10] The OP position in the second stage of labor is also associated with higher rates of oxytocin augmentation of labor, chorioamnionitis, labor arrest disorders, operative delivery, obstetrical anal sphincter injury, postpartum hemorrhage, birth trauma, and admission to the neonatal intensive care unit (NICU).[1,4,11−15]

Prophylactic manual rotation entails a vaginal examination with rotation of the presenting vertex from the OP position to the occiput anterior (OA) position with the aim of achieving an unassisted vaginal birth.[16] In the second stage of labor, this procedure is commonly used by some obstetricians and midwives to reduce the probability of operative delivery and the complications associated with the OP position.[17−20] Prophylactic manual rotation is performed with the intention of allowing the woman to continue in labor and achieve a vaginal delivery and is distinct from manual rotation performed to facilitate instrumental delivery.[21,22]

There is a paucity of robust evidence evaluating prophylactic manual rotation. There are 2 randomized trials, both of

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AJOG MFM at a Glance

Why was this study conducted?

Prophylactic manual rotation from the occiput posterior position to the occiput anterior position in the second stage of labor is considered a safe and easy to perform procedure that in observational studies has shown promise as a method for preventing operative deliveries. To date, only 2 small randomized controlled trials have been published on manual rotation in labor.

Key findings

Prophylactic manual rotation did not result in a reduction in the rate of operative delivery; however, there was a trend toward fewer operative births. More research is required to assess the impact of manual rotation on operative delivery and the role of operator experience.

What does this add to what is known?

This study is an adequately powered, blinded randomized controlled trial of prophylactic manual rotation in labor. In addition, other trials are being conducted, and future meta-analyses may clarify the role of manual rotation for preventing operative delivery.

which have inadequate sample sizes for important clinical outcomes.[23,24] Observational studies suggest that prophylactic manual rotation reduces the rate of operative delivery, but these studies are susceptible to selection bias.[19,20] These studies suggest that complications are uncommon but have not reported on important outcomes, such as women's satisfaction with their birth and quality of life, or long-term outcomes, such as breastfeeding and pelvic floor function. Based on the current state of knowledge, there have been calls for adequately powered randomized controlled trials.[16,20,25,26]

The Persistent Occiput Posterior Position-Outcomes (POP-OUT) Trial was designed to determine the efficacy of prophylactic manual rotation in the management of OP position for preventing operative delivery. The hypothesis was that among women who are at least 37 weeks pregnant and whose baby is in the OP position early in the second stage of labor, manual rotation will reduce the rate of operative delivery compared to the "sham" rotation.

Materials and Methods

Trial design

The POP-OUT Trial was a prospective, superiority, double-blinded, multicenter, randomized controlled clinical trial that recruited from 4 tertiary hospitals in Australia from April 2012 to January 2017. The study protocol[27] was approved by the Ethics Review Committee of the South Eastern Sydney Local Health District (Royal Prince Alfred Hospital [RPAH] Zone) (protocol number X11-0410 and HREC/11/RPAH/637) and the ethics review boards of each clinical site before recruitment started. Written informed consent was obtained from all participants before randomization. An independent Data Safety Monitoring Committee, consisting of a neonatologist, an obstetrician, and a statistician, monitored the trial and reviewed all serious maternal and neonatal complications.

Participants

Nulliparous and parous women with a singleton term (≥37 weeks' gestation) cephalic-presenting pregnancy, at least 18 years old, planning a vaginal birth, and with fetal OP position on transabdominal ultrasound in the second stage of labor just before planned intervention were included. The exclusion criteria were any contraindications to vaginal birth, previous cesarean delivery, a brow or face presentation, pathologic cardiotocograph, and any other maternal or fetal indications that would require an operative delivery. Full eligibility criteria are provided in the published protocol.[27] We conducted a similar randomized trial for women with a fetus in the occiput transverse (OT) position that will be reported separately.[28]

Baseline characteristics included maternal age, booking body mass index (at 14–18 weeks' gestation), ethnicity (self-reported), level of education, gestational age at delivery, parity, gestational diabetes, hypertension in pregnancy (systolic blood pressure of ≥140 mm Hg or diastolic blood pressure of ≥90 mm Hg on 2 occasions at least 4 hours apart), induction of labor, thick meconium liquor, oxytocin augmentation of labor, epidural analgesia, fetal station (station 0, leading part of the fetal skull at the level of the ischial spines and divided into thirds such that station +3, presenting part visible at the introitus without parting the labia), fetal caput (nil; +, small amount; ++, moderate; +++, large, clinically estimated), fetal molding (at sagittal and/or lambdoid sutures: +, adjacent bones touching; ++, overlapping, reducible; +++, overlapping, not reducible), fetal deflexion (clinically estimated), asynclitism (fetal head tilted to the left or right, based on clinical assessment of the position of the sagittal suture), birthweight, and infant sex.

Intervention

The intervention was manual rotation planned for when the woman had the first urge to push or 1 hour after full cervical dilatation was diagnosed, whichever occurred first. The technique employed was at the discretion of the investigator or operator performing the procedure. There were 38 investigators who performed the procedures. Most procedures were performed by investigators who had performed ≥20 prophylactic manual rotations. The techniques employed varied and included both "whole-hand" and 2-finger techniques. The techniques are described in detail in the Appendix.

Comparator

Women randomized to the "sham" (pretend) rotation had the same apparent vaginal examination as the

intervention with no rotational force applied to the presenting part.

