

# Delivery Mode After Manual Rotation of Occiput Posterior Fetal Positions

## A Randomized Controlled Trial

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**OBJECTIVE:** To evaluate whether manual rotation of fetuses in occiput posterior positions at full dilation increases the rate of spontaneous vaginal delivery.

**METHODS:** In an open, single-center, randomized controlled trial, patients with a term, singleton gestation, epidural analgesia, and ultrasonogram-confirmed occiput posterior position at the start of the second stage of labor were randomized to either manual rotation or expectant management. Our primary endpoint was the rate of spontaneous vaginal delivery. Secondary endpoints were operative vaginal delivery, cesarean delivery, and maternal and neonatal morbidity. Analyses were based on an intention-to-treat method. A sample size of 107 patients per group (n=214) was planned to detect a 20% increase in the percent of patients with a spontaneous vaginal delivery (assuming 60% without manual rotation vs 80% with manual rotation) with 90% power and alpha of 0.05.

**RESULTS:** Between February 2017 and January 2020, 236 patients were randomized to either manual rotation (n=117) or expectant management (n=119). The success rate of the manual rotation maneuver, defined by conversion to an anterior position as confirmed by ultrasonogram, was 68%. The rate of the primary endpoint did not differ between the groups (58.1% in manual rotation group vs 59.7% in expectant management group (risk difference -1.6; 95% CI -14.1 to 11.0). Manual rotation did not decrease the rate of operative vaginal delivery (29.9% in manual rotation group vs 33.6% in expectant management group (risk difference -3.7; 95% CI -16.6 to 8.2) nor the rate of cesarean delivery (12.0% in manual rotation group vs 6.7% in expectant management group (risk difference 5.3; 95% CI -2.2 to 12.6). Maternal and neonatal morbidity was also similar across the two groups.

**CONCLUSION:** Manual rotation of occiput posterior positions at the start of second stage of labor does not increase the rate of vaginal delivery without instrumental assistance.

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The authors did not report any potential conflicts of interest.

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The frequency of occiput posterior positions at the onset of labor is approximately 20%, and up to 10% persist at birth.<sup>1,2</sup> Cephalic presentations with posterior positions (left occiput posterior, direct occiput posterior, and right occiput posterior) are associated with lower rates of spontaneous vaginal delivery, and higher rates of operative vaginal delivery and cesarean delivery when compared with occiput anterior positions.<sup>1,3-5</sup> Operative vaginal deliveries are associated with maternal morbidity (higher rates of postpartum hemorrhage, infections, and obstetric anal sphincter injuries compared with spontaneous vaginal deliveries).<sup>6</sup> Occiput posterior positions also

are associated with increased neonatal morbidity.<sup>1,7-9</sup> Lower Apgar scores and lower umbilical cord arterial pH values, as well as an increased rate of neonatal trauma, intensive care admissions, and encephalopathy are described with occiput posterior fetal head position at delivery.<sup>1,7-9</sup>

Numerous studies have, therefore, focused on different strategies for converting posterior positions to anterior positions with the aim of reducing maternal and neonatal morbidity. Changes in maternal position<sup>10-14</sup> and the use of oxytocin<sup>15</sup> have been shown to be ineffective. Instrumental rotations using forceps or Thierry spatulas (nonarticulating instruments, commonly used in France) may result in increased risks of birth injury for the fetus and higher degree perineal laceration in the mother.<sup>16-20</sup>

Manual rotation of an occiput posterior position to an anterior position is a common and accepted practice in obstetrics. Success rates of the maneuver range from 70% to 90%, depending on the operator.<sup>21-25</sup> However, data are limited and inconsistent regarding the effect of manual rotation on mode of delivery,<sup>23,24</sup> with some studies demonstrating a reduction in rates of cesarean and operative delivery and others finding no difference. Data from randomized controlled trials are needed.

