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# Prophylactic manual rotation of occiput posterior and transverse positions to decrease operative delivery: the PROPOP randomized clinical trial

Julie Blanc, MD, PhD; Pierre Castel, MD, PhD; Franck Mauviel, MD; Karine Baumstarck, MD, PhD; Florence Bretelle, MD, PhD; Claude D'Ercole, MD, PhD; Jean-Baptiste Haumonte, MD

**BACKGROUND:** Persistent occiput posterior and occiput transverse positions are the most common malpositions of the fetal head during labor and are associated with prolonged second stage of labor, cesarean deliveries, instrumental deliveries, severe perineal tears, postpartum hemorrhage, and chorioamnionitis. Manual rotation is one of several strategies described to deal with these malpositions.

**OBJECTIVE:** This study aimed to determine if the trial of prophylactic manual rotation at the early second stage of labor is associated with a decrease in operative deliveries (instrumental and/or cesarean deliveries).

**STUDY DESIGN:** We conducted a multicenter, open-label, randomized controlled trial in 4 French hospitals. Women with singleton term pregnancy and occiput posterior or occiput transverse position confirmed by ultrasound at the early second stage of labor and with epidural analgesia were eligible. Women were randomly assigned (1:1) to either undergo a trial of prophylactic manual rotation of occiput posterior or occiput transverse position (intervention group) or no trial of prophylactic manual rotation (standard group). The primary outcome was operative delivery (instrumental and/or cesarean deliveries). The secondary outcomes were length of the second stage of labor, maternal complications (postpartum hemorrhage, operative complications during cesarean delivery, episiotomy and perineal tears), and neonatal complications (Apgar score of <5 at 10

minutes, arterial umbilical pH of <7.10, neonatal injuries, neonatal intensive care unit admission). The main analysis was focused on intention-to-treat analysis.

**RESULTS:** From December 2015 to December 2019, a total of 257 women (mean age, 30.4 years; mean gestational age, 40.1 weeks) were randomized: 126 were assigned to the intervention group and 131 were assigned to the standard group. Operative delivery was significantly less frequent in the intervention group compared with the standard group (29.4% [37 of 126] vs 41.2% [54 of 131];  $P=.047$ ; differential [intervention-standard] [95% confidence interval] =  $-11.8$  [ $-15.7$  to  $-7.9$ ]; unadjusted odds ratio [95% confidence interval] =  $0.593$  [ $0.353-0.995$ ]). Women in the intervention group were more likely to have a significantly shorter second stage of labor.

**CONCLUSION:** Trial of prophylactic manual rotation of occiput posterior or occiput transverse positions during the early second stage of labor was statistically associated with a reduced risk of operative delivery. This maneuver could be a safe strategy to prevention operative delivery.

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

## Introduction

Occiput posterior (OP) and occiput transverse (OT) positions are the most common fetal malpositions during labor with an estimated prevalence of 20% during labor, and approximately 5% of the fetuses remain in persistent OP position at delivery.<sup>1-3</sup> Several studies have shown that a persistent OP position at delivery was significantly associated with longer labor periods, higher risks of operative vaginal deliveries and cesarean

deliveries, and severe perineal lacerations.<sup>2-6</sup>

Various methods have been considered to promote rotation from a posterior or transverse to an anterior position.<sup>7,8</sup> Instrumental rotations with forceps, spatulas, or a vacuum device are rarely used, but contemporary studies have suggested that Kielland forceps, in experienced hands, could be an effective and safe method to deal with posterior position.<sup>9-11</sup> The learning curve of such method needs to be evaluated. Over the last decades, studies have evaluated the efficacy of maternal posturing during labor to deal with the persistent OP and OT positions, without conclusive results.<sup>12-17</sup>

Several studies have reported manual rotation as a safe and simple technique to rotate the fetal head from a posterior or transverse to an anterior position, and 2 techniques have been described.<sup>18-21</sup> Existing literature has shown an

association between this procedure and reducing risks of cesarean delivery and operative vaginal delivery, but only with low to moderate levels of evidence.<sup>22-25</sup>

