Randomised Italian Sonography for Occiput POSition Trial Ante Vacuum (R.I.S.POS.T.A.)

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Short title: Ultrasound for fetal position before vacuum

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Abstract

Objective: To assess whether the ultrasound diagnosis of fetal head position reduces the risk of failed vacuum delivery and improves labor outcomes.

Methods: R.I.S.POS.T.A. (Randomised Italian Sonography for Occiput POSition Trial Ante Vacuum) was a randomised controlled trial conducted from April 2014 to June 2017 and involving thirteen Italian maternity hospitals. Singleton term pregnancies with cephalic presentation where a decision for instrumental delivery by vacuum extractor was made were included. Patients were randomized to either vaginal examination (VE) only (Group A) or VE plus transabdominal ultrasound (US) evaluation (Group B) to determine fetal head position before attempted instrumental delivery. The primary outcome of the study was the emergency Caesarean section rate due to failed vacuum delivery. A sample size of 653 per group (n=1306) was planned to compare the primary outcome between the two groups. The sample size estimation was based on the hypothesis that the risk of failed vacuum delivery in the VE group would be 5% and that ultrasound assessment of fetal position prior to vacuum would decrease this risk to 2%.

Results

Overall, 222 women were randomized and 221 were included in data analysis, of whom 132 (59.4%) were randomized to VE and 89 (40.6%) to VE plus US evaluation prior to vacuum delivery. No significant differences in the occurrence of emergency Caesarean section due to failed instrumental delivery and in other maternal and fetal outcomes were noted between the two groups. At interim analysis (n=221), the trial was stopped for futility. Women randomized to VE plus US showed higher rates of episiotomy and non-occiput anterior (OA) position at randomization and at delivery, and a lower incidence in incorrect diagnosis of non-OA position.

Conclusions

Our prematurely stopped randomised trial did not demonstrate any reduction in failed instrumental delivery and maternal and fetal morbidity in women submitted to sonographic assessment of fetal position prior to vacuum delivery.

Introduction

Instrumental vaginal delivery by vacuum extractor is a widely performed obstetric procedure[1,2] used to expedite delivery when there is substantial risk for the mother or fetus during the second stage of labour.

Although successful in most cases, a 4-6% failure rate has been reported following attempted vacuum delivery[3-5]. Caesarean section or sequential instrumental delivery with forceps represent the options to achieve the delivery of the fetus after vacuum failure, however an increase in maternal and fetal complications has been reported in such cases[5,6].

Fetal head malpositions, mainly represented by occiput transverse (OT) and occiput posterior (OP) positions, are among the main determinant of failed fetal extraction using vacuum, as a high expertise is required in order to apply the suction cup on the flexion point. Furthermore, in such cases the traction is technically more challenging[7,8].

Over the last decades, several studies have demonstrated that clinical diagnosis of fetal head position by means of digital examination is highly inaccurate, particularly in cases of OP and OT position[9-14]. On the other hand, the evaluation of fetal head position with transabdominal ultrasound (US), either during labor or before an instrumental delivery, has proven to be far more accurate[9,10,14]. No studies have been designed in order to evaluate whether the knowledge of the actual fetal head position by means of intrapartum US before an obstetric intervention with obstetric vacuum may be clinically beneficial for the mother or the fetus. The aim of this study was to assess whether US diagnosis of fetal head position before vacuum extraction can reduce the chance of failed procedures and improve maternal and perinatal outcomes in women submitted to instrumental delivery by vacuum extractor.

Material and methods

The Randomised Italian Sonography POSition of occiput Trial Ante- vacuum (R.I.S.POS.T.A., ClinicalTrials.gov Identifier: NCT01991665) is a randomized controlled trial promoted by the University of Parma and involving several Italian maternity units with over 2000 deliveries/year and a ≥4% vacuum delivery rate.

According to the R.I.S.POS.T.A. protocol, which was in compliance with the revised CONSORT statement for reporting randomized trials[15], nulliparous women above 18 years with term (37^{+0}-41^{+6} weeks of gestation) singleton pregnancy and requiring instrumental vaginal delivery were eligible for the study purposes. A priori exclusion criteria for study entry were represented by age <18 or >50 years, any contraindication to instrumental vaginal delivery by vacuum extractor (e.g. non-vertex presentation, cervical dilatation <10 cm, non-engaged fetal head, suspected cephalopelvic disproportion, fetal coagulopathy) and fetal head station >+3 cm. Furthermore, patients were excluded from randomization in all cases in which emergency delivery was necessary due to intrapartum fetal distress or when a sonographic evaluation of fetal head position had been made before randomization.

