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

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KEYWORDS: emergency Cesarean section; failed instrumental delivery; fetal head position; intrapartum ultrasound; occiput posterior; vacuum delivery

ABSTRACT

Objective *To assess whether sonographic diagnosis of fetal head position before instrumental vaginal delivery can reduce the risk of failed vacuum extraction and improve delivery outcome.*

Methods *Randomised Italian Sonography for occiput POSition Trial Ante vacuum (R.I.S.POS.T.A.) is a randomized controlled trial of term (37 + 0 to 41 + 6 weeks' gestation) singleton pregnancies with cephalic presentation requiring instrumental delivery by vacuum extraction, which was conducted between April 2014 and June 2017 and involved 13 Italian maternity hospitals. Patients were randomized to assessment of fetal head position before attempted instrumental delivery by either vaginal examination (VE) alone or VE plus transabdominal sonography (TAS). Primary outcome was incidence of emergency Cesarean section due to failed vacuum extraction. A sample size of 653 women per group 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 extraction would decrease this risk to 2%.*

Results *On interim analysis, the trial was stopped for futility. During this period, 222 women were randomized and 221 were included in the final data analysis, of whom 132 (59.7%) were randomized to evaluation of fetal head position by VE only and 89 (40.3%) to assessment by VE plus TAS prior to vacuum extraction. No significant differences were observed between the two groups with respect to incidence of emergency Cesarean section due to failed instrumental delivery and other maternal and fetal outcomes. Women randomized to assessment by VE plus TAS showed higher incidence of non-occiput anterior position of the fetal head at randomization and lower incidence of incorrect diagnosis of occiput position compared with women undergoing assessment by VE alone. A higher rate of episiotomy was noted in the women undergoing both VE and TAS compared with those in the VE-only group.*

Conclusions *Our prematurely discontinued randomized controlled trial did not demonstrate any benefit in terms of reduced risk of failed instrumental delivery or maternal and fetal morbidity in women undergoing sonographic assessment of fetal head position prior to vacuum extraction. Copyright © 2018 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

Instrumental vaginal delivery by vacuum extraction 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 labor. Although successful in most cases, a 4–6% failure rate has been reported following attempted vacuum delivery[3–5]. Cesarean section and sequential instrumental delivery with forceps are the available options to achieve delivery of the fetus after failure of vacuum extraction, but increased risk of maternal and fetal complications has been reported in such cases[5,6].

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Fetal head malposition, mainly represented by occiput transverse and occiput posterior positions, is among the main determinants of failed fetal extraction using vacuum, as a high level of 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 past decades, several studies have demonstrated that clinical diagnosis of fetal head position by means of digital examination is highly inaccurate, particularly in cases of occiput posterior or occiput transverse position[9–15]. On the other hand, evaluation of the fetal head position using transabdominal sonography (TAS), either during labor or before instrumental delivery, has proven to be far more accurate[9,10,14,15]. No study has been performed to evaluate whether knowledge of the actual fetal head position by means of intrapartum ultrasound before obstetric intervention by vacuum extraction may be clinically beneficial for the mother or the fetus. The aim of this study was to assess whether ultrasound diagnosis of fetal head position before vacuum extraction can reduce the incidence of failed procedure and improve maternal and perinatal outcomes in women undergoing instrumental delivery by vacuum extraction.

SUBJECTS 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 (RCT) led by the University of Parma and involving several Italian maternity units with over 2000 deliveries/year and a vacuum delivery rate $\geq 4\%$.

According to the R.I.S.POS.T.A. protocol, which followed the revised CONSORT statement for reporting randomized trials[16], nulliparous women > 18 years with term ($37+0$ to $41+6$ weeks of gestation) singleton pregnancy that required instrumental vaginal delivery by vacuum extraction were eligible for inclusion. *A-priori* exclusion criteria were maternal age < 18 or > 50 years, any contraindication to instrumental vaginal delivery by vacuum extraction (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 sonographic evaluation of fetal head position had been performed before randomization.

All potentially eligible women were counseled regarding the study purpose and were provided with information material on admission; informed consent for randomization was obtained in the early second stage of labor before active pushing. The study protocol was first approved by the Ethics Committee (No. OST07/13) of the pilot center and subsequently by the local institution of all participating centers.

