

Journal Pre-proof



Prophylactic manual Rotation of Occiput POsterior and transverse Positions to decrease operative Delivery: The PROPOP Randomized Clinical Trial

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PII: S0002-9378(21)00586-X

DOI: <https://doi.org/10.1016/j.ajog.2021.05.020>

Reference: YMOB 13872

To appear in: *American Journal of Obstetrics and Gynecology*

Received Date: 2 February 2021

Revised Date: 3 May 2021

Accepted Date: 3 May 2021

Please cite this article as: BLANC DJ, CASTEL DP, MAUVIEL DF, BAUMSTARCK DK, BRETELLE PF, D'ERCOLE PC, HAUMONTE DJ-B, Prophylactic manual Rotation of Occiput POsterior and transverse Positions to decrease operative Delivery: The PROPOP Randomized Clinical Trial, *American Journal of Obstetrics and Gynecology* (2021), doi: <https://doi.org/10.1016/j.ajog.2021.05.020>.

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1 **Title page**

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3 **Prophylactic manual Rotation of Occiput POsterior and transverse Positions to decrease**
4 **operative Delivery: The PROPOP Randomized Clinical Trial**

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21 **Disclosure of interests:**

22 The authors report no conflict of interests.

23 **Source of supports:**

24 Appel d'Offre Recherche clinique Junior 2014 Assistance Publique Hôpitaux de Marseille.

25 **Role of the Funding source:** The Assistance Publique Hôpitaux de Marseille had no role in
26 the design and conduct of the study ; collection, management, analysis, and interpretation
27 of the data; preparation, review, or approval of the manuscript; and decision to submit the
28 manuscript for publication. Specifically, the funder had no right to veto publication or to
29 control the decision regarding to which journal the manuscript was submitted.

30

31 **Trial registration:** ClinicalTrials.gov Identifier: NCT02695238,
32 <https://www.clinicaltrials.gov/ct2/show/NCT02695238?term=NCT02695238&draw=2&rank=>

33 1

34

35 **Paper presentation information:** the findings have been selected for an oral presentation on
36 January 28, 2021 during the 41th Annual Meeting of The Society of Maternal Fetal Medicine
37 and received the 2021 Award of Research Excellence of the oral plenary session I.

38

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48 **Manuscript word count:** Abstract: 351 ; Main text: 3490 ; Number of Tables and Figures: 4

49 **Condensation:** Prophylactic manual rotation should be considered as a technique to deal
50 with occiput posterior and transverse positions at the early second stage of labor.

51 **Short title:** Prophylactic manual rotation of occiput posterior and transverse positions

52 **AJOG at a Glance:**

53 **A. Why was this study conducted?** This multicenter randomized controlled trial was
54 conducted to determine if the trial of prophylactic manual rotation at the early
55 second stage of labor is associated with a decrease of operative deliveries
56 (instrumental and/or cesarean deliveries).

57 **B. What are the key findings?** In women at early stage of labor with an occiput
58 posterior and transverse positions, the trial of prophylactic manual rotation was
59 significantly associated with decreasing risk of operative delivery. Women in the
60 intervention group were more likely to have a significantly shorter second stage of
61 labor.

62 **C. What does this study add to what is already known?** These findings support that the
63 trial of prophylactic manual rotation could be considered as an effective technique to
64 deal with occiput posterior and transverse positions at the early second stage of
65 labor.

66 **Abstract**

67 **Background:** Persistent occiput posterior and occiput transverse positions are the
68 commonest malpositions of the fetal head during labor and are associated with prolonged
69 second stage of labor, cesarean sections, instrumental deliveries, severe perineal tears,
70 postpartum hemorrhage and chorioamnionitis. Manual rotation is one of several strategies
71 described to deal with these malpositions.

72 **Objective:** The purpose of this study was to determine if the trial of prophylactic manual
73 rotation at the early second stage of labor is associated with a decrease of operative
74 deliveries (instrumental and/or cesarean deliveries).

75 **Study design:** We conducted a multicenter, open-label, randomized controlled trial in four
76 French hospitals. Women with singleton term pregnancy and occiput posterior or transverse
77 position confirmed by ultrasound at the early second stage of labor and with epidural
78 analgesia were eligible. Women were randomly assigned (1:1) to either undergo a trial of
79 prophylactic manual rotation of occiput posterior or transverse position (intervention group)
80 or no trial of prophylactic manual rotation (standard group). The primary outcome was
81 operative delivery (instrumental and/or cesarean deliveries). Secondary outcomes were
82 length of the second stage of labor, maternal complications (post-partum hemorrhage,
83 operative complications during cesarean, episiotomy and perineal tears) and neonatal
84 complications (Apgar score < 5 at 10 min, arterial umbilical pH < 7.10, neonatal injuries,
85 neonatal intensive care unit admission). The main analysis was focus on intention-to-treat
86 analysis.