All the potentially eligible women were counselled regarding the study aim and provided informative material on admission, while informed consent for randomization was obtained in the early second stage of labor before active pushing.

In all women fulfilling the study entry criteria, randomization occurred after the decision to perform instrumental delivery by the attending physician. A dedicated online programme was responsible for the data entry and randomization. Allocation concealment was guaranteed as in all cases the physician performing the instrumental delivery was not responsible for the randomization process. Once demographic data were recorded, all the randomized women were given an ID number and included into one of the two study arms: among patients randomised to the control group (VE) fetal head position and station before applying the vacuum extractor were determined only by means of vaginal examination, while in the intervention group (VE + US) fetal occiput position was assessed also by means of transabdominal ultrasound after the vaginal examination and before the application of the vacuum cup. Fetal head position at randomization was classified into occiput anterior (OA) (left and right) and non-OA position, which included occiput posterior (left and right) and transverse (left and right). OA position was described when

the occiput was comprised between 10 and 2 o'clock[16]. Fetal head position at delivery was classified into occiput anterior (OA) and non-OA position, which included occiput posterior and transverse (left and right). Fetal station was classified according to the guidelines of the Royal College of Obstetricians and Gynaecologists by dividing the birth canal in 11 different stations from -5 cm to +5 cm according to the position of the largest diameter of the presenting part in relation to the ischial spines[17]. The sonographic diagnosis of fetal head position was performed transabdominally with the patient lying in supine position as previously described[18]. All the obstetricians involved in patient recruitment were trained in intrapartum ultrasound and capable to confidently evaluate the fetal occiput position on transabdominal ultrasound.

The primary outcome of the study assessed in the two arms was represented by the rate of failure of vacuum extraction and the need to perform an emergency caesarean. Criteria for failed instrumental delivery were not specified in the study protocol, therefore failed vacuum extraction was defined by the attending physician based on the subjective interpretation of the clinical scenario. All these patients underwent emergency caesarean delivery as forceps extraction is no longer performed in most of the maternity units in Italy and the option of sequential instrumental delivery after vacuum failure does not represent the standard of care.

Secondary outcomes included the number of cup detachments, the time (in minutes) between cup application and delivery, need for episiotomy to accomplish delivery, perineal tears involving the anal sphincter (third- and fourth-degree tears, as defined by the injury of the anal external sphincter or the anal mucosa, respectively) and postpartum haemorrhage, as defined by a fall in the hemoglobin level >=4,0 g/dL within 24 hours from birth; neonatal trauma (intracranial haemorrhage [ICH], cephalohematoma, retinal haemorrhage, facial nerve palsy, brachial plexus injury and fractures), APGAR score <7 at 5 minutes, neonatal acidosis as defined by umbilical artery pH <7.00 or base excess (BE) <-12 mEq/L, admission to the neonatal intensive care unit (NICU) and shoulder dystocia, as defined by the failure to deliver the fetal shoulder with gentle downward traction on the fetal head, requiring additional obstetric maneuvers to effect delivery[19]. Some of these outcome measures have been included before the commencement of the study but after that the study protocol had been preliminary approved and published on the clinicaltrial.gov website. This decision was undertaken after a shared among the leading investigators participating to the study.

Additional information recorded on the dedicated online database included demographic features such as maternal age, height, weight, body mass index (BMI); gestational age at recruitment, use of epidural analgesia during labor; vacuum type (Kiwi, Mityvac, Silastic cup or other); head station and position at randomization and at delivery; perinatal outcomes such as neonatal weight and sex; longitudinal and lateral distance between the centre of the chignon and the flexion point, as measured on the fetal head by flexible measuring tape (yardstick) (the longitudinal distance represented the measurement between the centre of the chignon and the flexion point along the sagittal suture; the lateral distance was measured only in the case of paramedian applications and represented the distance between the centre of the chignon and the flexion point); decision of the physician not to perform instrumental delivery after randomization; decision of the physician not to perform instrumental delivery because of the result of the intrapartum scan (only for patients randomized in the group B).

Incorrect diagnosis of fetal head position was defined in the case of discordance between the fetal position at clinical or sonographic assessment before vacuum extraction and the actual occiput position at delivery.

The study protocol was first approved by the Ethics Committee (n OST07/13) of the pilot Centre and subsequently by the local institution of all the participating Centres.