Study conduct

Eligible women were provided with written information on the study at 35 to 37 weeks' gestation. Written consent was obtained antenatally, in the latent phase of labor (<4 cm cervical dilatation) or in the active phase of the first stage of labor with effective epidural anesthesia. A transabdominal ultrasound was performed at full cervical dilatation by the clinician caring for the woman. The transducer was placed transversely in the midline above the maternal symphysis pubis and angled downward. Fetal OP position was established by obtaining a transverse view of the fetal orbits.[2,29,30] OA and OT positions were determined by either imaging the midline structures of the fetal cranium or tracing the cervical spine down to its connection with the fetal skull,[2,29] depending on the preference of the investigator and the degree of shadowing from the symphysis pubis. OP position was defined as a posterior fetal occiput within 45° of the midline.[2]

An on-call study investigator with no clinical responsibility for the woman's care was called to attend. The investigator verified the OP position on ultrasound, verbally reconfirmed the woman's consent, and performed the randomization. After manual rotation or sham rotation by the investigator, a repeat ultrasound, blinded to the treating clinicians, was performed. Midwives could be present during the manual or sham rotation, but the screen was oriented away from the midwife during the postprocedure ultrasound to maintain blinding to treatment allocation.

Randomization and allocation concealment

Women were randomly allocated to manual rotation or sham rotation in a 1:1 ratio. Block randomization using computerized sequence generation was administered by the Clinical Trials Center, University of Sydney, Australia, and was accessed by telephone immediately before manual or sham rotation. Randomization was stratified by parity, hospital site, and epidural analgesia. Each investigator completed a data collection form contemporaneously, which included the treatment allocation, findings on vaginal examination, and postprocedure ultrasound findings. The participants, clinicians, and data collectors were blinded to the study group allocation. Unblinding occurred only if there was a clinical necessity.

After the first 20 randomizations, we decided to ask the midwife caring for the woman to guess treatment allocation after manual rotation or sham rotation was performed with the aim of assessing if blinding was effective.

Trial outcomes

The primary outcome was operative delivery defined as cesarean delivery or vacuum or forceps delivery. The secondary outcomes were cesarean delivery, serious maternal morbidity and mortality, and serious perinatal morbidity and mortality. The latter 2 were combined outcome measures and are described in detail in the trial protocol.[27]

Other prespecified outcomes included length of the second stage of labor, time from the manual or sham rotation until delivery, visually estimated blood loss at delivery, any perineal or vaginal trauma requiring suturing, and length of hospital stay. The use of episiotomy was a posthoc outcome added because it has been identified as a core outcome measure for maternity care.[31]

Follow-up outcomes at 6 weeks, 6 months, and 1 year included currently breastfeeding, satisfaction with birth (visual analog scale), if a health professional was consulted for depression since delivery, and health-related quality of life (12-Item Short Form Health Survey, version 1).[32] Pelvic floor function (bowel, urinary, prolapse, and sexual function domains) was assessed at 1 year using the Australian Pelvic Floor Questionnaire.[33]

Sample size

We assumed a baseline rate of operative delivery of 68% in the control arm,[1,7] and reducing this rate to 50% was clinically significant.[17,18] For a 2-tailed α-value of 0.05 and a β-value of 0.20, 127 women were required in each arm of the trial. There was no adjustment for losses to follow-up because we expected complete ascertainment for the primary outcome (operative delivery), which occurred within a few hours of randomization.

Statistical analysis

Outcomes were compared by treatment allocation (intention to treat). For categorical outcomes, proportions were compared using chi-square tests adjusted for stratification variables using the Mantel-Haenszel method or Fisher exact test when the expected value of $\geq$50% of cells was <5. For normally distributed data, means were compared using *t* tests, and data were summarized using means and standard deviations. For nonnormally distributed data, medians were compared using the Wilcoxon rank-sum test, and data were summarized using medians and interquartile ranges. No interim analysis was undertaken.

The logistic regression model-building strategy is described in the POP-OUT Trial protocol.[27] We repeated the analysis using log-binomial regression because the results can be expressed as risk ratios considered to be more easily interpreted by clinicians than odds ratios.[34] The regression model was adjusted for stratification variables as not adjusting for these variables results in overestimation of standard errors and inappropriately wide confidence intervals (CIs).[35]

Subgroup analysis was performed according to the technique of manual rotation used (manual or whole-hand vs digital or fingers) and according to investigator experience (performed $\geq$20 prophylactic manual rotations previously vs <20). Following expert feedback, a posthoc subgroup analysis was also performed by fetal head deflexion at the time of the manual or sham rotation.