Randomization

In all women fulfilling the study inclusion criteria, randomization was carried out after the decision to perform instrumental delivery was made by the attending physician. A dedicated online program was used for 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 randomized women were given an ID number and included in one of the two study arms: in the control group, fetal head position and station were determined only by means of vaginal examination (VE) before vacuum extraction; in the intervention group, fetal occiput position was assessed by VE followed by TAS, before 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) position. OA position was assigned when the occiput was between 10 h and 2 h on a clock face[17]. Fetal head position at delivery was classified into OA and non-OA position, which included occiput posterior and transverse (left and right). Fetal station was classified by dividing the birth canal into 11 different stations from -5 cm to $+5$ cm according to the level of the leading part of the fetal head in relation to the ischial spines[18]. The sonographic diagnosis of fetal head position was performed transabdominally with the patient lying in a supine position as previously described[19]. All obstetricians involved in patient recruitment were trained in intrapartum ultrasound and were able to evaluate confidently the fetal occiput position on TAS.

Outcome measures

The primary outcome of the study, assessed in both arms, was incidence of failed vacuum extraction and need to perform emergency Cesarean delivery. Criteria for failed instrumental delivery were not specified in the study protocol, and therefore failed vacuum extraction was defined by the attending physician based on his or her subjective interpretation of the clinical scenario. All such patients underwent emergency Cesarean 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, time (in min) between cup application and delivery, need for episiotomy to accomplish delivery, perineal tears involving the anal sphincter (third- or fourth-degree tears, as defined by the injury of the anal external sphincter or the anal mucosa, respectively), postpartum hemorrhage (fall in hemoglobin level ≥ 4.0 g/dL within 24 h from birth), neonatal trauma (intracranial hemorrhage, cephalohematoma, retinal hemorrhage,

facial nerve palsy, brachial plexus injury and fractures), 5-min Apgar score < 7, neonatal acidosis (umbilical artery pH < 7.00 or base excess < −12 mEq/L), admission to the neonatal intensive care unit and shoulder dystocia (failure to deliver the fetal shoulder with gentle downward traction on the fetal head) requiring additional obstetric maneuvers to effect delivery[20]. Some of the secondary outcome measures were included after the study protocol had been preliminarily approved and published, but before commencement of the study, based on consensus among the principal investigators.

Additional information recorded on the dedicated online database included demographic features, such as maternal age, height, weight and body mass index; 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 center of the chignon and the flexion point, as measured on the neonatal head by flexible measuring tape (the longitudinal distance was that along the sagittal suture; the lateral distance was measured only in the case of paramedian applications); 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 to the intervention group).

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.

Sample-size calculation and recruitment

A sample size of 653 patients per group ($n = 1306$ in total) was planned to compare the primary outcome between the two groups. The sample size estimation was based on the hypothesis that assessment by TAS prevents the incorrect placement of the suction cup on the fetal head. Available data suggest that digital examination alone is associated with a suboptimal positioning of the vacuum cup in over 40% of cases, particularly in the case of fetal head malposition, which represents a known risk factor for failed instrumental delivery[9,21]. We assumed that the baseline risk of failed vacuum delivery in the control group (VE only) would be 5% and that additional ultrasound assessment of fetal position prior to vacuum extraction would decrease this risk to 2%. Furthermore, a 6–7% drop-out rate was estimated. Hence, we planned to enroll a total of 1400 patients (700 in each arm of the study). The sample size was computed using Power and Sample Size Calculator (Biostatistics Department, Vanderbilt University, Nashville, TN, USA) considering an 80% power and a *P*-value of 0.05.

Patient recruitment started on 1 April 2014 in 13 maternity units fulfilling the criteria of the R.I.S.POS.T.A. protocol and was expected to be completed after 3 years, by 31 May 2017. Additional centers joined after commencement of the study, but only those who provided at least one case were included in the final dataset.

The online randomization program could be accessed by all investigators from all centers involved in study recruitment, and they were allowed to manage independently data entry; however, the leading center (University of Parma) was responsible for the full control of data entry and the adherence of the participating units to the original protocol.

Only 17% of the estimated sample size was reached over a 3-year period from the beginning of the study. Consequently, a Data and Safety Monitoring Committee (DSMC) including independent experts in intrapartum ultrasound (Prof. Torbjørn Moe Eggebø, Norwegian University of Science and Technology, Trondheim, Norway) and labor management (Prof. Vincenzo Berghella, Jefferson University, Philadelphia, PA, USA) was instituted in order to review the available dataset and evaluate the prospect of discontinuing the trial. The intervention by the DSMC had not been prearranged as part of the study protocol but it was instituted due to the unexpected slow recruitment; therefore, no prespecified discontinuation rules had been established. Due to slow 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 discontinuation of R.I.S.POS.T.A. and reporting of the findings of the study.