Our primary objective was to evaluate whether manual rotation of occiput posterior positions increases the rate of spontaneous vaginal delivery. Our secondary objectives were to evaluate whether there were differences in rates of operative vaginal delivery, cesarean delivery, or maternal and neonatal morbidity between those undergoing manual rotation compared with those who did not.

## METHODS

Between February 2017 and January 2020, we conducted an open, single-center, randomized controlled trial on two parallel balanced groups at Angers University Hospital in France. Patients were randomized to either manual rotation or expectant management. The study was approved by the French regulatory authorities (IRB number 2016-38). The study protocol was published at the onset of the trial<sup>26</sup> and registered through [clinicaltrials.gov](https://clinicaltrials.gov) on April 1, 2017 (NCT03009435), before starting recruitment.

During the study period, patients considered for inclusion all were older than 18 years old with a term (gestational age of 37 weeks or more) singleton pregnancy in cephalic presentation with suspected posterior position, and efficacious epidural analgesia for whom a vaginal delivery was planned on admission for delivery.

Patients who were not eligible were those with clinical suspected fetopelvic disproportion, scarred uterus, preexisting diabetes, fetal malformations, fetal blood coagulation abnormalities, an abnormal fetal heart rate pattern requiring further testing (scalp pH), presentation of brow or face, suspected intrauterine infection, fever higher than 38°C during labor, or bleeding during the first phase of labor.

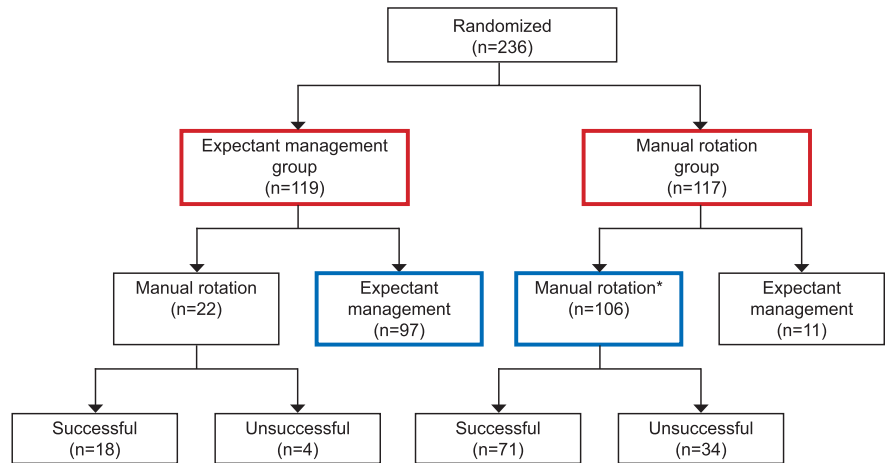
Among patients who met other eligibility criteria, a transabdominal ultrasonogram was performed to confirm occiput posterior position as soon as complete dilation was observed. Position was determined by placing the ultrasound probe transversely above the pubic symphysis and evaluating midline and orbit positions. Posterior position was confirmed as soon as an orbit was visible anteriorly.<sup>27</sup>

After confirmation of eligibility and before randomization, the investigators confirmed that the available obstetric team (physician, midwife, or a senior 4<sup>th</sup> or 5<sup>th</sup> year obstetrics resident) had the experience to perform manual rotation. Patients were then randomized to either expectant management or manual rotation. Randomization was stratified by parity (primiparous or multiparous) and contained blocks of varying sizes. Patients were given treatment according to an inclusion number assigned based on chronological order of entry into the study for each stratum. Randomization was performed securely online using the randomization module in Ennov Clinical.