The trial of manual rotation at diagnosis of full dilation, that is, a prophylactic manual rotation, seems to be associated with higher chances of success of the maneuver, whereas rotation for failure to progress, that is, a therapeutic manual rotation, with higher risks of failure.<sup>22</sup> Despite the moderate quality of evidence, the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine have issued strong recommendations to consider manual rotation of the fetal head in the second stage of labor as a reasonable intervention before moving to operative or cesarean delivery.<sup>26</sup>

This multicenter randomized clinical trial was conducted to determine the effect of trial of prophylactic manual rotation at the early second stage of labor

### Why was this study conducted?

This multicenter randomized controlled trial was conducted to determine whether the trial of prophylactic manual rotation at the early second stage of labor is associated with a decrease in operative deliveries (instrumental and/or cesarean deliveries).

### Key findings

In women at the early stage of labor with occiput posterior and occiput transverse positions, the trial of prophylactic manual rotation was significantly associated with decreasing risk of operative delivery. Women in the intervention group were more likely to have a significantly shorter second stage of labor.

### What does this add to what is known?

The findings in the study supported that the trial of prophylactic manual rotation could be considered as an effective technique to deal with occiput posterior and occiput transverse positions at the early second stage of labor.

on risks of operative delivery (instrumental and/or cesarean deliveries). It was hypothesized that in women at the early second stage of labor, a trial of prophylactic manual rotation would reduce operative deliveries compared with no trial of prophylactic manual rotation.

## Materials and Methods

### Ethical and regulatory issues

The ethics committee (Comité de Protection des Personnes Sud Méditerranée V) and the French National Agency for the Safety of Medicines and Health Products (Agence Nationale de Sécurité du Médicament et des Produits de Santé) approved this trial on February 20, 2015, and July 10, 2015, and the trial was nationally registered (reference number 2015-A00225-44). The [ClinicalTrials.gov](http://ClinicalTrials.gov) website was updated when ethical and regulatory approvals were obtained. Each woman provided written informed consent before randomization.

### Trial design

We performed an open-label, multicenter trial (4 centers in the South of France: 2 academic and 2 nonacademic community hospitals) in which women were randomly assigned in a 1:1 ratio to either trial of prophylactic manual rotation of OP or OT position (intervention group) or no trial of prophylactic manual rotation (standard group).

### Patient selection

Women were eligible if they were aged at least 18 years, at least 37 weeks of gestation of a singleton pregnancy, at the early second stage of labor (at the diagnosis of full dilation), with ruptured membranes, with a fetus in cephalic OP or OT position on physical examination and confirmed by ultrasound (defined in the pelvic horizontal plane as an angle of  $<90^\circ$  between the median line of the brain and an anterior-posterior, virtual sacropubic line, with the plan of orbits facing forward), and with epidural analgesia. We chose to include only women with epidural analgesia to optimize the acceptability of the study because the trial of manual rotation could be a painful maneuver. Women with contraindications to vaginal delivery (previous fourth-degree perineal tears or Crohn disease with anal injury), sensitive perineum (bleeding perineum during vaginal examination), contraindication to operative vaginal delivery (such as known fetal hemostasis pathology or risk of fetal thrombopenia), nonreassuring fetal heart rate (FHR) with suspicion of fetal acidosis, known congenital fetal malformation, scarred uterus (risk factor of cesarean delivery), fetus in noncephalic position, and without medical insurance were excluded.

We assumed that all eligible women were candidates for the trial of

prophylactic manual rotation whatever the features of their pelvis.

### Intervention allocation

Randomization was performed when the diagnosis of OP or OT position was given at the early second stage of labor. Participants were randomized to either trial of prophylactic manual rotation or the standard group. A computer-generated randomization sequence was prepared by the study methodologist (K.B.) using blocks of 4, unknown to the investigators and stratified by center. A woman's assignment to a group was obtained from a secure website after a study number and confirmation of eligibility were entered and locked. The clinical care team could not be blinded to the intervention.