Statistical analysis

Statistical analysis was performed using SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA). Data are reported as mean ± SD for normally distributed continuous data, median (range) for other continuous data, and *n* (%) for categorical data. Categorical variables were compared using the chi-square test or Fisher's exact test. Between-group comparison of continuous variables was undertaken using Student's *t*-test for parametric analysis. Two-sided *P*-values were calculated and $P < 0.05$ was considered statistically significant.

RESULTS

Patient recruitment was carried out over a 37-month period, from 1 April 2014 to 30 June 2017. Overall, 222 women were enrolled during the study period. The number of women excluded due to fetal distress, low head station or because they had already undergone sonographic assessment of fetal head position was unknown. In one of the enrolled cases, the physician responsible for the patient decided not to perform instrumental delivery after randomization into the VE plus TAS group. The baby was eventually delivered by an uncomplicated Cesarean section. This case was excluded, leaving 221 women with full outcome data for analysis, of whom 132 (59.7%) were randomized to VE only

and 89 (40.3%) to VE plus TAS evaluation of the fetal occiput position prior to vacuum delivery. A flow diagram of patient enrollment, based on the revised CONSORT statement for reporting randomized trials[16], is shown in Figure 1.

Patients were recruited from seven centers, of which the University Hospital in Parma (108 cases, 48.9%) and the University Hospital of Turin (93 cases, 42.1%) contributed the majority of patients. The participating centers and their relative contribution to the final sample size are provided in Table 1.

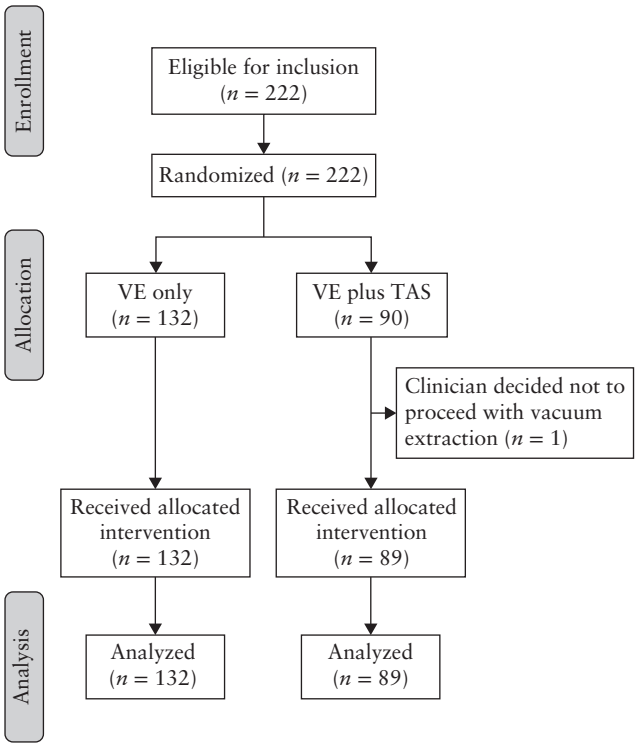

Figure 1 Flowchart showing enrollment into study of nulliparous women with term singleton pregnancy requiring instrumental vaginal delivery, and randomization to assessment of fetal head position by vaginal examination (VE) only or by VE plus transabdominal sonography (TAS) before vacuum extraction.

Demographic and clinical characteristics of the two study groups are presented in Table 2. Baseline maternal, neonatal and delivery characteristics were similar between the two groups. However, a significantly higher incidence of non-OA fetal head position at randomization (15.7% *vs* 3.0%, $P < 0.01$) was recorded in the VE plus TAS compared with the VE-only group, whereas a higher incidence of incorrect diagnosis of occiput position was noted in the VE-only group compared with the group undergoing both VE and TAS (17/132 (12.9%) *vs* 4/89 (4.5%), $P = 0.04$).