Manual rotation was performed as soon as possible after randomization for patients assigned to the manual rotation group. The fetal head was rotated 135° from a posterior to an anterior position, with the choice of manual rotation technique being left to the operator. The authorized techniques were either the Tarnier and Chantreuil technique or the Society of Obstetricians and Gynaecologists of Canada (SOGC) technique.<sup>28</sup> The Tarnier and Chantreuil technique was performed with the right hand of the operator behind the right ear of the fetus for left posterior positions, and the left hand of the operator behind the left ear of the fetus in cases of right posterior positions. The maneuver consisted of both a rotational (counterclockwise for left posterior positions and clockwise for right posterior positions) and upward movement, towards the pubic symphysis synchronized with the patients pushing effort. The SOGC technique was performed with the operator's entire hand in the patient's vagina, and with the palm facing upward, the head of the fetus was slightly flexed, and constant gentle pressure exerted. Anterior rotation was applied to the occiput by pronation or supination of the operator's forearm. Successful manual rotation was defined by

**Fig. 1.** Study population. Flow chart summarizing our study population after randomization. Successful manual rotation was defined by the nonvisualization of orbits during a verification trans-abdominal ultrasonogram carried out immediately after the maneuver. Red boxes indicate intention-to-treat analysis; blue boxes indicate per-protocol analysis. \*Data missing for one patient.

Verhaeghe. Manual Rotation for Occiput Posterior Position. *Obstet Gynecol* 2021.



nonvisualization of orbits during a verification trans-abdominal ultrasonogram carried out immediately after the maneuver.

Patients assigned to the expectant management group received routine care during second stage of labor. Modification of maternal position and the introduction of oxytocin were, therefore, allowed. Patients in the manual rotation group also received routine care after the manual rotation attempt.

In France, if circumstances allow for it, current guidelines recommend allowing 3 hours at complete dilation if the presenting part of the fetus has not fully passed through the pelvic inlet before proceeding with cesarean delivery.<sup>29</sup> The administration of oxytocin is recommended after 2 hours at full dilation if uterine contractions are considered inadequate. Thus, the study protocol allowed for a maximum time of 3 hours at complete dilatation before cesarean delivery was considered.

The primary endpoint was the rate of spontaneous vaginal delivery. Secondary endpoints were the rate of operative vaginal delivery (vacuum, spatula, or forceps) and the rate of cesarean delivery. Additional maternal secondary endpoints included estimated blood loss, postpartum hemorrhage (bleeding in excess of 500 mL after vaginal or cesarean delivery), right medio lateral episiotomy, obstetric anal sphincter injuries or cervical lacerations, need for uterine exploration or manual extraction of the placenta, surgical injury in the event of cesarean delivery (ureteral, bladder or bowel injury), and postpartum complications (vaginal hematoma, phlebitis, pulmonary embolism, any infection [defined by a temperature greater than 38.5°C on two readings during the 24 hours after delivery], abnormal perineal wound healing, bowel obstruction, fistula, or death).

Additional fetal secondary endpoints included occurrence of shoulder dystocia, Apgar score at birth, arterial pH and lactate values on umbilical cord gas, the need for a nasogastric tube or orotracheal intubation and ventilation, transfer to the neonatal intensive care unit, phototherapy, blood transfusion, presence of traumatic injuries (fracture, hematoma), intraventricular or intracerebral hemorrhage, and death.

Durations of the first and second stages of labor as well as duration of maternal and neonatal hospitalizations also were recorded.

Serious maternal or neonatal adverse events that occurred between inclusion and discharge were reported according to procedures detailed in the protocol.<sup>26</sup>

We estimated that 214 patients (107 per group) with a fetus in occiput posterior position at full dilation were needed to detect a 20% increase in the percentage of vaginal deliveries, from 60% without manual rotation to 80% with manual rotation, with a 5% alpha and a statistical power of 90%. We planned to include a total of 238 eligible patients to allow for 10% loss to follow up.