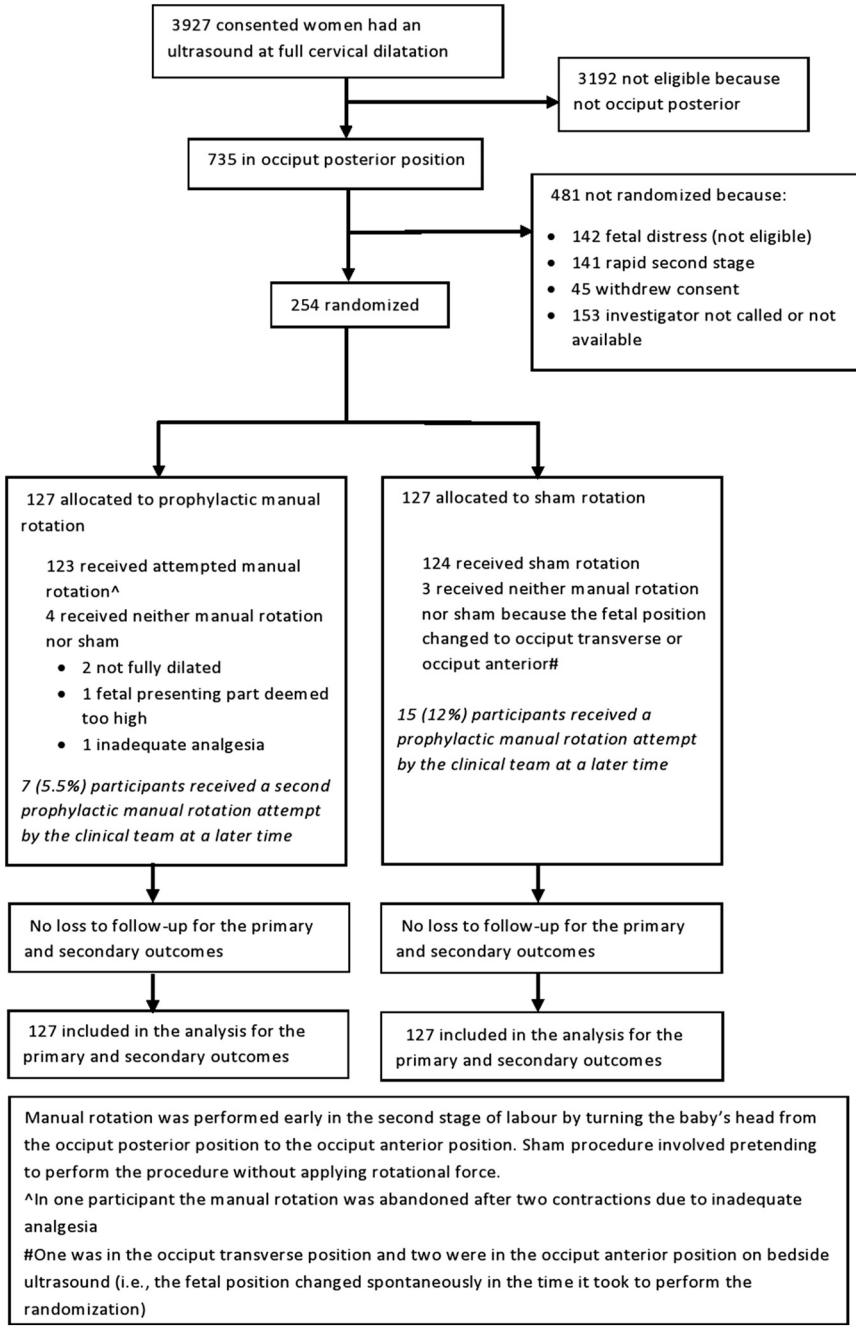
All analyses were performed using Statistical Analysis Software (SAS/STAT) (version 9.4; SAS Institute, Cary, NC).

Results

Participants and recruitment

Approximately 8637 women were asked to participate in the study, of whom 6468 provided informed consent, 2169 declined to participate in the study, and

FIGURE
POP-OUT clinical trial flow diagram



POP-OUT, Persistent Occiput Posterior Position-Outcomes.

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2541 became ineligible before or at full cervical dilatation. Of the women included in the study, 3927 had a bedside ultrasound to determine fetal position (Figure). Of these women, 3192 (81%) did not have a fetus in the OP position, 735 (19%) had a fetus in the OP position, and 254 were randomized. The reasons why 481 women were not randomized are shown in the Figure.

The 2 study groups had similar baseline characteristics except that there were more women of Southeast Asian ethnicity in the manual rotation group (20% vs 15%) and fewer women of other ethnicities than Southeast Asian, South Asian, or white in the manual rotation group (2% vs 8%). Overall, 84% of women were nulliparous and 94% had an epidural analgesia, and the median gestational age at randomization was 40 weeks (Table 1).

Protocol adherence

Here, 7 participants (2.8%) did not receive their allocated treatment, including 4 women in the manual rotation arm and 3 in the sham rotation arm (Figure). The proportion of women who received prophylactic manual rotation later (after randomization) in the manual rotation and the sham rotation arms was 5.5% and 12%, respectively (Figure).

Of the 127 women assigned to manual rotation, the postprocedure ultrasound showed that 77 women (61%) had a baby in the OA position, 23 women (18%) had a baby in the OT position, and 27 women (21%) had a baby in the OP position.

A total of 93 midwives were asked to guess treatment allocation, primarily in 1 center. In the manual rotation group, 30 of 47 midwives (64%) guessed a manual rotation had been performed, and in the sham rotation group, 27 of 46 midwives (59%) guessed a manual rotation had been performed.

Primary and other maternal and perinatal outcomes

Operative delivery occurred in 62% of women in the manual rotation group and 71% of women in the sham rotation group (χ^2, 2.87; common risk difference [CRD], 12; 95% CI, −1.7 to 26; P=.09) (Table 2).

The risk ratio for operative delivery among women in the manual rotation group compared with the sham rotation group was 0.87 (95% CI, 0.73−1.03) in the log-binomial regression after adjusting for stratification variables. The logistic regressions showed similar results. No variable was identified as a confounder in the stepwise backward regression.