87 **Results:** From December 2015 to December 2019, a total of 257 women (mean age, 30.4
88 years, mean gestational age, 40.1 weeks) were randomized: 126 assigned to the intervention
89 group and 131 to the standard group. Operative delivery was significantly less frequent in

90 the intervention (I) group compared to the standard (S) group (29.4% [37/126] vs. 41.2%
91 [54/131], $p=.047$, Differentiel (I-S) [95% confidence interval, CI] = -11.8 [-15.7;-7.9];
92 unadjusted odds ratio [95% CI] = 0.593 [0.353-0.995]). Women in the intervention group
93 were more likely to have a significantly shorter second stage of labor.

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

97 **Keywords:** cesarean delivery, fetal position, instrumental delivery, manual rotation,
98 operative delivery, posterior position, second stage of labor, transverse position

99 **Main Text**100 **Introduction**

101 Occiput posterior (OP) and transverse (OT) positions are the common fetal malpositions
102 during labor with an estimated prevalence of 20% during labor, and approximately 5% of the
103 fetuses remain in persistent OP position at delivery.¹⁻³ Several studies have shown that
104 persistent OP position at delivery was significantly associated with longer labor, higher risks
105 of operative vaginal deliveries, cesarean deliveries and severe perineal lacerations.²⁻⁶
106 Various methods have been considered to promote rotation from a posterior or transverse
107 to an anterior position.^{7,8} Instrumental rotations with forceps, spatulas or a vacuum device
108 are rarely used but contemporary studies have suggested that Kielland forceps, in
109 experienced hands, could be an effective and safe method to deal with posterior position.⁹⁻
110 ¹¹ The learning curve of such method need to be evaluated. Over the last decades, studies
111 have evaluated the efficacy of maternal posturing during labor to deal with the persistent OP
112 and OT positions, without conclusive results.¹²⁻¹⁷
113 Several studies have reported manual rotation as a safe and simple technique to rotate the
114 fetal head from a posterior or transverse to an anterior position, and two techniques have
115 been described.¹⁸⁻²¹ Existing literature has shown an association between this procedure
116 and reducing risks of cesarean delivery and operative vaginal delivery, but only with low to
117 moderate levels of evidence.²²⁻²⁵ The trial of manual rotation at diagnosis of full dilatation,
118 i.e. a prophylactic manual rotation, seems to be associated with higher chances of success of
119 the maneuver, whereas rotation for failure to progress, i.e. a therapeutic manual rotation,
120 with higher risks of failure.²² Despite the moderate quality of evidence, the American College
121 of Obstetricians and Gynecologists and the Society of Maternal-Fetal Medicine have issued

122 strong recommendations to consider manual rotation of the fetal head in the second stage
123 of labor as a reasonable intervention before moving to operative or cesarean delivery.²⁶
124 This multicenter randomized clinical trial was conducted to determine the effect of trial of
125 prophylactic manual rotation at the early second stage of labor on risks of operative delivery
126 (instrumental and/or cesarean deliveries). It was hypothesized that in women at the early
127 second stage of labor, a trial of prophylactic manual rotation would reduce operative
128 deliveries compared with no trial of prophylactic manual rotation.

129 **Materials and Methods**

130 *Ethical and Regulatory Issues*

131 The ethics committee (Comité de Protection des Personnes Sud Méditerranée V), and the
132 French National Agency for the Safety of Medicines and health products (Agence Nationale
133 de Sécurité du Médicament et des Produits de Santé, ANSM) approved this trial on February
134 20, 2015 and July 10, 2015, and the trial was nationally registered (reference 2015-A00225-
135 44). The ClinicalTrials.gov website was updated as soon as ethical and regulatory approvals
136 were obtained. Each woman provided written informed consent prior to randomization.

137

138 *Trial Design*

139 This was an open-label, multicenter trial (4 centers in the South of France; 2 academic and 2
140 non-academic community hospitals) in which women were randomly assigned in a 1:1 ratio
141 either to trial of prophylactic manual rotation of OP or OT position (intervention [I] group) or
142 to no trial of prophylactic manual rotation (standard [S] group).