A sample size of 653 per group (n=1306) was planned to compare the primary outcome between the two groups. The sample size estimation was based on the hypothesis that transabdominal US prevents the incorrect placement of the suction cup on the fetal head. Available data suggest that digital examination only is associated with a suboptimal positioning of the vacuum cup in over 40% of cases particularly in the case of fetal head malpositions, which represent an acknowledged risk factor for failed instrumental delivery[9,20]. We assumed that the baseline risk of failed vacuum delivery in the VE group would have been 5% and that ultrasound assessment of fetal position prior to vacuum would have decreased this risk to 2%. Furthermore, a 6-7% drop-out percentage was estimated. Hence, we planned to enroll a total number of 1400 patients (700 for each arm of the study). The sample size was computed using Power and Sample Size Calculator (Biostatistics Department, Vanderbilt University, Nashville, TN, USA) and considering a 80% power and a p value of 0.05.

Patient recruitment started on April 1st, 2014 in 13 maternity units fulfilling the criteria of the R.I.S.POS.T.A. protocol and was expected to be completed after three years by May 31st, 2017. Additional centres joined the study group beyond April 2014, however only those who provided at least one case were included in the final dataset.

The online randomization programme could be accessed by all the investigators from all the centres involved in study recruitment, who were allowed to independently manage the data entry, whereas the leading centre (University of Parma) was responsible for the full control of data entry and the adherence to the original protocol by the participating units.

Only the 16% of the estimated sample size was covered over a three-year period from the beginning of the study, therefore a Data and Safety Monitoring Committee (DSMC) including independent experts in intrapartum ultrasound (Professor Torbjørn Moe Eggebø, Norwegian University of Science and Technology, Trondheim, Norway) and labor management (Professor Vincenzo Berghella, Jefferson University, Philadelphia, United States of America) was instituted in order to review the available dataset and evaluate the opportunity to discontinue the trial. The DSMC had not been established before the study commencement as part of the protocol but it was instituted due to the slow recruitment. No pre-specified stopping rules had been set up in the study protocol as the slow recruitment was unexpected. Due to poor patient recruitment, it became evident that it was not possible to reach the sample size necessary to investigate the primary outcome within the estimated timeframe. In June 2017, the DSMC recommended to stop R.I.S.POS.T.A. and report its data.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v. 21.0 (IBM Inc., Armonk, NY, USA). Data are reported as mean + standard deviation for normally distributed continuous data, median (range) for other continuous data, and as number (percentage) for categorical data. Categorical variables were compared using the Chi-square or Fisher exact test. Between-group comparison of continuous variables was undertaken using T-test for parametric analysis. Two sided p-values were calculated and p values <0.05 were considered as statistically significant.

Results

Patients were recruited over a 37-month period, from 1st April 2014 to 30th June 2017. Overall, 222 women were randomized in the study period, while the number of women excluded due to fetal distress or low station is unknown. In one of the included cases the physician responsible for patient care decided not to undertake instrumental delivery after randomization. This patient was allocated to the VE+US group and the baby was eventually delivered by an uncomplicated caesarean section. This case was excluded, leaving 221 women with full outcome data for analysis, of whom 132 (59.4%) were randomized to VE and 89 (40.6%) to VE plus US evaluation of the fetal occiput position prior to vacuum delivery. Flow diagram of patient enrollment in compliance with the revised CONSORT statement for reporting randomized trials[15] is shown in Figure 1.

Data entry occurred in 7 Centres, among whom the major contribution came from the leading Unit (108 cases, 48.8%) and the University Hospital of Turin (93 cases, 42.1%). Details on the participating Centres and their relative contribution to the final sample size are summarized in Table 1.

Demographic and clinical characteristics of the two study arms are presented on Table 2. Baseline maternal, neonatal and labor features were similar between the two groups, even though a significantly higher incidence of non-OA position at randomization (15.7% vs 3.1%, p <0.01) and of correct diagnosis of occiput position (4/89, 4.4% vs 17/132, 12.9% vs, p 0.04) were recorded in the VE + US compared to VE only group.

The labor and perinatal outcomes of the two randomization arms are summarized in Table 3. The occurrence of the primary outcome did not differ between the two groups, with only two emergency Caesarean sections due to failed instrumental delivery performed in the VE group. Significantly higher rates of episiotomy (86.5% vs 71.2%, p 0.009) were recorded in the VE + US group compared to the only VE group, while other maternal and neonatal complications did not differ significantly between the two study groups. All deliveries were performed by Obstetrics Consultants and the Kiwi cup was used in all Centres.