All statistical analyses were predetermined in the research protocol and followed CONSORT (Consolidated Standards of Reporting Trials) guidelines. The statistical analysis was carried out with R software version 1.2.5033. The intention-to-treat method was adopted for the primary analysis. As such, patients were analyzed according to their randomization group, regardless of the care strategy ultimately given (manual rotation or expectant management). We also performed a per-protocol sensitivity analysis to account for protocol deviations. For the descriptive analysis of patients and newborns, qualitative variables were reported as headcounts and percentages, and quantitative variables were reported as a mean

and standard deviation. The analyses comparing mode of delivery between groups were completed using a difference in proportions. No interim analyses were planned nor conducted.

The corresponding author has exclusive access to the data and is ultimately responsible for submitting this article for scientific publication.

## RESULTS

Two hundred and thirty-eight patients agreed to participate in the study and signed a consent form after occiput posterior position was confirmed by ultrasonogram examination at full dilation. Two patients withdrew their consent. Thus, 236 patients were randomized: 117 patients were randomized to the manual rotation group and 119 to the expectant management group. These 236 patients constitute the intention-to-treat population (Fig. 1). Patient characteristics were similar between groups (Table 1).

The percentage of spontaneous vaginal deliveries did not differ significantly between the two groups, with 59.7% of patients in the expectant management group and 58.1% in the manual rotation groups delivering vaginally without instrumental assistance (risk difference  $-1.6$ ; 95% CI  $-14.1$  to  $11.0$ ) (Table 2).

No significant difference was detected in the operative vaginal delivery rate between groups (29.9% in the manual rotation group vs 33.6% in the expectant management group (risk difference  $-3.7$ ; 95% CI  $-16.6$  to  $8.2$ ). Furthermore, no significant difference was detected in the cesarean delivery rates between the two groups (12% in the manual rotation group vs 6.7% in the expectant management group (risk difference  $5.3$ ; 95% CI  $-2.2$  to  $12.6$ ) (Table 2).

Seventy-two patients (61.5%; 95% CI 52.1–70.4) in the manual rotation group delivered in anterior position and 45 (38.5%; 95% CI 29.6–47.9) delivered in posterior position. In the expectant management group, 59 patients delivered in anterior position (49.6%; 95% CI 95.40.3–58.9), 59 delivered in posterior position (49.6%; 95% CI 95.40.3–58.9), and delivery position was not recorded for one participant (Table 3). The time from randomization to delivery was shorter in the manual rotation group in comparison with the expectant management group (1.66 hours vs 2.16 hours,  $P=.045$ ) (Table 3).

No statistical differences in neonatal characteristics at birth between the two groups were found. There were no serious neonatal complications in either the expectant management or manual rotation groups (Table 4).

One hundred sixty-eight primiparous patients were randomized, 83 to the manual rotation arm and 85 to the expectant management arm. Of these patients, 47.0% had spontaneous vaginal delivery in the manual rotation group, compared with 50.6% in the expectant management group.

The duration of maternal and neonatal hospitalizations was the same, as all mothers were discharged on the same day as their respective newborns.

In the manual rotation group, the maneuver was actually performed for 106 of the 117 patients (90.6%). The 11 patients for whom the maneuver was not performed were those who gave birth before the manual rotation could be performed ( $n=9$ ) or who had a rotation attempted with an instrument (vacuum or spatula,  $n=2$ ).

**Table 1. Descriptive Characteristics of Patients in the Two Randomization Groups: Expectant Management and Manual Rotation**

Variables	Expectant Management (n=119)	Manual Rotation (n=117)
Median age (y) (IQR)	27.85 (4.76)	28.74 (4.93)
BMI (kg/m <sup>2</sup> )	26.89±5.52	26.99±5.76
Multiparous	34 (28.6)	34 (29.1)
Ethnicity		
White	110 (92.4)	105 (89.7)
African	7 (5.9)	11 (9.4)
Other*	2 (1.7)	1 (0.9)
Gestational age (wk)	39.39±1.12	39.58±1.17
Labor induction (yes) <sup>†</sup>	39 (32.8)	27 (23.1)
Oxytocin (yes) <sup>‡</sup>	97 (81.5)	84 (71.8)
Duration of 1st phase of labor (h)	6.76±4.09	6.64±3.99

IQR, interquartile range; BMI, body mass index.