Delivery and perinatal outcomes of the two randomization groups are summarized in Table 3. Incidence of the primary outcome did not differ between the two groups, with only two emergency Cesarean sections due to failed

Table 1 Centers in which recruitment of patients for Randomised Italian Sonography POSition of occiput Trial Ante vacuum (R.I.S.POS.T.A.) was performed and their contribution to study sample

Center	*Cases included in data analysis (n = 221)*
Maggiore University Hospital, Parma	108 (48.9)
Sant'Anna University Hospital, Turin	93 (42.1)
Mangiagalli University Hospital, Milan	9 (4.1)
Fatebenefratelli San Peter Hospital, Rome	4 (1.8)
Sant'Orsola University Hospital, Bologna	3 (1.3)
University Rome Tor Vergata, Rome	2 (0.9)
University Hospital of Brescia, Brescia	2 (0.9)

Data are presented as *n* (%).

Table 2 Maternal, neonatal and delivery characteristics of 221 nulliparous women with singleton pregnancy requiring instrumental vaginal delivery, randomized to assessment of fetal head position by vaginal examination (VE) only or by VE plus transabdominal sonography (TAS)

Variable	*All (n = 221)*	*VE only (n = 132)*	*VE plus TAS (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 ± 1+1	40+0 ± 1+1	39+6 ± 1+1	0.403
Male gender	136 (61.5)	79 (59.8)	57 (64.0)	0.57
Birth weight (g)	3317 ± 430	3295 ± 381	3349 ± 495	0.36
Epidural analgesia	144 (65.2)	91 (68.9)	53 (59.6)	0.20
Head station	1 (0–3)	1 (0–3)	1 (0–3)	0.86
Fetal head position				
At randomization				< 0.01
OA	203 (91.9)	128 (97.0)	75 (84.3)	
Non-OA	18 (8.1)	4 (3.0)	14 (15.7)	
At delivery				0.40
OA	190 (86.0)	111 (84.1)	79 (88.8)	
Non-OA	31 (14.0)	21 (15.9)	10 (11.2)	
Incorrect diagnosis of occiput position†	21 (9.5)	17 (12.9)	4 (4.5)	0.04

Data are presented as mean ± SD, *n* (%) or median (range). *VE only *vs* VE plus TAS. †Occiput position at delivery used as reference standard. BMI, body mass index; OA, occiput anterior.

Table 3 Labor and perinatal outcomes of 221 nulliparous women with singleton pregnancy requiring instrumental vaginal delivery, randomized to assessment of fetal head position by vaginal examination (VE) only or by VE plus transabdominal sonography (TAS)

*Outcome**	*VE only* (n = *132*)	*VE plus TAS* (n = *89*)	P†
Mode of delivery			0.24
Vacuum	130 (98.5)	89 (100)	
Cesarean section	2 (1.5)	0 (0)	
Number of cup detachments	0 (0–3)	(0–2)	0.16
Time between cup application and delivery (min)	3 (1–17)	3 (0–10)	0.75
Episiotomy	94 (71.2)	77 (86.5)	0.009
Third- or fourth-degree perineal tear	7 (5.3)	5 (5.6)	1.00
Postpartum hemorrhage	18 (13.6)	13 (14.6)	0.85
5-min Apgar score < 7	2 (1.5)	1 (1.1)	0.81
UA pH	7.23 (6.70–7.40)	7.25 (7.05–7.40)	0.74
UA pH < 7.00	2 (1.5)	1 (1.1)	0.81
UA base excess > −12 mEq/L	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 flexion point and chignon (cm)	1.64 ± 1.55	1.57 ± 0.99	0.72

Data are presented as *n* (%), median (range) or mean ± SD. *Neonatal trauma (intracranial hemorrhage, retinal hemorrhage, facial nerve palsy, brachial plexus injury and fractures) was also assessed but no event was recorded and therefore it is not listed. †VE only *vs* VE plus TAS. NICU, neonatal intensive care unit; UA, umbilical artery.

instrumental delivery performed in the VE-only group. Significantly higher incidence of episiotomy was noted in the group that underwent both VE and TAS compared with the VE-only group (86.5% *vs* 71.2%, $P = 0.009$), whereas other maternal and neonatal outcomes did not differ significantly between the two study groups. All deliveries were performed by obstetrics consultants and the Kiwi cup was used in all participating centers.

DISCUSSION

Within the R.I.S.POS.T.A. study, the rate of emergency Cesarean section due to failed vacuum delivery was not significantly different between women who underwent only digital assessment of the fetal head position and those who had both digital and sonographic assessment before the procedure. Maternal and perinatal outcomes were also comparable between the two groups.