Discussion

Within our R.I.S.POS.T.A. study, the rate of caesarean section due to failed vacuum delivery was not significantly different between women undergoing digital assessment only compared to those allocated to digital and sonographic assessment of the fetal position before the procedure. Maternal and perinatal outcomes were also comparable.

As shown by a previous RCT (14), our data confirmed that the combination of digital and ultrasound assessment before an attempted instrumental delivery is more accurate than the vaginal examination only in the diagnosis of fetal head position (14). Also in our series, as previously reported by Ramphul et al. (14), the more accurate knowledge of occiput position before vacuum allowed by US assessment did not seem to yield any clinical benefit. However, the former RCT including vacuum and forceps deliveries was not powered to demonstrate significantly different clinical outcomes in women submitted to VE vs VE+ US before attempted instrumental delivery (21), although a non significantly higher trend in the caesarean delivery rate was noted in the VE only group.

The main objective of our study was to evaluate whether a more accurate diagnosis of fetal position achieved by ultrasound could favorably affect the outcome of instrumental vaginal delivery, reducing the small risk of failed extraction and emergency Caesarean section. Failed instrumental delivery is associated with a dramatic worsening in perinatal and maternal outcomes (6,22,23). However, given the low frequency of such adverse outcomes, a large number of randomized cases is warranted in order to evaluate a possible benefit of ultrasound over clinical examination.

After the time interval planned for patient recruitment our study was discontinued without reaching the numbers needed to answer our clinical question. In three years the patient recruitment was by far slower than expected (16.9% of the total). A possible explanation for this is that in Italy the use of ultrasound before instrumental vaginal delivery has become standard practice although not recommended by scientific guidelines. As two former randomized controlled trials (14,24) demonstrated that the use of US prior to instrumental vaginal delivery allow a more accurate diagnosis of fetal head position and a more precise placement of the vacuum cup on the fetal head than digital examination alone, it seems reasonable to hypothesize that most practitioners commonly perform ultrasound before attempted vacuum extraction even in the absence of any evidence supporting its clinical benefit.

An additional factor which has further reduced the clinical validity of our results is the low rate of failed vacuum delivery observed in our study population. Within our cohort, the vacuum delivery

failure rate was considerably lower than formerly reported and expected (1% vs 5%) (3-5). A possible explanation for such finding is that physicians involved in patient recruitment opted to randomize only women in which fetal extraction was considered to be easy, while US was systematically performed in the case of potentially challenging instrumental delivery. Given the low rate of failed fetal extraction found in our results, the estimated sample size needed to demonstrate a clinical benefit of combined VE and US assessment compared to VE only would have been five times greater than that a priori estimated. Although the only two emergency caesarean sections performed due to failed instrumental delivery occurred in the only VE group, this was not statistically significant.

As mentioned above, our results confirmed that incorrect diagnosis of the fetal head position before instrumental vaginal delivery, particularly non-OA position, is significantly more common following digital examination only (14,24). Indeed, even assuming that fetal head rotation from non-OA to OA position can occur between randomization and delivery, the incorrect diagnosis of occiput position was recorded more frequently in the VE only group. Rotation of the fetal head from non-OA to OA during traction may explain why in few cases the actual position of the head at delivery may differ from the sonographic diagnosis prior to the procedure. The acknowledged low accuracy in the clinical diagnosis of fetal position may account for the apparently lower incidence of non-OA position at randomization among the VE only group. On the other hand, differently from what it had been reported in a previous RCT (24), the more reliable diagnosis of fetal position provided by ultrasound before vacuum extraction did not improve the accuracy of vacuum cup placement as witnessed by comparable distance between the flexion point and the chignon among the two study arms.

In our study we found a nearly 80% rate of episiotomy, which is higher than formerly reported (25). It is interesting to note that episiotomy was performed more frequently within the VE + US group than in the only VE one, and this may be related to the higher incidence of non-OA position diagnosis in the former group.

The usefulness of intrapartum ultrasound in the prediction of failed instrumental delivery has been investigated over the last few years. A series of sonographic parameters mostly derived by transperineal ultrasound have shown to be accurate and reproducible in the assessment of the fetal head station in the second stage of labor (26-28). On this basis, several observational studies have investigated their usefulness in women submitted to vacuum extraction (2,29,30) and demonstrated that ultrasound is more reliable than digital examination in predicting the risk of vacuum extraction failure.