Subgroup analyses

Table 2 shows the planned subgroup analyses by investigator experience and

TABLE 1
Maternal, neonatal, and intrapartum characteristics

Characteristics	Manual rotation (n=127)	Sham rotation (n=127)
Maternal age (y)	31 (28–34)	29 (26–32)
<35 y (%)	109 (86)	108 (85)
Antepartum body mass index (kg/m^2)	24 (22–28)	25 (22–29)
Ethnicity		
White	83 (65)	79 (62)
Southeast Asian	26 (20)	19 (15)
South Asian	15 (12)	19 (15)
Other	3 (2)	10 (8)
Tertiary education	78 (61)	71 (56)
Gestational age (wk)	40 0/7 (39 0/7–40 6/7)	40 1/7 (39 1/7–40 6/7)
Nulliparous	107 (84)	105 (83)
Gestational diabetes mellitus	12 (9)	8 (6)
Hypertension	12 (9)	12 (9)
Induction of labor	59 (47)	57 (45)
Thick meconium (before randomization)		
Yes	20 (16)	10 (8)
No	107 (84)	117 (92)
Oxytocin augmentation in the first stage of labor	43 (34)	42 (33)
Epidural during labor	120 (94)	118 (93)
Duration of first stage of labor (h)[a]	7.2 (5.1–10.5)	7.0 (4.5–9.4)
Fetal station (preprocedure)[b]		
≤−1	10 (9)	8 (7)
0	35 (30)	24 (21)
+1	57 (49)	65 (56)
≥+2	14 (12)	19 (16)
Fetal caput (preprocedure)[b]		
Nil	14 (11)	18 (15)
Small amount	56 (45)	53 (43)
Moderate	43 (35)	41 (33)
Large, clinically estimated	11 (9)	12 (10)
Fetal molding (preprocedure)[b]		
None	29 (24)	40 (33)
Adjacent bones touching	64 (52)	64 (52)
Overlapping, reducible	26 (21)	18 (15)
Overlapping, not reducible	3 (2)	1 (1)
Fetal head deflexed (preprocedure)[b]		
Yes	87 (72)	91 (76)
No	34 (28)	28 (24)

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(continued)

TABLE 1
Maternal, neonatal, and intrapartum characteristics *(continued)*

Characteristics	Manual rotation (n=127)	Sham rotation (n=127)
Fetal head asynclitic (preprocedure)[b]		
Yes	43 (35)	27 (23)
No	80 (65)	92 (77)
Birthweight (kg)	3.50 (3.19–3.77)	3.56 (3.17–3.84)
Female infant	58 (46)	52 (41)

Data are presented as median (interquartile range) or number (percentage).

[a] The onset of labor was defined as the presence of 5-minute contractions with cervical change to ≥4 cm dilatation as determined by the caring midwife; [b] Data are missing for 22 women having a vaginal examination (including 6 for fetal station, 6 for caput, 9 for molding, 14 for deflexion, and 12 for asynclitism).

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investigator technique. There was no difference in operative delivery by treatment allocation within any of the subgroups. Among investigators who had performed ≥20 prophylactic manual rotations, operative delivery occurred in 46 of 74 patients (62%) in the manual rotation group and 52 of 71 patients (73%) in the sham rotation group (χ^2, 3.22; CRD, 18; 95% CI, −0.5 to 36; *P*=.07).

In the posthoc subgroup analysis, among the 62 participants with a flexed fetal head, operative delivery occurred in 15 of 44 participants (44%) in the manual rotation group and 21 of 28 participants (75%) in the sham rotation group (χ^2, 5.36; CRD, 32; 95% CI, 6.5–58; *P*=.02).

Maternal outcomes

There was no difference in the mode of birth between the 2 groups (Table 2). The cesarean delivery rate was 22% of women in both the manual rotation and sham rotation groups. Instrumental delivery occurred in 45% of women in the manual rotation group and 54% of women in the sham rotation group (χ^2, 2.13; CRD, 9.6%; 95% CI, −3.1 to 22; *P*=.14). The incidence of fetal position at delivery was as follows: 67 of 123 women (54%) had a baby in the OA position, 15 of 123 women (12%) had a baby in the OT position, and 41 of 123 women (33%) had a baby in the OP position.

Serious adverse maternal outcomes occurred in 13% of women in the manual rotation group and 18% of women in the sham rotation group (χ^2, 1.19; CRD, 9.6%; 95% CI, −7.3 to 26; *P*=.36) (Table 3). There was no difference in any of the components of the combined serious adverse maternal outcome measure (Table 3).

Perinatal outcomes

Serious adverse perinatal outcomes occurred in 17% of women in both the manual rotation and sham rotation groups (Table 3). There was 1 umbilical cord prolapse (0.8%) in the manual rotation group. At the time of manual rotation, the umbilical cord was palpated by the investigator adjacent to the fetal head, but not prolapsed into the vagina, and the caring clinicians were informed. An emergency cesarean delivery was performed 40 minutes later for umbilical cord prolapse. Apgar results were 9 at 1 minute and 5 minutes, and there was no admission to the NICU. There was no difference in any of the components of the combined serious adverse perinatal outcome measure (Table 3).

Other short-term outcomes

There was no difference in the prespecified outcomes of duration of the second stage of labor, time from manual or sham rotation until delivery, estimated blood loss at birth, any perineal trauma requiring suturing, or length of hospital stay (Table 3). Episiotomy, a posthoc outcome, occurred in 40% of participants in the manual rotation group and 54% of participants in the sham rotation group (χ^2, 4.56; CRD, 14%; 95% CI, 1.4–26; *P*=.03).