Data are mean±SD or n (%) unless otherwise specified.

\* Other category regroups patients that were neither African nor White.

<sup>†</sup> Labor induction was carried out by Cook's balloon or prostaglandins.

<sup>‡</sup> Use of oxytocin during the first stage of labor.

**Table 2. Mode of Delivery According to Randomization Group (Expectant Management or Manual Rotation), Intention-To-Treat and Per-Protocol Analysis**

Analyses	Expectant Management	Manual Rotation	Risk Difference	95% CI
Intention-to-treat (N=236)	n=119	n=117		
Primary endpoint				
Spontaneous vaginal	71 (59.7)	68 (58.1)	-1.6	-14.1 to 11.0
Secondary endpoints (%)				
Operative vaginal delivery	40 (33.6)	35 (29.9)	-3.7	-16.6 to 8.2
Cesarean delivery	8 (6.7)	14 (12)	5.3	-2.2 to 12.6
Per-protocol (n=203)	n=97	n=106		
Primary endpoint				
Spontaneous vaginal	62 (63.9)	59 (55.7)	-8.2	-21.7 to 5.2
Secondary endpoints (%)				
Operative vaginal delivery	27 (27.8)	33 (31.1)	3.3	-9.2 to 15.8
Cesarean delivery	8 (8.2)	14 (13.2)	5.0	-3.5 to 13.4

Data are n (%) unless otherwise specified.

In the expectant management group, 97 patients (81.5%) received expectant management, and manual rotation was attempted at some point for 22 patients (18.5%). We, therefore, included 203 patients in the per-protocol analysis.

The frequency of spontaneous vaginal delivery did not differ significantly between the two groups in the per-protocol analysis: 59 of the 106 patients in the manual rotation group (55.7%; 95% CI 45.7–65.3) compared with 62 of 97 patients in the expectant management group (63.9%; 95% CI 53.5–73.4) delivered

vaginally without instrumental assistance (risk difference -8.2; 95% CI -21.7 to 5.2) (Table 2).

## DISCUSSION

In this randomized trial, patients in the manual rotation group had a similar rate of spontaneous vaginal delivery to patients in the expectant management group. Attempting manual rotation did not reduce the rate of operative vaginal delivery (risk difference -3.7; 95% CI -16.6 to 8.2) or cesarean delivery (risk difference 5.3; 95% CI -2.2 to 12.6).

**Table 3. Delivery and Maternal Morbidity According to Randomization Group (Expectant Management or Manual Rotation), Intention-to-Treat Analysis**

	Expectant Management (n=119)	Manual Rotation (n=117)	P
Manual rotation attempted (yes)	22 (18.5)	106 (90.6)	
Manual rotation achieved (yes)	18 (66)	71 (67)	.132
Time from randomization to delivery (h)	2.16 (2.49)	1.66 (0.93)	.045
Position at delivery			.075
Anterior	59 (49.6)	72 (61.5)	
Posterior	59 (49.6)	45 (38.5)	
Blood loss (mL)	200.0 (100.0–300.0)	200.0 (100.0–300.0)	.098
Postpartum hemorrhage (yes)*	18 (15.1)	14 (11.7)	.446
Right mediolateral episiotomy (yes) <sup>†</sup>	28 (23.5)	23 (19.7)	.472
Shoulder dystocia (yes) <sup>‡</sup>	5 (4.2)	4 (3.4)	.752
Manual extraction of placenta (yes)	10 (8.4)	12 (10.3)	.621
Uterine exploration (yes)	20 (16.8)	15 (12.8)	.390
OASIS 3rd degree (yes)	4 (3.4)	1 (0.9)	.167
OASIS 4th degree (yes)	1 (0.8)	0 (0.0)	.242
Blood transfusion (yes)	2 (1.7)	0 (0.0)	.096

OASIS, obstetric anal sphincter injuries.