### Trial interventions

Women in the intervention group had a trial of prophylactic manual rotation by the technique described by Tarnier and Chantreuil.<sup>18</sup> This technique was described on a mannequin during the implementation visit of the study in each center (Figure 1). All the coinvestigators had to attend these training courses. The maneuver was attempted after sonographic confirmation of the OP or OT position and fetal spine position. With the bladder emptied, the woman was placed in the lithotomy position, lying on her back with her feet in stirrups. When the uterus was relaxed, the trained operator placed 1 hand behind the fetal ear (right for left positions and left for right positions). During the uterine contraction, while the woman was pushing, the operator rotated the anterior fetal head by pressing on the hand, moving the occiput toward the anterior pelvic girdle. FHR was monitored continuously throughout these procedures, and the fetal position was controlled by ultrasound immediately after the maneuver. In case of failure, the procedure could be repeated if the FHR was reassuring. Women in the standard group had no trial of prophylactic manual rotation.

In France, and in these 4 centers the common practices are to observe a passive second stage of labor and wait for

the deepest engagement of the fetal head before pushing at full dilation.

### Outcome measures and data collection

Here, the primary outcome was operative delivery (instrumental delivery and/or cesarean delivery). The indication of operative vaginal delivery, the type of instrument used, and the position and station of the fetal head were noted. The indication of the cesarean delivery and the position of the fetal head during the cesarean delivery were specified.

The secondary outcomes were length of the second stage of labor (from diagnosis of full dilation to delivery); maternal complications, such as postpartum hemorrhage (blood loss  $\geq 500$  mL); blood transfusion; maternal intensive care unit (ICU) admission; operative complications during cesarean delivery; episiotomy; perineal tears and obstetrical anal sphincter injuries; and neonatal complications (Apgar score of  $< 5$  at 10 minutes, arterial umbilical pH of  $< 7.10$ , neonatal trauma, and neonatal ICU [NICU] admission). Participants were monitored until discharge from the labor ward.

The women's demographic, antepartum, intrapartum, intraoperative, and postpartum course data were extracted from medical records by research staff.

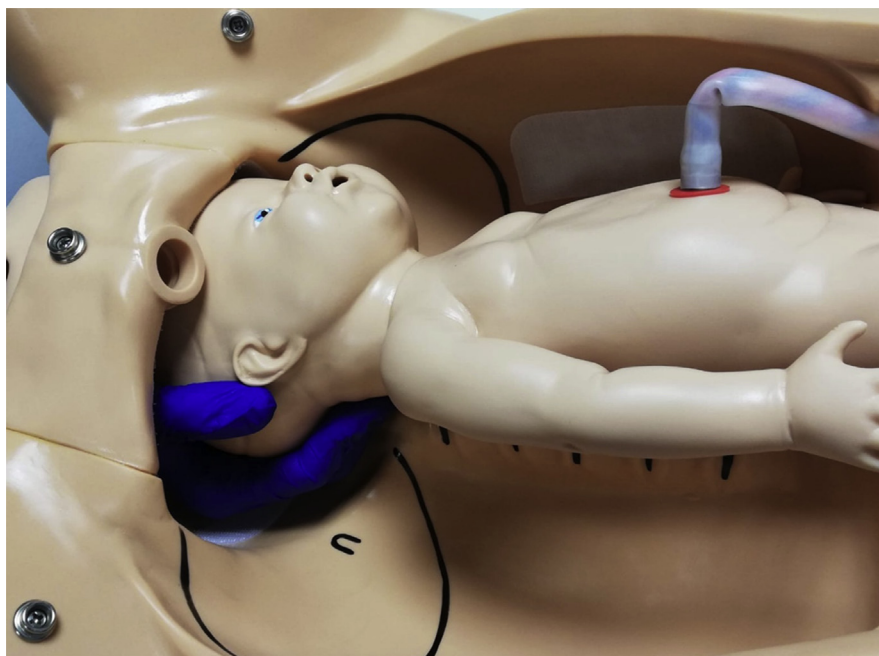
### Sample size

During the study period, we pursued our analysis of scientific literature, and because of recent evidence,<sup>17</sup> we found that our previous sample size calculation ( $n=400$ ) was not realistic or consistent with available data. The sample size was corrected by an amendment with a favorable opinion on May 9, 2019 (Comité de Protection des Personnes Sud Méditerranée V: reference number 15.031). The originally approved protocol and the approved amendment are available in [Supplements 1 and 2](#).