143

144 *Patient selection*

145 Women were eligible if they were aged at least 18 years, at least 37 weeks of gestation (WG)
146 of a singleton pregnancy, at the early second stage of labor (at the diagnosis of full
147 dilatation), with ruptured membranes, with a fetus in cephalic OP or OT position on physical
148 exam and confirmed by ultrasound (defined in the pelvic horizontal plane as an angle $< 90^\circ$
149 between median line of brain and an anteriorposterior, virtual sacropubic line, with plan of
150 orbits faced forwards), and with epidural analgesia. We chose to include only women with
151 epidural analgesia to optimize the acceptability of the study because the trial of manual
152 rotation could be a painful maneuver. Women with contraindications to vaginal delivery

153 (previous fourth-degree perineal tears or Crohn's disease with anal injury), sensitive
154 perineum (bleeding perineum during vaginal examination), contraindication to operative
155 vaginal delivery (such as known fetal hemostasis pathology or risk of fetal thrombopenia),
156 non-reassuring fetal heart rate (FHR) with suspicion of fetal acidosis, known congenital fetal
157 malformation, scarred uterus (risk factor of cesarean delivery), fetus in non-cephalic
158 position, and without medical insurance were excluded.

159 We assumed that all eligible women were candidates for the trial of prophylactic manual
160 rotation whatever the features of their pelvis.

161

162 *Intervention allocation*

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

170

171 *Trial interventions*

172 Women in the intervention group had a trial of prophylactic manual rotation by the
173 technique described by Tarnier and Chantreuil.¹⁸ This technique was described on a
174 mannequin during the implementation visit of the study in each center (Figure 1). All the co-
175 investigators had to attend these training courses. The maneuver was attempted after
176 sonographic confirmation of OP or OT position and of the fetal spine position. The woman,

177 bladder emptied, was placed in the lithotomy position, lying on her back with her feet in
178 stirrups. When the uterus was relaxed, the trained operator placed one hand behind the
179 fetal ear (right for left positions and left for right positions). During the uterine contraction,
180 while the woman was pushing, the operator rotated the anterior fetal head by pressing on
181 the hand, moving the occiput toward the anterior pelvic girdle. FHR was monitored
182 continuously throughout these procedures and the fetal position was controlled by
183 ultrasound immediately after the maneuver. In case of failure, the procedure could be
184 repeated if the FHR was reassuring.

185 Women in the standard group had no trial of prophylactic manual rotation.

186 In France, and in these 4 centers, the common practices are to observe a passive second
187 stage of labor and wait for the deepest engagement of the fetal head before pushing at full
188 dilatation.

189

190 *Outcome Measures and Data collection*

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

195 Secondary outcomes were length of the second stage of labor (from diagnosis of full
196 dilatation to delivery), maternal complications such as post-partum hemorrhage (blood loss
197 ≥ 500 mL), blood transfusion, maternal intensive care unit (ICU) admission, operative
198 complications during cesarean, episiotomy, perineal tears and obstetrical anal sphincter
199 injuries, and neonatal complications (Apgar score < 5 at 10 min, arterial umbilical pH < 7.10 ,
200 neonatal trauma, and neonatal ICU admission).

201 Participants were monitored until discharge from the labor ward.

202 The women's demographics, antepartum, intrapartum, intraoperative, and postpartum

203 course data were extracted from their medical record by research staff.

204

205 *Sample size*

206 During the ongoing study, we pursued our analysis of scientific literature and thanks to

207 recent evidence,¹⁷ we found that our previous sample size calculation (n=400) was not

208 realistic or consistent with available data. The sample size was corrected by an amendment

209 with a favorable opinion on May 9, 2019 (Comité de Protection des Personnes Sud

210 Méditerranée V, ref 15.031). The original approved protocol and the approved amendment

211 are available as Supplements 1 and 2.

212 Based on epidemiological data from prospective studies, the rate of operative delivery is

213 16% in case of delivery in occiput anterior position and 62% in case of persistent

214 OP.^{3,17,22,23,27,28} The sample size was calculated assuming that we expected a rate of

215 operative delivery of 38% in the standard group, taking into account that in 60% of cases the

216 OP would spontaneously turn to an anterior position during the second stage of labor.¹⁷ In

217 the intervention group, the expected rate of operative delivery was 22%, assuming that the

218 maneuver would succeed in 9 cases of 10.²²

219 To detect this 16-point difference between groups, with 80% power and the threshold for

220 statistical significance set at a p-value of 0.05, assuming a potential 3% of patients were lost

221 to follow-up, the amended sample size was 260 women needed. No interim analysis was

222 planned.

223

224 *Statistical analysis*

225 Statistical analyses of this study were carried out in a blinded manner. The data were
226 analyzed using SPSS version 20.0 software (SPSS Inc., Chicago, IL). Statistical significance was
227 defined as $P < 0.05$. The methodology was based on the Consolidated Standards of Reporting
228 Trials statement (CONSORT, <http://www.consortstatement.org/consort-statement/>). The
229 intention-to-treat population was used in the primary analysis. For the primary outcome, the
230 operative delivery rates were compared between groups (using χ^2 or Fisher's exact tests,
231 two-tailed). The odds ratio (OR) with the 95% Confidence interval (CI) was provided. As a
232 secondary analysis, the primary outcome was provided: 1) on the per protocol population; 2)
233 after adjustment for parity (nulli- vs multiparous), for body mass index, and for the two
234 parameters (logistic regression, enter method, adjusted ORs and CIs provided); 3) stratified
235 by parity (nulli- vs multiparous). The secondary outcomes were compared between the 2
236 groups: using χ^2 test or Fisher's exact test for binary variables; using Student's t-test or
237 Mann-Whitney's test for continuous variables, as appropriate. There was no imputation of
238 data (there was no missing data for the primary outcome and we observed less than 5%
239 missing data for any variable).