Data are n (%) or median (interquartile range) unless otherwise specified. None of the secondary outcome events of cervical lesions, vaginal hematoma, surgical wounds, postpartum endometritis, postpartum fever, problematic tissue repair, deep vein thrombosis, pulmonary embolism, intestinal occlusion, fistula, transfer to ICU, or death occurred in our study.

\* Bleeding in excess of 500 mL after vaginal or cesarean delivery.

<sup>†</sup> Episiotomy with incision at the vulvar fork, at a 45° angle toward the right ischiatic region.

<sup>‡</sup> Absence of shoulder clearance of the fetus after expulsion of the head, necessitating the use of obstetric maneuvers other than gentle traction of the head or the restitution (external rotation).

**Table 4. Neonatal Characteristics and Neonatal Morbidity According to Randomization Group (Expectant Management or Manual Rotation), Intention-to-Treat Analysis**

	Expectant Management (n=119)	Manual Rotation (n=117)	P
Sex (male )	58 (48.7)	58 (49.6)	1.000
Weight (g)	3,368.13±395.20	3,350.11±390.90	.725
5-min Apgar score less than 7	5 (4.2)	4 (3.4)	1.000
Arterial pH	7.21±0.09	7.22±0.09	.270
7.00 < pH<7.10	8 (7.2)	9 (8.2)	.985
pH less than 7.10	3 (2.7)	1 (0.9)	.620
Lactates (mmol/L)	5.15±2.03	4.85±1.84	.257
Intubation (yes)	1 (0.8)	0 (0.0)	1.000
NG tube (yes)	0 (0)	0 (0)	NA
ICU admission (yes)	0 (0)	0 (0)	NA
Phototherapy (yes)	8 (6.8)	6 (5.1)	.795
No. of phototherapy sessions	1.0 (1.0–1.25)	1.0 (1.0–1.0)	.647
Fracture (yes)	0 (0)	0 (0)	NA
Intracerebral hemorrhage (yes)	0 (0)	0 (0)	NA
Hypoxic-ischemic encephalopathy (yes)	0 (0)	0 (0)	NA
Neonatal transfusion (yes)	0 (0)	0 (0)	NA
Neonatal death (yes)	0 (0)	0 (0)	NA
Duration of hospitalization (d)	4.33±1.81	4.27±1.13	.783

NA, not applicable; NG, nasogastric; ICU, intensive care unit.

Data are n (%), mean±SD, or median (interquartile range) unless otherwise specified.

Furthermore, blood loss, episiotomy, and obstetric anal sphincter injury rates were similar in both groups. There were no serious adverse events and no neonatal complications in either group.

Most studies found in the available literature are retrospective studies that do not evaluate manual rotation attempts, but rather successful manual rotations. When manual rotation is successful, these studies find a decrease in the rate of cesarean deliveries, operative vaginal deliveries, and maternal complications.<sup>22,30,31</sup> However, many of these studies have methodologic concerns including selection bias and small sample sizes.

In a prospective comparative study, Le Ray and colleagues compared a strategy of systematic manual rotation in one hospital to a policy of abstinence from manual rotation in another hospital. The authors found a lower rate of operative vaginal delivery at the center providing manual rotation but did not find a significant difference in cesarean delivery rates.<sup>24</sup> The study design with a comparison of two different centers may have resulted in a control group that was not representative of the population at the intervention center.