Based on epidemiologic data from prospective studies, the rate of operative delivery is 16% in case of delivery in occiput anterior (OA) position and 62% in case of persistent OP position.<sup>3,17,22,23,27,28</sup> The sample size was

**FIGURE 1**

**Technique of manual rotation described by Tarnier and Chantreuil**



With the bladder emptied, the woman was placed in the lithotomy position, lying on her back with her feet in stirrups. When the uterus was relaxed, the trained operator placed 1 hand behind the fetal ear (right for left positions and left for right positions). During the uterine contraction, while the woman was pushing, the operator rotated the anterior fetal head by pressing on the hand, moving the occiput toward the anterior pelvic girdle.

calculated assuming that we expected a rate of operative delivery of 38% in the standard group, taking into account that the OP position would spontaneously turn to an anterior position during the second stage of labor in 60% of cases.<sup>17</sup> In the intervention group, the expected rate of operative delivery was 22%, assuming that the maneuver would succeed in 9 of 10 cases.<sup>22</sup>

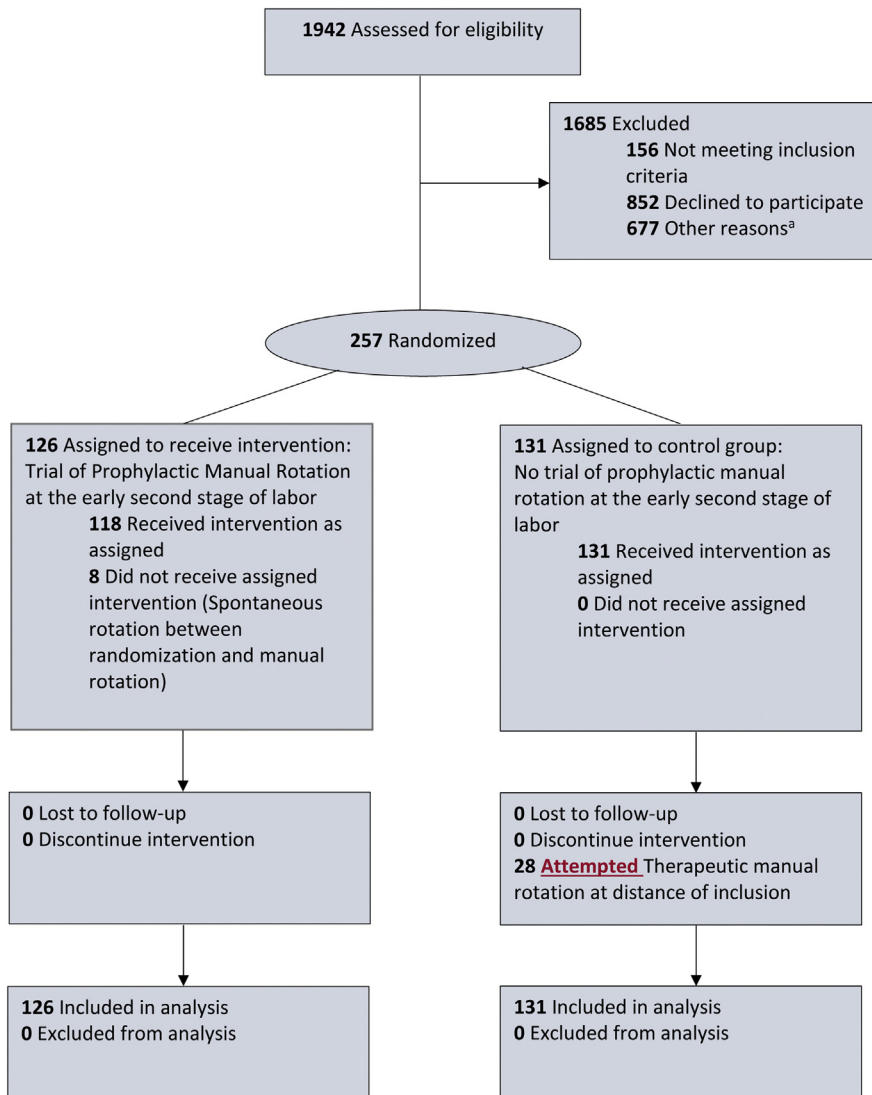
To detect this 16-point difference between groups, with 80% power and the threshold for statistical significance set at a  $P$  value of 0.05, assuming a potential 3% of patients were lost to follow-up, the amended sample size was 260 women. No interim analysis was planned.