240 **Results**

241 *Study participants*

242 From December 2015 to December 2019, a total of 1942 women were assessed for eligibility
243 (screened for participation before confirmation by ultrasound). One hundred and fifty-six
244 women did not meet the inclusion criteria at the last check before randomization, 852
245 women declined to participate and 677 were not randomized for other reasons (women not
246 approached because physician was unavailable or missed by physician). Of the remaining
247 257 women, 126 were randomly assigned to trial of prophylactic manual rotation and 131
248 women to no trial of prophylactic manual rotation (Figure 2). No participants were lost to
249 follow-up leaving 257 women included in the primary analysis. The mean age of participants
250 was 30.4 (SD, 5.6) years and the mean body mass index was 26.8 (SD, 5.6). Participants
251 included 71.6% nulliparous women, the mean gestational age was 40.1 (SD, 1.1) weeks, and
252 78.2% of participants had a spontaneous onset of labor. Baseline characteristics were well-
253 balanced between the study groups (Table 1).

254

255 *Primary Outcome*

256 Operative delivery occurred in 37 women (29.4%) in the intervention group – trial of
257 prophylactic manual rotation – and 54 women (41.2%) in the standard group (Table 2). The
258 risk of operative delivery was significantly less frequent in the intervention (I) group
259 compared to the standard (S) group (Differential (I-S) [95% confidence interval, CI] = -11.8 [-
260 15.7;-7.9]; unadjusted odd ratio [95% CI] = 0.593 [0.353-0.995]). Instrumental delivery
261 concerned 31 women (24.6%) in the intervention group and 45 women (34.4%) in the
262 standard group. Cesarean delivery concerned 6 women (4.8%) in the intervention group and
263 9 women (6.9%) in the standard group.

264 In the per-protocol analysis, operative delivery occurred in 36/118 women (30.5%) in the
265 intervention group and in 54/131 women (41.2%) in the standard group ($P= .079$).
266 After logistic regression models, the intervention group remained significantly associated
267 with less frequent operative delivery (parity: adjusted OR [95% CI] = 0.552 [0.317-0.962], $P=$
268 .036; body mass index: adjusted OR [95% CI] = 0.587 [0.349-0.987], $P= .045$); parity and body
269 mass index: adjusted OR [95%CI] = 0.547 [0.313-0.955]). After stratification by parity, the
270 intervention group remained significantly associated with less frequent operative delivery
271 for the subgroup of nulliparous patients (36,7% in the intervention group vs. 55.3% in the
272 standard group, $P= .011$), but was not different for the subgroup of multiparous patients
273 (11,1% in the intervention group vs. 5.4% in the standard group, $P= .430$).

274

275 *Pre-specified Secondary Outcomes*

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

278 There were no significant differences between-groups in the risk of post-partum
279 hemorrhage (OR, 1.363 [95% CI, 0.492 to 3.777]). No women were admitted to ICU. The risks
280 of perineal tears, episiotomy, or obstetrical anal sphincter injury were not different between
281 groups (Table 2). No cases of cervical laceration were noticed.

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

284 There were no significant differences in following neonatal outcomes: Apgar score < 5 at 10
285 minutes, and arterial umbilical pH < 7.10. No neonatal head trauma was noticed in either
286 group.

287

288 *Detailed characteristics of the trial of prophylactic manual rotation*

289 In most cases, the fetuses were in right OP position controlled by ultrasound and the head
290 station was between -2 and 0 before the trial of prophylactic manual rotation.

291 Ninety-five (88.8%) of the physicians performing the manual rotation were right-handed and
292 physicians used their right hand in 54 (50.9 %) cases.

293 The success rate of prophylactic manual rotation was 89.7 % in the immediate moment of
294 the procedure. The successful manual rotations resulted in a spontaneous vaginal delivery in
295 76.0% of cases.

296 Fetal heart rate abnormalities (repetitive decelerations) occurred in 22 (17.5%) cases after
297 the trial of prophylactic manual rotation but without indication of emergency delivery.

298

299 *Additional data*

300 Among women delivering vaginally (operative or spontaneous vaginal deliveries), 116
301 (96.7%) women delivered in occiput anterior position in the intervention group versus 106
302 (86.9%) in the standard group ($P= .009$).