In contrast, Shaffer et al<sup>23</sup> in a retrospective cohort study found a significantly lower cesarean delivery rate with manual rotation compared with expectant management (8.6% vs 41.4%,  $P<.001$ ). However, no significant decrease in the rate of instrumental assistance was shown (41% in the rotation group vs 39% in the control group,  $P=.373$ ).<sup>20</sup> For

this study, the control group was defined as deliveries that occurred with the fetus in a posterior position; a more appropriate control group would have been fetuses in a posterior position at the start of the second stage before manual or spontaneous rotation. Specifically, the choice of control group could be responsible for an overestimation of the effects of attempted manual rotation on the rate of operative vaginal delivery.

The effects of manual rotation are likely also influenced by the success rate of the maneuver. Le Ray et al reported a success rate of 90%, which is higher than other rates in the literature. Shaffer et al reported a success rate for manual rotation of 74%,<sup>22</sup> and, recently, Bertholdt et al<sup>25</sup> reported a success rate of 71.7%. In our study, the success rate (defined by the nonvisualization of orbits during a verification transabdominal ultrasonogram carried out immediately after the maneuver) was 68% and, therefore, comparable.

The percentage of patients with a spontaneous vaginal delivery was similar in both groups, according to parity. We stratified on parity because two studies reported that higher parity was associated with success of manual rotation.<sup>22,31</sup> In our study, as is described by Bertholdt et al,<sup>25</sup> multiparity was not associated with an increased success rate of the manual rotation maneuver.

One of the main strengths of our study lies in its design as a randomized controlled trial. The trial rigorously applied a prespecified protocol,<sup>26</sup> and we reached the desired sample size. The posterior

position was confirmed by ultrasonogram.<sup>27</sup> There was, therefore, no inclusion error. Finally, all our results were robust as demonstrated by our per-protocol sensitivity analysis which confirmed the same findings.

One of the primary limitations of our study is the number of protocol deviations (33/238 patients). However, our results were consistent when we analyzed per-protocol. Furthermore, we do not know the true number of posterior positions at full dilation for all patients who gave birth during this period. Indeed, some posterior positions may not have been clinically detected and, therefore, were not included in the study. It also would have been valuable to have the rate of patient acceptance; this was not tracked during the study. Also, the pelvic architecture of our patients, a factor that could influence obstetric outcome, was not evaluated. Finally, we were unable to study the rate of spontaneous vaginal delivery according to the manual rotation technique used owing to a large amount of missing data for this variable.

Even though the characteristics of our study population are different from those of the North American trials, such as, for example, older patients with a lower average body mass index (BMI) in comparison with the population of the ARRIVE (A Randomized Trial of Induction Versus Expectant Management) trial,<sup>32,33</sup> the patients in our study accurately reflect the characteristics of the French population.<sup>34</sup>

We chose to study the effects of attempting manual rotation at complete dilation, because attempting this maneuver before complete dilation is associated with a higher rate of failure.<sup>22,24,25</sup> We did not collect data with respect to the engagement of the fetal head at the time of attempting the maneuver. By allowing manual rotation to be performed by a midwife, intern, resident, or attending physician, and by using different rotation techniques (Chantreuil and Tarnier or SOGC), the results are generalizable.

Although we did not identify a benefit of manual rotation of occiput posterior at complete dilation, other studies are necessary to confirm our findings. In particular, a prospective population-based study that evaluates practices across different maternity wards would be valuable. Statistical methods of causal inference such as a propensity score, or other randomized trials, also could provide further insight into this research question.

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### Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Individual participant data as well as the data dictionary will be available to researchers upon request.*

What data in particular will be shared? *All data can be provided, but only the data necessary for the applicant's work will be provided.*

What other documents will be available? *Study protocol will be available.*

When will data be available (start and end dates)? *Data are available now and with no end date.*

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Data collected are considered sensitive by the general regulation on the protection of personal data of the European Union and the French Data Protection Act. To use the data from this study, a protocol must be submitted to the coordinator (you). The applicant's protocol will be submitted to the Ethics Committee of the CHU d'Angers. The data can only be transmitted after approval by the ethics committee and validation by the CHU d'Angers promoter of the study.*

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