### Statistical analysis

Statistical analyses of this study were carried out in a blinded manner. The data were analyzed using the Statistical Package for the Social Sciences software (version 20.0; SPSS Inc, Chicago, IL).

Statistical significance was defined as  $P < .05$ . The methodology was based on the Consolidated Standards of Reporting Trials statement (<http://www.consortstatement.org/consort-statement/>). The intention-to-treat population was used in the primary analysis. For the primary outcome, the operative delivery rates were compared between groups (using  $\chi^2$  or Fisher exact tests, 2-tailed). The odds ratio (OR) with 95% confidence interval (CI) was provided. As a secondary analysis, the primary outcome was provided: (1) on the per-protocol population; (2) after adjustment for parity (nulli- vs multiparous), for body mass index, and for the 2 parameters (logistic regression, enter method, adjusted ORs, and CIs provided); and (3) stratified by parity (nulli- vs multiparous). The secondary outcomes were compared between the 2 groups: using  $\chi^2$  test or the Fisher exact test for binary variables and the Student  $t$  test or

**FIGURE 2**  
**Randomization and follow-up of study participants**



<sup>a</sup> Other reasons were women not approached because physician were unavailable or missed by physician

were randomly assigned to trial of prophylactic manual rotation, and 131 were randomly assigned to no trial of prophylactic manual rotation (Figure 2). No participant was lost to follow-up, leaving 257 women included in the primary analysis. The mean age of the participants was 30.4 years (standard deviation [SD], 5.6 years), and the mean body mass index was 26.8 kg/m<sup>2</sup> (SD, 5.6 kg/m<sup>2</sup>). Here, 71.6% of the participants were nulliparous, the mean gestational age was 40.1 weeks (SD, 1.1 weeks), and 78.2% of the participants had a spontaneous onset of labor. Baseline characteristics were well balanced between the study groups (Table 1).

### Primary outcome

Operative delivery occurred in 37 women (29.4%) in the intervention group—trial of prophylactic manual rotation—and 54 women (41.2%) in the standard group (Table 2). The risk of operative delivery was significantly less frequent in the intervention group compared with that of the standard group (differential [intervention-standard] [95% CI] = -11.8 [-15.7 to -7.9]; unadjusted odds ratio [95% CI] = 0.593 [0.353–0.995]). Instrumental delivery was a concern for 31 women (24.6%) in the intervention group and 45 women (34.4%) in the standard group. Cesarean delivery was a concern for 6 women (4.8%) in the intervention group and 9 women (6.9%) in the standard group. In the per-protocol analysis, operative delivery occurred in 36 of 118 women (30.5%) in the intervention group and in 54 of 131 women (41.2%) in the standard group ( $P=0.079$ ).

Results from logistic regression models showed that the intervention group remained significantly associated with less frequent operative delivery (parity: adjusted OR [95% CI]=0.552 [0.317–0.962];  $P=0.036$ ; body mass index: adjusted OR [95% CI]=0.587 [0.349–0.987];  $P=0.045$ ; parity and body mass index: adjusted OR [95% CI]=0.547 [0.313–0.955]). After stratification by parity, the intervention group remained significantly associated with less frequent operative delivery for the subgroup of nulliparous patients (36.7% in the intervention group vs 55.3% in the

Mann-Whitney test for continuous variables, as appropriate. There was no imputation of data (there was no missing data for the primary outcome, and we observed <5% missing data for any variable).

## Results

### Study participants

From December 2015 to December 2019, a total of 1942 women were

assessed for eligibility (screened for participation before confirmation by ultrasound). Of these women, 156 women did not meet the inclusion criteria at the last check before randomization, 852 women declined to participate, and 677 women were not randomized for other reasons (women not approached because the physician was unavailable or missed by the physician). Of the remaining 257 women, 126

standard group;  $P=.011$ ) but was not different for the subgroup of multiparous patients (11.1% in the intervention group vs 5.4% in the standard group;  $P=.430$ ).

### Prespecified secondary outcomes

The mean length of the second stage of labor was significantly shorter in the intervention group (intervention group, 146.7 minutes; standard group, 164.4 minutes;  $P=.028$ ).