Follow-up outcomes

We received completed follow-up questionnaires from 180 of 254 participants (71%) at 6 weeks, 171 of 254 participants (67%) at 6 months, and 165 of 254 participants (64%) at 1 year (Table 4). At 6 weeks, more women in the manual rotation group were satisfied, with a birth visual analog score of >5 (83% vs 65%; χ^2, 8.76; CRD, 26%; 95% CI, 9.6–42; *P*=.003). There was no difference in the median satisfaction with the birth score or any of the other follow-up outcomes (Table 4).

Structured Discussion or Comment

Principal findings

In this double-blinded multicenter trial, prophylactic manual rotation from the OP position in the second stage of labor was not associated with operative delivery compared with a sham rotation. In addition, there was no difference in combined maternal and perinatal adverse outcomes and no difference in rates of cesarean delivery.

Results in the context of what is known

Two small randomized trials have assessed the efficacy of prophylactic manual rotation, including the POP-OUT Pilot Trial, but these trials were not powered to detect a difference in operative delivery.[23,24] In addition, 2 observational studies suggested that prophylactic manual rotation is associated with a reduction in operative deliveries, including

TABLE 2
Primary and delivery outcomes

Outcome	Manual rotation (n=127)	Sham rotation (n=127)	*P* value
Operative delivery	79 (62)	90 (71)	.09
Normal vaginal birth	48 (38)	37 (29)	
Cesarean delivery	22 (17)	22 (17)	.93
Slow progress	15 (12)	1 (13)	
Fetal concerns	6 (5)	3 (2)	
Other	1 (1)	2 (2)	
Instrumental	57 (45)	68 (54)	.14
Indication			
Slow progress	42 (33)	44 (35)	
Fetal concerns	15 (12)	24 (19)	
Type			
Vacuum	18 (14)	24 (19)	
Forceps	39 (31)	44 (35)	
Rotation			
Rotational[a]	31 (24)	44 (35)	
Nonrotational	26 (20)	24 (19)	
Operative delivery, subgroups			
Investigator experience			
More experienced	46/74 (62)	52/71 (73)	.07
Less experienced	29/46 (63)	31/49 (63)	.96
Investigator technique[b]			
Digital rotation	45/72 (62)	51/72 (71)	.19
Whole-hand rotation	29/47 (62)	29/44 (66)	.57
Fetal deflexion[c]			
Flexed	15/44 (44)	21/28 (75)	.02
Deflexed	59/87 (68)	64/91 (70)	.55
Fetal occiput position			
After intervention (ultrasound)			
Anterior	77 (61)	5 (4)	
Transverse	23 (18)	5 (4)	
Posterior	27 (21)	117 (92)	
At delivery[c]			
Anterior	67/123 (54)	31/124 (25)	
Transverse	15/123 (12)	14/124 (11)	
Posterior	41/123 (33)	79/124 (64)	

Data are presented as number (percentage) or number/total number (percentage).

[a] Rotational instrumental delivery was defined as occiput posterior or occiput transverse fetal position immediately before the assisted delivery; [b] The technique routinely used by the investigator: 144 manual rotations or sham rotations were performed by investigators who routinely used digital rotations, 91 by investigators who routinely used whole-hand rotations, 5 by investigators who reported that their practice varied, and 14 by investigators whose technique was unknown; [c] Missing data for 14 participants for fetal flexion at the time of the manual or sham rotation and for 6 participants for fetal occiput position at delivery. One brow presentation at delivery in the sham rotation group.

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TABLE 3
Serious maternal outcomes, serious perinatal outcomes, and other outcomes

Outcomes	Manual rotation (n=127)	Sham rotation (n=127)	*P* value
Serious maternal adverse outcomes	17 (13)	23 (18)	.28
Third- or fourth-degree perineal trauma	7 (6)	13 (10)	
Admission to high-dependency unit[a]	5 (4)	4 (3)	
Blood transfusion	3 (2)	3 (2)	
Uterine evacuation	3 (2)	2 (2)	
Wound dehiscence or infection	2 (2)	1 (1)	
Postpartum fever	1 (1)	1 (1)	
Pneumonia	1 (1)	1 (1)	
Organ injury[b]	0 (0)	2 (2)	
Genital fistula	0 (0)	2 (2)	
Vulvar or perineal hematoma	0 (0)	1 (1)	
Venous thromboembolism	0 (0)	1 (1)	
Vertical uterine incision, cervix laceration, bowel obstruction, or admission to ICU	0 (0)	0 (0)	
Serious adverse perinatal outcomes	21 (17)	22 (17)	.6
Phototherapy for jaundice	10 (8)	10 (8)	
Arterial cord base excess <-15 mEq/L^{-1}	3 (2)	6 (5)	
Subgaleal hemorrhage	3 (2)	5 (4)	
Shoulder dystocia	4 (3)	1 (1)	
Arterial cord pH <7.0	1 (1)	2 (2)	
5-min Apgar score <4	1 (1)	0 (0)	
Neuropraxia	0 (0)	1 (1)	
NICU admission >4 d, fracture, ICH, HIE, blood transfusion	0 (0)	0 (0)	
Other outcomes			
Duration of second stage of labor (h)	3.0 (2.0–3.7)	3.0 (2.3–3.8)	.57
Duration of second stage of labor ≤ 3 h	66 (52)	64 (50)	.80
Time from manual rotation or sham rotation to delivery (h)	1.8 (0.85–2.70)	1.9 (1.20–2.70)	.22
Second-, third-, or fourth-degree perineal trauma	84 (66)	96 (76)	.12
Second degree (includes episiotomy)	74 (58)	82 (65)	
Third degree	7 (6)	13 (10)	
Fourth degree	0 (0)	0 (0)	
Episiotomy	51 (40)	68 (54)	.03
Estimated blood loss at delivery (mL)[c]	350 (300–500)	400 (300–500)	.34
Maternal length of hospital stay	3.7 (2.5–4.9)	3.7 (2.6–4.7)	.96

Data are presented as number (percentage) or median (interquartile range).