We strongly hope that an indisputable response on the clinical usefulness of ultrasound in labor will be achieved by means an adequately powered RCT. The introduction of various interventions without proof of efficacy is not uncommon in medicine and may lead to harm.

In this respect, one RCT (31) demonstrated that the systematic use of intrapartum ultrasound to determine fetal head position among low risk women yields an increase in the instrumental delivery and in the Caesarean section rate without any improvement in maternal and perinatal outcomes. However, based on the available literature and the difficulties we have experienced across this study, we suspect that the use of ultrasound before instrumental delivery might be incorporated in the clinical practice before a strong evidence provided by a RCT would be obtained.

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Disclosure of Interests

The Authors state no financial disclosures nor conflict of interest related to this work.

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Figure Legend:

Figure 1 - Flow diagram of patient enrollment in compliance with the revised CONSORT statement for reporting randomized trials

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

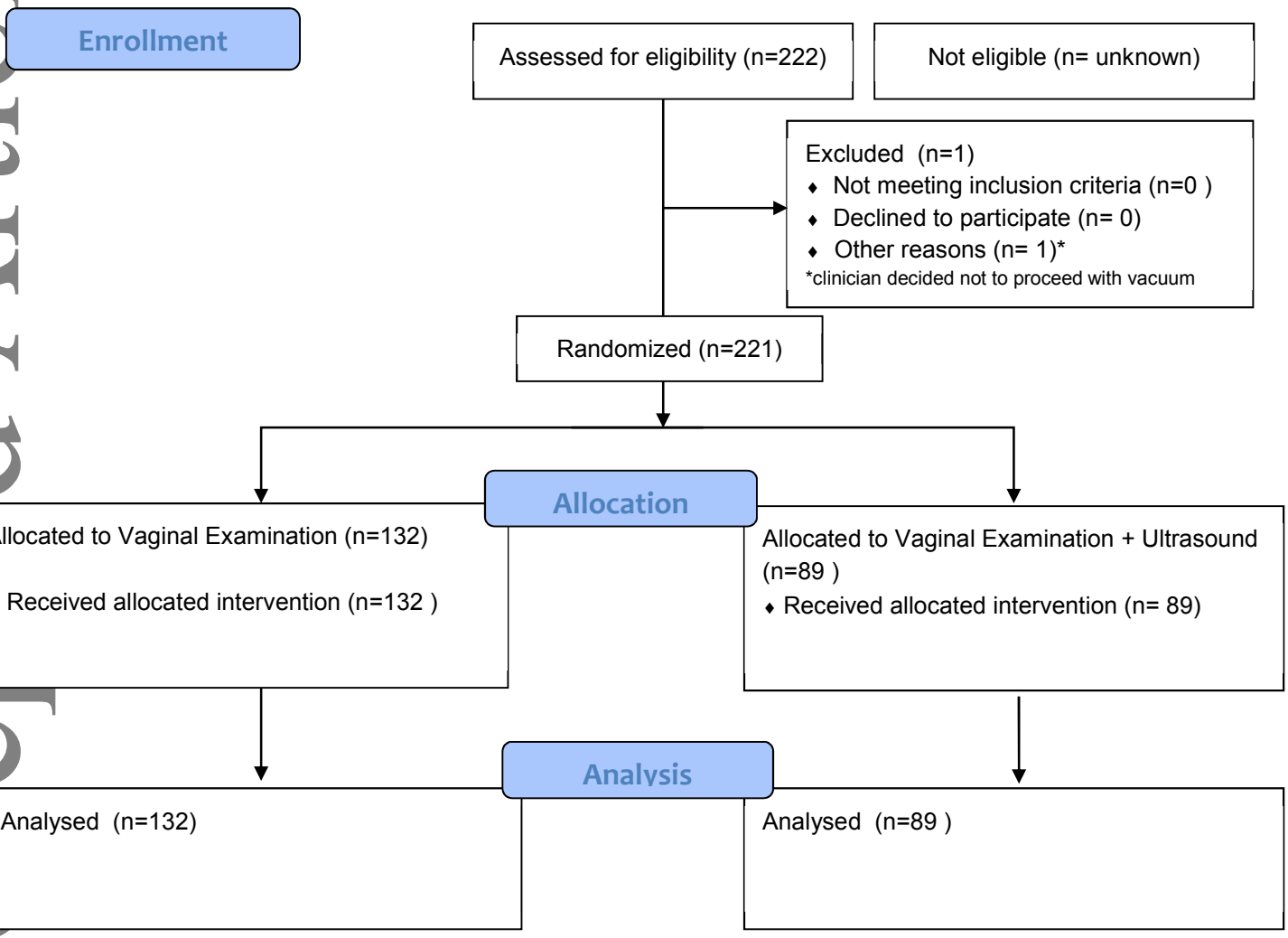

Table 1 – Participating centres and relative contribution to patient randomization.