There was no significant difference in the risk of postpartum hemorrhage between groups (OR, 1.363; 95% CI, 0.492–3.777). No woman was admitted to the ICU. The risks of perineal tears, episiotomy, or obstetrical anal sphincter injury were not different between groups (Table 2). No case of cervical laceration was noted.

The mean Apgar score at 5 minutes was significantly higher for the neonates in the intervention group (intervention group, 9.8; standard group, 9.6;  $P=.049$ ).

There was no significant difference in the following neonatal outcomes: Apgar score of  $<5$  at 10 minutes and arterial umbilical pH of  $<7.10$ . No neonatal head trauma was noted in either group.

### Detailed characteristics of the trial of prophylactic manual rotation

In most cases, the fetuses were in the right OP position controlled by ultrasound, and the head station was between  $-2$  and  $0$  before the trial of prophylactic manual rotation. Moreover, 95 physicians (88.8%) performing the manual rotation were right-handed, and physicians used their right hand in 54 cases (50.9%). The success rate of prophylactic manual rotation was 89.7% in the immediate moment of the procedure. The successful manual rotations resulted in a spontaneous vaginal delivery in 76.0% of cases. FHR abnormalities (repetitive decelerations) occurred in 22 cases (17.5%) after the trial of prophylactic manual rotation but without indication of an emergency delivery.

### Additional data

Among women delivering vaginally (operative or spontaneous vaginal

Characteristics	Number of women (%)	
	Intervention (trial of prophylactic manual rotation) (n=126)	Standard (no trial of prophylactic manual rotation) (n=131)
Age (y)	30.2±5.6	30.5±5.6
Nulliparous	90 (71.4)	94 (71.8)
Body mass index (kg/m <sup>2</sup> )	28.5±5.7	28.7±5.4
Gestational age (wk)	40.0±1.1	40.1±1.0
Anterior position of placenta	71 (58.2)	65 (51.6)
Gestational diabetes mellitus	19 (15.2)	18 (13.7)
Suspected macrosomia <sup>a</sup>	9 (7.1)	4 (3.1)
Spontaneous onset of labor	101 (80.2)	100 (76.3)
Oxytocin administration during labor	95 (75.4)	109 (83.2)
Length of active phase of labor (from 6 cm to full dilation) (min)	187.8±105.7	206.1±116.9
Cervical dilation at diagnosis of posterior position (cm)	7.9±2.0	7.8±1.9
Nonreassuring fetal heart rate before full dilation <sup>b</sup>	40 (31.7)	50 (38.5)
Postural strategies to deal with posterior position during labor <sup>c</sup>	37 (30.1)	41 (31.8)
Birthweight (g)	3433.5±409.0	3424.6±466.6

Data are presented as mean±standard deviation or number (percentage).

<sup>a</sup> Estimated fetal weight above the 95th percentile confirmed by ultrasound in the third trimester of pregnancy; <sup>b</sup> Suspicious cardiotocography (International Federation of Gynaecology and Obstetrics 2015 classification); <sup>c</sup> Women adopting postures that differed from the dorsal recumbent position during labor.

deliveries), 116 (96.7%) in the intervention group vs 106 (86.9%) in the standard group delivered in OA position ( $P=.009$ ). In the standard group, 28 women (21.4%) had an attempted therapeutic manual rotation secondarily after randomization because of nonreassuring FHR or failure of progression of the fetal head. This procedure was a success in 23 cases (82.1%).

## Discussion

### Principal findings

This multicenter randomized clinical trial on women with a fetus in cephalic OP or OT position confirmed by ultrasound showed a significant reduction in operative delivery with the trial of prophylactic manual rotation at the early second stage of labor. Furthermore, the trial of prophylactic manual rotation was

associated with a shorter length of second stage of labor.