HIE, hypoxic-ischemic encephalopathy; *ICH*, intracranial hemorrhage; *ICU*, intensive care unit; *NICU*, neonatal intensive care unit.

[a] High dependency units are a specially staffed and equipped area of the hospital, which provide a level of care intermediate between intensive care and general ward care; [b] Both bladder injuries occurring during cesarean delivery; [c] n=240 (excludes 1 participating center that categorized estimated blood loss in 500 mL intervals). When the midpoint of the range was used as the point estimate for the 12 participants from this center, the results for estimated blood loss were similar.

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TABLE 4
Follow-up at 6 weeks, 6 months, and 1 year

Variable	Manual rotation	Sham rotation	*P* value
6 wk follow-up			
Satisfaction with birth	(n=90)	(n=89)	
VAS[a]	8 (6–10)	8 (5–10)	.15
Satisfied (VAS >5)	75/90 (83)	58/89 (65)	.003[b]
Currently breastfeeding	70/91 (77)	65/89 (73)	.86[b]
Depression			
Felt significantly depressed	8/91 (9)	11/89 (12)	.29[b]
Saw a doctor for depression	2/91 (2)	0/89 (0)	.50[c]
Health-related quality of life (SF-12v1)	(n=90)	(n=88)	
Physical health T-score	54 (45–54)	52 (45–55)	.14
Mental health T-score	55 (48–58)	53 (46–58)	.64
6 mo follow-up			
Currently breastfeeding	49/86 (57)	50/85 (59)	.51[b]
Depression			
Felt significantly depressed	9/86 (10)	11/84 (13)	.71[b]
Saw a doctor for depression	3/86 (3)	1/84 (1)	.62[c]
Health-related quality of life (SF-12v1)	(n=86)	(n=85)	
Physical health T-score	55 (52–57)	56 (50–57)	.84
Mental health T-score	54 (50–58)	54 (48–58)	.45
1 y follow-up			
Currently breastfeeding	31/85 (36)	30/80 (38)	.61[a]
Health-related quality of life (SF-12v1)	(n=85)	(n=78)	
Physical health T-score	56 (53–57)	56 (52–57)	.63
Mental health T-score	55 (50–58)	56 (49–58)	.84
Australian Pelvic Floor Function Questionnaire			
Prolapse score	0 (0–0) (n=86)	0 (0–0) (n=80)	.67
Bladder score	2 (1–6) (n=85)	2 (0–4) (n=80)	.07
Bowel score	3 (1–5) (n=86)	3 (1–5) (n=77)	.93
Sexual function score	2 (0–4) (n=84)	2 (0–4) (n=80)	.77
Total pelvic floor score	3 (1–4) (n=83)	2 (1–5) (n=77)	.94

Data are presented as median (interquartile range) or number/total number (percentage).

SF-12v1, 12-Item Short Form Health Survey, version 1; *VAS*, visual analog scale.

[a] Participants were asked "Were you satisfied with your birth?" and to mark an "X" on a horizontal scale labeled "Not at all satisfied" and "Extremely satisfied" at each end; [b] Mantel-Haenszel chi-square test; [c] Fisher exact test.

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cesarean delivery,[19,20] leading to interest in this procedure as 1 method of addressing the global increase in cesarean delivery rates.[10,36] However, we found identical cesarean delivery rates in both arms of the POP-OUT Trial. This apparent discrepancy could be explained by selection bias in the observational studies, potentially because of the use of historic controls[19] or use of OP position at the time of delivery as a surrogate for OP position during the second stage of labor in the control group.[20]

Clinical implications

In the POP-OUT Trial, prophylactic manual rotation did not result in a decrease in the operative delivery rate. However, the procedure seems to be safe, and it would be reasonable to offer manual rotation on a case-by-case basis.

The POP-OUT Trial was powered to detect an 18% absolute risk difference in operative delivery, but the sample size may have been insufficient to allow the detection of differences in the rates of instrumental (forceps or vacuum) delivery. We observed a nonsignificant common risk difference in instrumental deliveries of 12%, and it remains possible that data from ongoing randomized controlled trials[37,38] will contribute toward the detection of a smaller clinically significant reduction in instrumental delivery, especially rotational procedures. This is important because instrumental deliveries are associated with maternal complications, including obstetrical anal sphincter injury, levator avulsion, and postpartum hemorrhage,[13,15,39,40] and perinatal complications, including subgaleal hemorrhage, intracranial hemorrhage, nerve injury, and skull fracture.[41–44] The difference in episiotomies (40% in the manual rotation group vs 54% in the sham rotation group) could be because of fewer instrumental births in the manual rotation group. Episiotomy rates were high because of the high rate of instrumental births and consistent with previous reports of nulliparous women with epidural analgesia and a fetus in the OP position.[1]