Centre	**Number of cases randomized and included in data analysis**	**Relative contribution to study sample size**
Maggiore University Hospital, Parma	108	47.5%
Sant'Anna University Hospital, Turin	93	41.2%
Mangiagalli University Hospital, Milan	9	4.1%
Fatebenefratelli San Peter Hospital, Rome	4	1.8%
Sant'Orsola University Hospital, Bologna	3	1.3%
Rome Tor Vergata	2	0.9%
Brescia	2	0.9%

Table 2 – Maternal, neonatal and labor baseline characteristics.

	All (n=221)	VE only (n=132)	VE + US (n=89)	p*
Maternal age (years)	32.5 ± 6.3	33.2 ± 5.8	32.1 ± 6.1	0.214
Maternal height (cm)	175.4 ± 6.1	165.2 ± 5.7	165.4 ± 6.7	0.777
BMI at delivery (kg/m^2)	26.5 ± 4.3	26.6 ± 5.2	26.4 ± 4.1	0.819
Gestational age at delivery (weeks)	$39^{+6} \pm 1^{+1}$	$40^{+0} \pm 1^{+1}$	$39^{+6} \pm 1^{+1}$	0.403
Gender male	136 (61.3%)	79 (59.4%)	57 (64%)	0.57
Birthweight (g)	3317 ± 430	3295 ± 381	3349 ± 495	0.36
Epidural analgesia	144 (64.9%)	91 (68.4%)	53 (59.6%)	0.20
Head station	1 (0-3)	1 (0-3)	1 (0-3)	0.86
Diagnosed occiput position at randomization				<0.01
OA	203 (81.9%)	128 (96.9%)	75 (84.3%)	
Non OA	18 (8.1%)	4 (3.1%)	14 (15.7%)	
Occiput position at delivery				0.40
OA	190 (86.0%)	111 (84.1%)	79 (88.8%)	
Non OA	31 (14.0%)	21 (15.9%)	10 (12.2%)	
Incorrect diagnosis of occiput positio	21 (9.5%)	17 (12.9%)	4 (4.4%)	0.04

* VE only vs VE + US
BMI: body mass index
VE: vaginal examination
US: ultrasound
OA: occiput anterior
[@]Occiput position at delivery as reference standard

Table 3 – Labor and perinatal outcomes according to randomization group[@].

	VE only (n=132)	VE + US (n=89)	p*
Mode of delivery			0.24
Vacuum	130 (99.2%)	89 (100%)	
Caesarean section	2 (0.8%)	0 (0%)	
Number of cup detachments	0 (0-3)	(0-2)	0.16
Time between cup application and deliver (minutes)	3 (1 – 17)	3 (0 – 10)	0.75
Episiotomy	94 (71.2%)	77 (86.5%)	0.009
III-IV degree perineal tear	7 (5.3%)	5 (5.6%)	1.00
Postpartum haemorrhage	18 (13.5%)	13 (14.6%)	0.85
APGAR <7 at V minutes	2 (1.5%)	1 (1.1%)	0.81
Arterial pH	7.23 (6.70-7.40)	7.25 (7.05-7.40)	0.74
Arterial pH <7.00	2 (1.5%)	1 (1.1%)	0.81
Arterial base excess >-12	15 (11.4%)	8 (9.0%)	0.57
Cephalohematoma	5 (3.8%)	2 (2.2%)	0.70
NICU admission	9 (6.8%)	5 (5.6%)	0.72
Shoulder dystocia	2 (1.5%)	4 (4.5%)	0.22
Distance between the flexion point and th chignon (cm)	1.64 $\pm$ 1.55	1.57 $\pm$ 0.99	0.72

* VE only vs VE + US
VE: vaginal examination
US: ultrasound
OA: occiput anterior
NICU: neonatal intensive care unit
[@]outcomes not listed in the Table if no events recorded (intracranial haemorrhage, retinal haemorrhage, facial nerve palsy, brachial plexus injury and fractures)