### Results in context

This randomized controlled trial (RCT) showed a concern about the interest of prophylactic manual rotation and showed positive results. To the best of our knowledge, 1 pilot RCT was published as a feasibility study, and it included 30 women.<sup>29</sup> The results of that study showed neither statistical significance nor a trend about the mode of delivery or maternal outcomes. The rates of operative delivery were particularly high (80%–87%) in the study as were the rates of NICU admission (20%–40%). Very recently, the same team has published the results of the trial following this pilot study.<sup>30</sup> In this RCT involving 254 women, the rates of

TABLE 2

## Primary and secondary outcomes by randomization group

Outcome	Intervention group (trial of prophylactic manual rotation) (n=126)	Standard group (no trial of prophylactic manual rotation) (n=131)	Odds ratio (95% CI)	Pvalue
Primary outcome				
Operative delivery	37 (29.4)	54 (41.2)	0.593 (0.353–0.995)	.047
Primary outcome components				
Instrumental delivery	31 (24.6)	45 (34.4)	0.624 (0.362–1.073)	.087
Cesarean delivery	6 (4.8)	9 (6.9)	0.678 (0.234–1.963)	.471
Prespecified secondary outcomes				
Length of second stage of labor (min)	146.7±64.4	164.4±58.2		.028
Postpartum hemorrhage	9 (7.1)	7 (5.3)	1.363 (0.492–3.777)	.551
Perineal tears, No. (%)	92 (73.0)	96 (73.8)	0.958 (0.550–1.669)	.880
Obstetrical anal sphincter injury	4 (4.7)	4 (4.7)		>.99
Episiotomy	24 (26.1)	27 (28.1)	0.902 (0.474–1.717)	.753
Apgar score at 5 min	9.8 (0.7)	9.6 (1.0)		.049
10-min Apgar score<5	0	1 (0.8)		>.99
Arterial umbilical pH<7.10	5 (4.0)	4 (3.1)	3.803 (0.419–34.531)	.235
Neonatal intensive care unit admission	1 (0.8)	4 (3.1)		.371

Data are presented as number (percentage) or mean±standard deviation, unless otherwise specified.

CI, confidence interval; SD, standard deviation.

operative delivery (62%–71%) and serious adverse neonatal outcomes (17%) were high.

Another RCT (n=65 women) has been reported as an abstract, but the corresponding detailed results have not been published and the abstract reported no difference in operative vaginal delivery.<sup>31</sup> Moreover, 2 other RCTs have been registered on [ClinicalTrials.gov](https://www.clinicaltrials.gov) and should be published soon.<sup>32–34</sup>

This study dealt with prophylactic manual rotation at the early second stage of labor. We chose to study prophylactic manual rotation at this stage rather than therapeutic manual rotation because literature has shown that attempted rotation before full dilation and rotation for failure to progress are 2 major risk factors for failure of the procedure.<sup>22,35</sup>

The success rate of prophylactic manual rotation was as expected for the calculation of the sample size and congruent with data in literature.<sup>22,25</sup>

The high success rate (89.7%) could be related to the previously cited obstetrical factors and also to the systematic use of ultrasound before the procedure. Indeed, the sonographic evaluation of the fetal spine position has been shown to be associated with the success of manual rotation.<sup>36</sup> The success rate we reported was higher than shown in the previously cited RCT.<sup>29,30</sup> This could be explained by the time of the randomization in these studies “at the first urge to push or 1 hour after full dilation.”

Thus, the technique of manual rotation as described by Tarnier and Chan-treuil<sup>18</sup> may be an efficient procedure to deal with OP and OT positions.

Our study confirmed the association of trial of prophylactic manual rotation with a shorter second stage of labor as previously reported.<sup>24,31</sup> The differential in the length of labor (18 minutes) seemed clinically relevant to us. Contrary to the retrospective study of Shaffer et al,<sup>24</sup> we did not find an association

between trial of prophylactic manual rotation and the outcomes of perineal tears, episiotomy, and obstetrical anal sphincter injuries. The rate of episiotomy was higher than the mean national rate of episiotomy in France (20.1% in 2016)<sup>37</sup> but lower than reported in previous studies (44%–65%).<sup>22,23</sup> Furthermore, FHR abnormalities occurring after the trial of prophylactic manual rotation were not indications for an emergency delivery. Our trial did not report any cases of cord prolapse, described as a complication of the maneuver in a former study.<sup>19</sup> Therefore, the trial of prophylactic manual rotation seemed to be a safe procedure at the maternal and neonatal sides.