Complications of manual rotation

The medical literature does not suggest that prophylactic manual rotation is linked with serious complications, although a possible association with shoulder dystocia has been reported.[20] Such a relationship is plausible if manual rotation leads to vaginal delivery when cesarean delivery would otherwise have been performed, a possibility that is not supported by the POP-OUT Trial because cesarean delivery rates were identical in both arms. We observed 4 shoulder dystocias in the manual rotation group and 1 in the sham rotation group and conclude that there are insufficient data to assess this complication. The observational study by Shaffer et al[20] reported a higher rate of cervical laceration when manual rotation was performed (2.2% when manual rotation was performed vs 1.0% when it was not performed; P=.02). The absence of cervical lacerations in the POP-OUT Trial could be explained by the relatively small sample size, the performance of manual rotations at full cervical dilatation, or missed diagnoses as speculum examinations were not routinely performed. Cervical laceration should not occur at full cervical dilatation because the cervix is fully merged with the uterus and vagina. Future studies on manual rotation should report on shoulder dystocia and cervical laceration.

Umbilical cord prolapse is an obstetrical emergency, and we know of 1 case report of this complication associated with prophylactic manual rotation.[45] There was 1 umbilical cord prolapse in the manual rotation arm of the POP-OUT Trial. It is not possible to determine from the POP-OUT Trial or the medical literature if prophylactic manual rotation can cause prolapse of the umbilical cord. In the retrospective study by Shaffer et al,[20] there was no reported umbilical cord prolapse among 731 manual rotations, suggesting that this complication is rare. We speculate that excessive upward pressure or pushing between contractions during a manual rotation could increase the risk of umbilical cord prolapse.

Follow-up outcomes

There was no difference in median maternal satisfaction with care during labor, but women allocated to manual rotation were more likely to score higher than 5 on the birth visual analog scale for maternal satisfaction with birth. This finding is difficult to interpret, but it does suggest that manual rotation does not adversely affect women's experience of labor. Our finding of no difference in depression, quality of life, breastfeeding, and pelvic floor function suggests that there is no medium-term adverse effect of prophylactic manual rotation.

Research implications

Two randomized controlled trials, each with a similar sample size to the POP-OUT Trial, are currently being conducted in France.[37,38] Future meta-analyses will provide further information about the possible benefits or harms of prophylactic manual rotation, particularly with regard to the prevention of instrumental births, and may provide more information about the impact of investigator experience. Based on our posthoc analysis, it would be useful to report results by flexion or deflexion of the fetal head. If manual rotation is found to confer benefit to women and their babies, there would be a need to train obstetricians and midwives who are not experienced with the procedure, and cost-effectiveness should be evaluated.

Strengths and limitations

The strengths of the POP-OUT Trial include prospective data collection; ultrasound-confirmed diagnosis of malposition, which is more accurate than digital examination[46]; and a primary outcome (operative delivery) that is easily ascertained, all of which reduce measurement bias. Randomization with blinding of clinicians and data collectors to treatment allocation reduces bias.[47,48] Our sample of midwives suggested blinding of clinicians was effective. There was no loss to follow-up for the primary outcome, which eliminated attrition bias.

The results of the POP-OUT Trial may not be generalizable to all settings (eg, centers with more obese maternal populations). Most participants were nulliparous women with epidural analgesia, potentially because OP position is associated with prolonged labor[1,2] or because epidural analgesia was a requirement for intrapartum consent.

Another limitation is that the POP-OUT Trial was not powered to assess secondary or rare outcomes, such as umbilical cord prolapse. Other limitations include the low rates of follow-up (64%–71%), which can lead to selection bias for medium-term outcomes.[49] In addition, clinicians performed a manual rotation later in the second stage of labor more commonly in the sham rotation group, which could bias our findings toward the null, although the size of this effect is likely to be small. Finally, any reduction in rotational assisted vaginal

deliveries in the manual rotation group could translate to an effect on cesarean sections in centers where clinicians are less comfortable with rotational vaginal deliveries.

The efficacy of procedural interventions can depend on investigator skill and experience. In the POP-OUT Trial, 61% of women in the manual rotation arm had a baby in the OA position after attempted manual rotation, and 18% of women in the same group had a baby in the OT position. Others have reported higher "success" rates of manual rotation of 74% to 93%[6,19,50] Explanations for the lower rate in the POP-OUT Trial include investigator ability; the definition of OA position (our definition required the fetal occiput to be within 45° of the midline); changes in fetal position back to OT or OP before the bedside ultrasound was conducted; reliance on the fetal position at birth (known to change during the second stage of labor)[2] to define success in other studies[19,50]; use of vaginal examination vs ultrasound to assess the fetal position after the procedure; and multiple attempts at manual rotation.[6] The observed difference in operative delivery between the 2 treatment groups was higher among more experienced proceduralists (Table 2), but the difference was not statistically significant (P=.07).

Our finding that planned manual rotation prevented operative delivery when the fetal head is not deflexed should be treated with caution because the sample size was small in this subgroup (n=62) and because this was a posthoc analysis. This should be investigated in future studies.

Conclusions

Prophylactic manual rotation did not prevent operative delivery, and there was no difference in maternal and perinatal adverse outcomes. However, there was a nonsignificant reduction in operative delivery, and it remains possible that the POP-OUT Trial was underpowered. Future trials should explore the potential impact of operator or investigator experience.

Highlights

What is already known on this topic?