303 In the standard group, 28 (21.4%) women had an attempted therapeutic manual rotation
304 secondarily after the randomization because of non-reassuring fetal heart rate or failure of
305 progression of the fetal head. This procedure succeeded in 23 (82.1%) cases.

306 **Discussion**

307 *Principal findings*

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

313 *Results in context*

314 This randomized controlled trial (RCT) concerned the interest of prophylactic manual
315 rotation and showed positive results.

316 To our knowledge, one pilot RCT was published as a feasibility study and it included 30
317 women.²⁹ The results of that study showed neither statistical significance nor a trend with
318 regards to mode of delivery or maternal outcomes. The rates of operative delivery were
319 particularly high (80 to 87%) in the study as were the rates of neonatal ICU admission (20 to
320 40%). Very recently, the same team has published the results of the trial following this pilot
321 study.³⁰ In this RCT involving 254 women, the rates of operative delivery were also high (62
322 to 71%) as well as the rates of serious adverse neonatal outcomes (17%).

323 Another RCT (n= 65 women) has been reported as an abstract but the corresponding
324 detailed results have not been published and the abstract reported no difference in
325 operative vaginal delivery.³¹

326 Two others RCT have been registered at clinicaltrials.gov and should probably be published
327 soon.³²⁻³⁴

328 The present study deals with prophylactic manual rotation at the early second stage of labor.

329 We chose to study prophylactic manual rotation at this stage rather than therapeutic manual

330 rotation because literature has shown that attempted rotation before full dilatation and
331 rotation for failure to progress, are two major risk factors for failure of the procedure.^{22,35}
332 The success rate of prophylactic manual rotation was as expected for the calculation of the
333 sample size, and congruent with data in literature.^{22,25} This high success rate (89.7%) could
334 be related to the previously cited obstetrical factors and also to the systematic use of
335 ultrasound before the procedure. Indeed, the sonographic evaluation of the fetal spine
336 position has been shown to be associated with the success of the manual rotation.³⁶ The
337 success rate we reported was higher than shown in the previously cited RCT.^{29,30} This could
338 be explained by the time of the randomization in these studies “at the first urge to push or
339 one hour after full dilatation”.

340 Thus, the technique of manual rotation as described by Tarnier and Chantreuil may be an
341 efficient procedure to deal with OP and OT positions.

342 Our study confirmed the association of trial of prophylactic manual rotation with a shorter
343 second stage of labor as previously reported.^{24,31} The differential in the length of labor (18
344 min) seemed clinically relevant to us.

345 Contrary to the retrospective study of Shaffer *et al.*, we did not find an association between
346 trial of prophylactic manual rotation and the outcomes of perineal tears, episiotomy and
347 obstetrical anal sphincter injuries.²⁴ The rate of episiotomy was higher than mean national
348 rate of episiotomy in France (20.1% in 2016)³⁷ but lower than reported in previous studies
349 (44 to 65%).^{22,23} Furthermore, fetal heart rate abnormalities occurring after the trial of
350 prophylactic manual rotation were not indications for emergency delivery. Our trial did not
351 report any cases of cord prolapse, described as a complication of the maneuver in a former
352 study.¹⁹ Therefore, the trial of prophylactic manual rotation seemed to be a safe procedure
353 at the maternal and the neonatal sides.

354 Furthermore, choosing a trial of prophylactic rather than therapeutic manual rotation could
355 be the most effective strategy to deal with the OP and OT positions. One could argue that
356 prophylactic manual rotation is more likely to have been unnecessary, as most posterior
357 position will rotate spontaneously. However, significantly more women delivered in occiput
358 anterior position in the prophylactic manual rotation in comparison with the standard group.
359 Furthermore, in the standard group of our trial, a therapeutic manual rotation was
360 subsequently performed in cases of non-reassuring fetal heart rate or failure of progression
361 of the fetal head, but with a lower success rate.
362 Therefore, in cases of OP or OT positions, the trial of prophylactic manual rotation could be a
363 safe and efficient procedure and with a small number needed to treat of 9 women.

364 *Strengths and limitations*

365 The present study has a number of strengths. Beyond the randomization allowing for a
366 comparison of the efficacy of two strategies with the highest level of evidence, we had no
367 loss to follow-up as the primary outcome was operative delivery which occurred within a
368 few hours after randomization. Indeed, the intention-to-treat analysis could have been
369 performed on primary outcome for all cases without missing data. Furthermore, an
370 ultrasound scan was performed before randomization and at each stage of the follow-up,
371 ensuring an objective and certain diagnosis of the fetal head position. This point ensured the
372 reliability of diagnosis of the fetal head position because of the documented risks of errors in
373 digital examination.³⁸⁻⁴⁰

374 This trial was performed in 4 maternity units with different volumes of activity and levels of
375 care (secondary and tertiary care units) suggesting the applicability of the results of this trial
376 elsewhere. The non-inclusion of pregnant women without medical insurance (according to

377 French law) did not reduce the representativeness of our results since a vast majority of
378 people have medical insurance in France.