In addition, choosing a trial of prophylactic manual rotation rather than a trial of therapeutic manual rotation could be the most effective strategy to deal with OP and OT positions. One could argue that prophylactic manual

rotation is more likely to have been unnecessary, as most posterior positions will rotate spontaneously. However, significantly more women delivered in OA position in the prophylactic manual rotation compared with the standard group. Furthermore, in the standard group of our trial, a therapeutic manual rotation was subsequently performed in cases of nonreassuring FHR or failure of progression of the fetal head, but with a lower success rate. Therefore, in cases of OP or OT positions, the trial of prophylactic manual rotation could be a safe and efficient procedure with less attempts needed to treat 9 women.

### Strengths and limitations

This study has several strengths. Beyond the randomization allowing for a comparison of the efficacy of 2 strategies with the highest level of evidence, we had no loss to follow-up as the primary outcome was operative delivery that occurred within a few hours after randomization. Indeed, the intention-to-treat analysis could have been performed on the primary outcome for all cases without missing data. Furthermore, an ultrasound scan was performed before randomization and at each stage of the follow-up, ensuring an objective and certain diagnosis of the fetal head position. This point ensured the reliability of the diagnosis of the fetal head position because of the documented risks of errors in digital examination.<sup>38–40</sup>

This trial was performed in 4 maternity units with different volumes of activity and levels of care (secondary and tertiary care units), suggesting the applicability of the results of this trial elsewhere. The noninclusion of pregnant women without medical insurance (according to French law) did not reduce the representativeness of our results as most people have medical insurance in France.

This study has several limitations. First, this study was not double blinded. However, we do not believe that there could be a placebo effect on the women with this kind of procedure, and the clinical team could not feasibly be blinded to the intervention. We acknowledge the possibility that delivering physicians

may have been influenced in their decisions by knowledge of the randomization group. Second, we faced the usual difficulties of clinical research during labor with low rates of consent; therefore, 852 of 1942 women declined participation in the trial. This rate raised questions of external validity. Third, the design of the follow-up did not allow exploration of long-term consequences. OP deliveries are known to be associated with perineal morbidity and pelvic floor dysfunction at 6 months after delivery.<sup>41</sup> Therefore, future research about manual rotation should study these outcomes. Fourth, the study was underpowered for each component of the primary outcome (instrumental vaginal and cesarean deliveries) and important secondary outcomes, such as neonatal morbidity and maternal morbidity (postpartum hemorrhage in particular). The generalizability of our results could be questionable as we reported a high frequency of instrumental vaginal delivery and notable cultural differences are reported in obstetrical practices. Fifth, the satisfaction of the women was not studied. Nowadays, evaluation of the maternal childbirth experience is essential in obstetrics research. Therefore, we plan to study maternal satisfaction in further studies about manual rotation.

### Conclusions

Among women presenting an OP or OT position at the early second stage of labor, the trial of prophylactic manual rotation was significantly associated with a lower risk of operative delivery. These findings supported that the prophylactic manual rotation should be considered as an effective and safe procedure to deal with OP or OT positions of the fetal head.

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## Author and article information

From the Department of Obstetrics and Gynecology, Nord Hospital, Assistance Publique - Hôpitaux de Marseille, Chemin des Bourrelly, Marseille, France (Drs Blanc, Castel, Bretelle, D'Ercole, and Haumonte); CEReSS, Health Service Research and Quality of Life Center, Aix-Marseille University, Marseille, France (Drs Blanc, D'Ercole, and Haumonte); Aix-Marseille Univ, Avignon Université, Centre National de Recherche Scientifique, Institut de Recherche pour le Développement, Institut Méditerranéen de Biodiversité et D'Ecologie marine et continentale, Marseille, France (Dr Castel); Department of Obstetrics and Gynecology, Sainte Musse Hospital, Toulon, France (Dr Mauviel); EA3279, CEReSS, Health Service Research and Quality of Life Center, Aix-Marseille University, Marseille, France (Dr Baumstark); Aix Marseille University, UM 63, CNRS 7278, IRD 198, INSERM 1095, Marseille, France (Dr Bretelle); and Department of Obstetrics and Gynecology, Saint Joseph Hospital, Marseille, France (Dr Haumonte).

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Corresponding author: Julie Blanc, MD, PhD. [blanc@ap-hm.fr](mailto:blanc@ap-hm.fr)