- Observational studies suggest that prophylactic manual rotation from the posterior position in the second stage of labor increases a woman's chance of having a spontaneous vaginal birth and decreases her chance of a cesarean delivery.
- Manual rotation in labor seems to be safe.
- Midwives and obstetricians would practice manual rotation if randomized controlled clinical trials showed a treatment benefit.

What this study adds

- This study is an adequately powered randomized controlled clinical trial assessing the efficacy of prophylactic manual rotation from posterior position in the second stage of labor for preventing operative delivery.
- Prophylactic manual rotation was not associated with operative delivery, cesarean delivery, or maternal or perinatal morbidity.
- There may have been a trend toward fewer instrumental deliveries, but our study was underpowered for this outcome.
- The possible impact of investigator experience on the efficacy of manual rotation requires further investigation. ■

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Author and article information

From the Sydney Institute for Women, Children and their Families, Sydney Local Health District, Sydney, New South Wales, Australia (Drs Phipps, Hyett, Tooher, and de Vries); Discipline of Obstetrics, Gynaecology and Neonatology, The University of Sydney, Sydney, New South Wales, Australia (Drs Phipps and Ludlow); Royal Prince Alfred Hospital Women and Babies Ambulatory Care, Royal Prince Alfred Hospital, Sydney, New South Wales, Australia (Drs Hyett, Ludlow, Narayan, Santiagu, and Tooher); Women's and Children's Hospital, Adelaide, South Australia, Australia (Drs Kuah, Matthews, Earl, and Wilkinson); Nepean Hospital, Penrith, New South Wales, Australia (Dr Pardey); Ultrasound Care, Sydney, New South Wales, Australia (Dr Ludlow); Royal Hospital for Women, Sydney, New South Wales, Australia (Dr Bisits); Discipline of Obstetrics, Gynaecology and Neonatology, School of Women's and Children's Health, University of New South Wales, Sydney, New South Wales, Australia (Dr Bisits); Maternity and Gynaecology, John Hunter

Hospital, Newcastle, New South Wales, Australia (Dr Carseldine); and Faculty of Medicine and Health, The University of Sydney School of Public Health, Sydney, New South Wales, Australia (Drs McGeechan and de Vries).

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Corresponding author: Hala Phipps, PhD. hala.phipps@health.nsw.gov.au

Appendix

Techniques of manual rotation used in the POPOUT Trial

The purpose of this appendix is to provide a brief description of the techniques used and the experience of the proceduralists who participated in the POPOUT Trial, because the efficacy of procedures in clinical trials is often operator-dependent.

Thirty- eight investigators performed manual rotations or sham procedures for the 254 randomisatons in the POPOUT Trial. Ninety-one rotations or sham procedures were performed by proceduralists who reported routinely using a whole hand rotation and 144 were performed by proceduralists who routinely performed a digital rotation. Five were performed by an investigator whose practice varied.

145 rotations or sham procedures were performed by experienced proceduralists (who had performed twenty or more prophylactic manual rotations before participating in the POPOUT Trial) and 95 were performed by less experienced proceduralists. For 14 randomisations, operator experience was unknown. Many proceduralists had experience with therapeutic manual rotation immediately prior to assisted vaginal delivery (e.g., manual rotation followed immediately by non-rotational forceps delivery) but not prophylactic manual rotation. If therapeutic manual rotations were included, 181 randomisations were performed by proceduralists who had performed 20 or more manual rotations and 59 were performed by less experienced proceduralists.

149 rotations or sham procedures were performed by proceduralists who routinely performed manual rotations during uterine contractions and 86 were performed by proceduralists who routinely performed manual rotations between uterine contractions. Five were performed by a proceduralist whose practice varied and 14 by proceduralists whose timing with respect to uterine contractions was unknown.

The techniques described by POPOUT Trial proceduralists varied. Some of the techniques used by investigators who randomised more than ten women are described below:

1. "For occiput posterior position, two fingers are placed over the sphenoid bone and gentle UP and around pressure is applied whilst the woman pushes turning the head to the occiput transverse position, then the fingers are placed behind the ear and a turning pressure is applied. Finally when able to reach easily, a pressure is applied to the raised edge of the parietal bone as it overrides the occiput and pressure around whilst NOT pushing up and, if possible, tracting slightly to complete flexion and rotation. The head is held in position for one to two contractions until descent is clearly felt and then the position is confirmed as correct after another contraction."
2. "Whole hand rotation is used, asynclytism is corrected and (critically) maximal flexion is obtained followed by descent. No intentional disimpaction or loss of station is required. To the contrary, clinically, it would be best to stay until descent beyond the starting point is achieved and the fetal head is "locked in position" before removing the hand. Once commenced, the hand never leaves the fetal head until the position is secured or a failed manual rotation is declared."
3. "Two fingers are placed on the lambdoid suture and rotational force is applied. The left hand is used for clockwise rotation, and the right hand for anti-clockwise rotation. Rotational force is applied during contractions. If this is not successful, rotational pressure may be applied to the temporal bone to get the baby to about the occiput transverse position first, with rotational force applied to the lambdoid suture from this point onwards. The aim is for rotation to occur over about three contractions and then for the fetal occiput to be held in the occiput anterior position while the mother pushes, for about another two contractions."
4. "Between contractions the fetal occiput is located and cupped in the operator's hand, and the fetal head is rotated. If the station is +2 or lower, two fingers are applied to the lambdoid suture and the occiput is gently pushed anteriorly during contractions. Both methods would be between (or during) three contractions at most."