379 This study has several limitations. First, this study was not double-blinded. However, we do
380 not believe that there could be a placebo effect on the women with this kind of procedure,
381 and the clinical team could not feasibly be blinded to the intervention. We acknowledge the
382 possibility that delivering physicians may have been influenced in their decisions by
383 knowledge of the randomization group.

384 Second, we faced the usual difficulties of clinical research during labor with low rates of
385 consent, and 852 out of 1942 women declined participation in the trial. This rate raises
386 questions of external validity.

387 Third, the design of the follow-up did not allow exploration of long-term consequences.
388 Occiput posterior deliveries are known to be associated with perineal morbidity and pelvic
389 floor dysfunction at 6 months postpartum.⁴¹ Therefore, future research about manual
390 rotation should study these outcomes.

391 Fourth, the study was underpowered for each component of the primary outcome
392 (instrumental vaginal delivery and cesarean delivery) and important secondary outcomes
393 like neonatal morbidity and maternal morbidity (postpartum hemorrhage particularly). The
394 generalizability of our results could be questionable since we reported a high frequency of
395 instrumental vaginal delivery and notable cultural differences are reported in obstetrical
396 practices.

397 Fifth, the satisfaction of the women was not studied. Nowadays, evaluation of the maternal
398 childbirth experience is essential in obstetrics research. So, we plan to study maternal
399 satisfaction in further studies about manual rotation.

400 **Conclusions**

401 Among women presenting an OP or OT position at the early second stage of labor, the trial
402 of prophylactic manual rotation was significantly associated with less risk of operative
403 delivery. These findings support that the prophylactic manual rotation should be consider as
404 an effective and safe procedure to deal with OP or OT positions of the fetal head.

405

406 **Acknowledgements:** We thank the participants in this trial. We also thank the following
407 individuals who contribute to this trial: Dr H el ene Heckenroth, MD, Dr Claire Tourette, MD,
408 Dr Marianne Capelle, MD, Dr Patrice Crochet, MD, Dr Audrey Pivano, MD, Dr Val erie
409 Verlomme, MD, Dr C eline Sadoun, MD, Dr Marion Gioan, MD, Pr Xavier Carcopino, MD, PhD,
410 Dr C ecile Chau, MD, Dr M elinda Petrovic, MD, Jean-Fran ois Cocallemen. We thank Justine
411 Buand for helping to correct the English.

412

413 **Authors contributions:** Drs Blanc and Baumstarck had full access to all of the data in the
414 study and take responsibility for the integrity of the data and the accuracy of the data
415 analysis.

416 *Concept and design:* Blanc, Haumont e, D'Ercole

417 *Acquisition, analysis, or interpretation of data:* Blanc, Castel, Mauviel, Baumstarck, Bretelle,
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- 427 **Data Sharing Statement:** see Supplement 3

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547 **Tables**

548 Table 1. Baseline participant characteristics

Characteristics	No. (%) of women	
	Intervention (Trial of prophylactic manual rotation) (n=126)	Standard (No trial of prophylactic manual rotation) (n=131)
Age, mean (SD), y	30.2 (5.6)	30.5 (5.6)
Nulliparous	90 (71.4)	94 (71.8)
Body Mass Index, mean (SD), kg/m²	28.5 (5.7)	28.7 (5.4)
Gestational age, mean (SD), w	40.0 (1.1)	40.1 (1.0)
Anterior position of placenta	71 (58.2)	65 (51.6)
Gestational diabetes	19 (15.2)	18 (13.7)
Suspected macrosomia^a	9 (7.1)	4 (3.1)
Spontaneous onset of labor	101 (80.2)	100 (76.3)
Oxytocin administration	95 (75.4)	109 (83.2)

during labor		
Length of active	187.8 (105.7)	206.1 (116.9)
phase of labor (from		
6 cm to full		
dilatation), mean		
(SD), min		
Cervical dilatation	7.9 (2.0)	7.8 (1.9)
at diagnosis of		
posterior position,		
mean (SD), cm		
Non reassuring fetal	40 (31.7)	50 (38.5)
heart rate before		
full dilatation^b		
Postural strategies	37 (30.1)	41 (31.8)
to deal with		
posterior position		
during labor^c		
Birthweight, mean	3433.5 (409.0)	3424.6 (466.6)
(SD), grams		

549 Data are expressed as mean (SD) or number (percentage)

550 ^a Estimated fetal weight above the 95th percentile in a third trimester ultrasound