In accordance with a previous RCT[15], our data confirmed that the combination of digital and ultrasound assessment before attempted instrumental delivery is more accurate than vaginal examination alone for the diagnosis of fetal head position. However, the more accurate knowledge of occiput head position before vacuum delivery offered by ultrasound assessment did not seem to yield any clinical benefit in our study cohort. This is again in agreement with the study of Ramphul *et al.*[15], but the RCT was not powered to demonstrate significantly different clinical outcomes in women who underwent only VE *vs* those who underwent both VE and ultrasound assessment before attempted instrumental delivery[22], although a non-significant trend towards higher incidence of Cesarean delivery was noted in the VE-only group.

The main objective of our study was to evaluate whether a more accurate diagnosis of fetal head position achieved by ultrasound could affect favorably the outcome of instrumental vaginal delivery, reducing the risk of failed extraction and emergency Cesarean section. Failed instrumental delivery is associated with a dramatic worsening in perinatal and maternal outcomes[6,23,24]. 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.

On conclusion of the time period scheduled for patient recruitment, our study was discontinued without reaching the patient number required to answer our clinical question. During the 3 years of the study, patient recruitment was far slower than had been anticipated (only 16.9% of the total sample size was reached). A possible explanation for this is that, in Italy, ultrasound assessment before instrumental vaginal delivery has become the standard practice, although not recommended by scientific guidelines. Since two former RCTs[15,25] demonstrated that the use of ultrasound prior to instrumental vaginal delivery allows a more accurate diagnosis of fetal head position and a more precise placement of the vacuum cup on the fetal head than does digital examination alone, it seems reasonable to hypothesize that most practitioners perform ultrasound commonly before attempted vacuum extraction even in the absence of any evidence supporting its clinical benefit.

An additional factor that further reduced the clinical validity of our results is the low incidence of failed vacuum delivery 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 this is that physicians involved in patient recruitment opted to randomize only women for whom fetal extraction was considered to be easy, whereas ultrasound assessment was performed systematically in the case of potentially challenging instrumental delivery.

Given the low incidence of failed vacuum extraction in our study, the estimated sample size needed to demonstrate a potential clinical benefit of VE plus TAS *vs* VE alone would have been five times higher than that estimated *a priori*. Although the only two emergency Cesarean sections performed due to failed instrumental delivery occurred in the VE-only group, this finding was not statistically significant.

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 alone[15,25]. 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 position during traction may explain why in a few cases the actual position of the fetal head at delivery may differ from the sonographic diagnosis prior to the procedure. The acknowledged low accuracy in the clinical diagnosis of fetal head position may account for the apparently lower incidence of non-OA position at randomization in the VE-only group compared with that in the VE plus TAS group. On the other hand, in contrast to the findings of Wong *et al.*[25], the more reliable diagnosis of fetal position provided by ultrasound assessment before vacuum extraction did not improve the accuracy of vacuum cup placement as witnessed by comparable distance between the flexion point and the chignon between the two study arms.

The rate of episiotomy in our study was nearly 80%, which is higher than that reported formerly[26]. It is worth noting that episiotomy was performed more frequently in the group of women that underwent VE plus TAS compared with those who had only VE, 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 widely over the past few years. A series of sonographic parameters mostly derived by transperineal ultrasound have been shown to be accurate and reproducible in the assessment of the fetal head station in the second stage of labor[27–29]. On this basis, several observational studies have investigated their usefulness in women undergoing vacuum extraction[2,30,31] and demonstrated that ultrasound is more reliable than digital examination in predicting the risk of vacuum extraction failure.

We hope that definitive evidence of the clinical usefulness of ultrasound in labor will be obtained by means of an adequately powered RCT. The introduction of various interventions without proof of their efficacy is not uncommon in medicine and may lead to harm. In this respect, one RCT[32] demonstrated that the systematic use of intrapartum ultrasound to determine fetal head position among low-risk women yielded an increase in instrumental delivery and in Cesarean section rate without improving maternal or perinatal outcomes.

However, based on the available literature and considering the difficulty in recruitment we experienced during this study, we suspect that the use of ultrasound prior to instrumental delivery may be implemented in clinical practice before strong scientific evidence is provided by a RCT.

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This article has been selected for Journal Club.

A slide presentation prepared by Dr Fiona Brownfoot, one of UOG's Editors for Trainees, is available online.

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Ensayo italiano aleatorizado de ecografías para saber la posición del occipucio antes del parto con ventosa

RESUMEN

Objetivo Evaluar si el diagnóstico mediante ecografía de la posición de la cabeza del feto antes del parto instrumentado vaginal puede reducir el riesgo de fracaso del parto con ventosa y mejorar el resultado del parto.