551 ^b Suspicious cardiotocography (FIGO 2015 classification)

552 ^c women adopting postures that differed from dorsal recumbent position during labor

553 Table 2. Primary and Secondary Outcomes by randomization group

	Intervention group Trial of prophylactic manual rotation (n=126)	Standard group No trial of prophylactic manual rotation (n=131)	Odds Ratio (95% CI)	P value
Primary outcome				
Operative delivery, No. (%)	37 (29.4)	54 (41.2)	0.593 (0.353- 0.995)	.047
Primary outcome components				
Instrumental delivery, No. (%)	31 (24.6)	45 (34.4)	0.624 (0.362- 1.073)	.087
Cesarean delivery, No. (%)	6 (4.8)	9 (6.9)	0.678 (0.234- 1.963)	.471
Prespecified secondary outcomes				
Length of second stage of labor in minutes, mean (SD)	146.7 (64.4)	164.4 (58.2)		.028

Post partum hemorrhage, No. (%)	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, No. (%)	4 (4.7)	4 (4.7)		>.99
Episiotomy, No. (%)	24 (26.1)	27 (28.1)	0.902 (0.474-1.717)	.753
Apgar score at 5 minutes	9.8 (0.7)	9.6 (1.0)		.049
Apgar score < 5 at 10 minutes, No. (%)	0	1 (0.8)		> .99
Arterial umbilical pH < 7.10, No. (%)	5 (4.0)	4 (3.1)	3.803 (0.419-34,531)	.235
Neonatal Intensive Care Unit Admission, No. (%)	1 (0.8)	4 (3.1)		.371

555 **Figure legends**

556 Figure 1. Technique of manual rotation described by Tarnier and Chantreuil

557 Figure 2. Randomization and follow-up of study participants

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Figure 1. Technique of manual rotation described by Tarnier and Chantreuil

The woman, bladder emptied, was placed in the lithotomy position, lying on her back with her feet in stirrups. When the uterus was relaxed, the trained operator placed one 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.

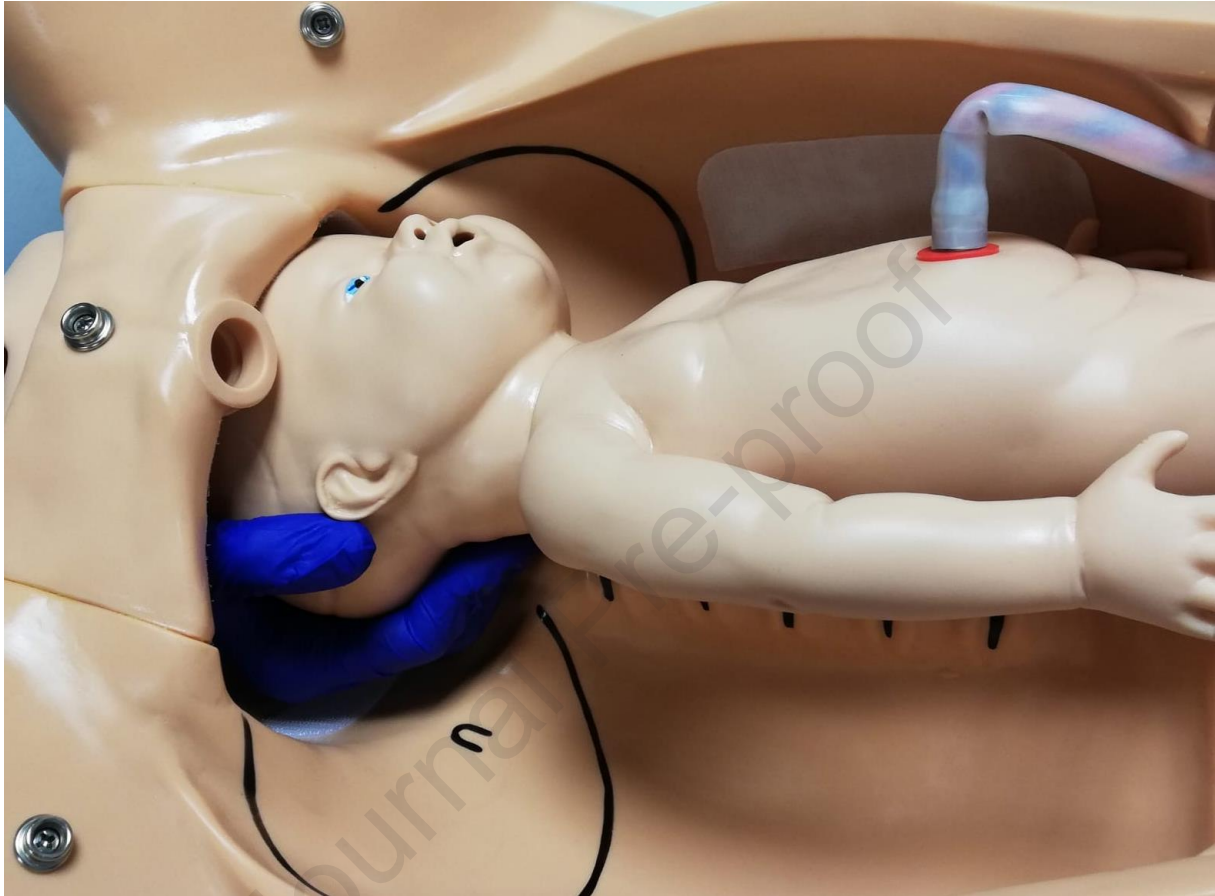
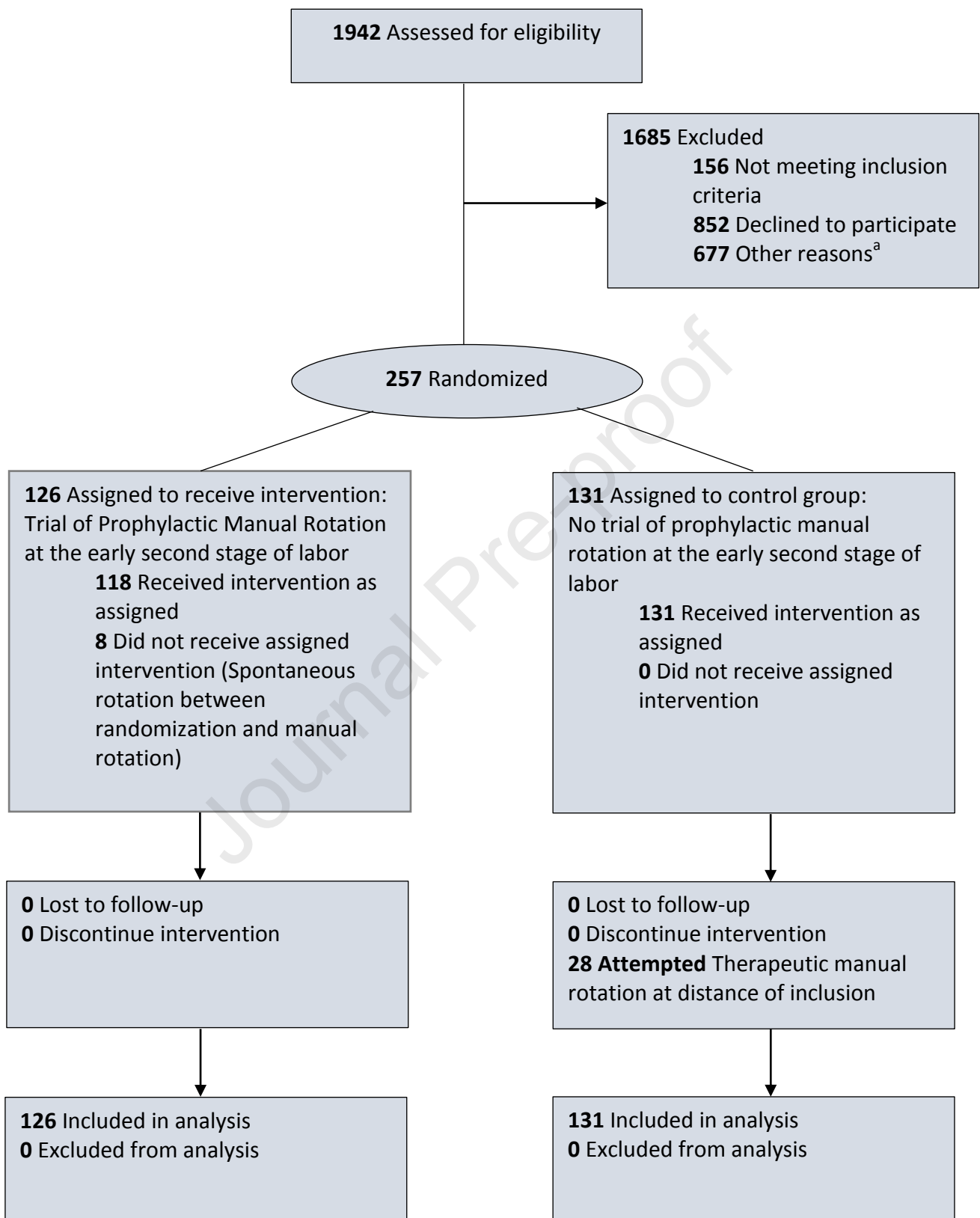


Figure 2. Randomization and follow-up of study participants



^a Other reasons were women not approached because physician were unavailable or missed by physician