Métodos El ensayo italiano aleatorizado de ecografías para saber la posición del occipucio antes del parto con ventosa (R.I.S.POS.T.A., por sus siglas en inglés) es un ensayo controlado aleatorizado de embarazos con feto único a término (de 37+0 a 41+6 semanas de gestación) y una presentación cefálica que requiere parto instrumentado con ventosa, que se llevó a cabo entre abril de 2014 y junio de 2017 y en el que participaron 13 maternidades italianas. Las pacientes fueron asignadas al azar a la evaluación de la posición de la cabeza del feto antes del intento de parto instrumentado mediante un examen vaginal (EV) o EV más una ecografía transvaginal (ETV). El resultado principal fue la frecuencia de la cesárea de urgencia debido al fracaso del parto con ventosa. Se planificó un tamaño de muestra de 653 mujeres por grupo con el que comparar el resultado primario entre los dos grupos. La estimación del tamaño de la muestra se basó en la hipótesis de que el riesgo de parto con ventosa fallido en el grupo EV sería del 5% y que la evaluación ecográfica de la posición fetal previa al parto con ventosa reduciría este riesgo al 2%.

Resultados En el análisis provisional, el ensayo se interrumpió por ser inútil. Durante este período, 222 mujeres fueron asignadas al azar y 221 fueron incluidas en el análisis final de los datos, de las cuáles 132 (59,7%) fueron asignadas al azar a la evaluación de la posición de la cabeza del feto por EV y 89 (40,3%) a la evaluación por EV más ETV, antes del parto con ventosa. No se observaron diferencias significativas entre los dos grupos con respecto a la frecuencia de cesárea de urgencia debido al fracaso del parto instrumentado y otros resultados maternofetales. Las mujeres asignadas al azar a la evaluación por EV más ETV mostraron una mayor frecuencia de posición anterior no occipital de la cabeza del feto en el momento de la asignación al azar y una menor incidencia de un diagnóstico incorrecto de la posición occipital en comparación con las mujeres que se sometieron a la evaluación por EV. Se observó una tasa más alta de episiotomía en las mujeres que se sometieron a EV más ETV, en comparación con las del grupo de sólo EV.

Conclusiones Nuestro ensayo controlado aleatorizado, interrumpido prematuramente, no demostró ningún beneficio en cuanto a la reducción del riesgo de fracaso del parto instrumentado o de la morbilidad materna y fetal en mujeres que se someten a una evaluación ecográfica de la posición de la cabeza fetal antes del parto con ventosa.

真空吸引前超声确定枕后位的随机意大利试验（R.I.S.POS.T.A.）

目的：评估器械助产前通过超声确定胎头位置能否降低真空吸引失败的风险，改善分娩结局。

方法：真空吸引前超声确定枕后位的随机意大利试验（R.I.S.POS.T.A.）是对因头位难产需要通过真空吸引进行器械助产的足月（孕 37^{+0}~41^{+6} 周）单胎妊娠进行的一项随机对照试验，试验于 2014 年 4 月至 2017 年 6 月间进行，包括 13 家意大利妇产医院。将患者随机分为器械助产前通过单纯阴道检查（vaginal examination，VE）或 VE 联合经腹部超声（transabdominal sonography，TAS）评估胎头位置。主要结局为由于真空吸引失败的急诊剖宫产率。计划每组 653 例孕妇，比较 2 组间的主要结局。根据以下假设估计样本量，即 VE 组真空吸引分娩失败的风险为 5%，真空吸引前超声评估胎头位置会将风险降至 2%。

结果：期中分析时，试验由于没有获益而终止。在此期间，222 例孕妇被随机分组，221 例被纳入最终数据分析，其中 132 例（59.7%）在真空吸引前通过单纯 VE 评估胎头位置，89 例（40.3%）通过 VE 联合 TAS 进行评估。2 组间由于器械助产失败的急诊剖宫产率以及其他母亲和胎儿结局未见明显差异。与单纯 VE 评估的孕妇相比，VE 联合 TAS 评估的孕妇随机分组时胎头位置为非枕前位的发生率较高，枕后位误诊的发生率较低。VE 联合 TAS 组孕妇与单纯 VE 组孕妇比较，会阴侧切发生率较高。

结论：我们过早终止了这项随机对照试验，未能证实真空吸引前通过超声评估胎头位置，对降低器械助产失败或母亲及胎儿病残的风险有益。

