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Title: A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS

Article Type: Original Research

Section/Category: Obstetrics

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Abstract: Background:
Complicated operative vaginal deliveries are associated with high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a cesarean delivery is needed. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination combined with the clinical expertise of the obstetrician. Currently, there is no method for objectively quantifying the likelihood of successful delivery. Intrapartum ultrasound has been introduced in clinical practice to help predict the progression and final method of delivery.

Objective: The aim of this study was to compare predictive models for identifying complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.
Study design: We performed a prospective cohort study in nulliparous women at term with singleton pregnancies and full dilatation who underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (angle of progression, progression distance, and midline angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters (estimated fetal weight, head circumference and biparietal diameter) was also carried out. An operative vaginal delivery was classified as 'complicated' when one or more of the following complications occurred: ≥3 tractions needed; 3rd-4th degree perineal tear; severe bleeding during episiotomy repair (decrease of ≥2.5 g/dL in the hemoglobin level); or significant traumatic neonatal lesion (subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).
Results: We recruited 84 nulliparous patients, of whom 5 were excluded due to the difficulty of adequately evaluating the biparietal diameter

and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in the occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight (3,243±425g versus 3,565±330g;P=.001), biparietal diameter (93.2±2.1 versus 95.2±2.3 mm;p=0.001), head circumference (336±12 versus 348±6.4 mm;p=0.001), sex (female 62.5% versus 29.0%;p=0.010), newborn weight (3,258±472g versus 3,499±383g;p=0.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);P<0.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under the ROC curve between 0.863 and 0.876(95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on the angle of progression and head circumference; this model has an area under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243; p<0.0005).
Conclusion:The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

*Detailed Response to Reviewers

Manuscript Number; W18-1107R1
Entitled; A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS

REVIEWER 1, POINT 1
EDITOR/REVIEWER COMMENTS:

1) The abstract could be edited to eliminate unnecessary words. For example (3rd line) "its needed to complete fetal extraction" is not required. This is obvious from the sentence.
2) Line 7 - carrying out the delivery is not necessary
3) Last sentence of background needs to be corrected. Says intrapartum US has the potential to improve precision in the assessment and management of operative vaginal deliveries. I don't understand what "improve precision in the assessment and management of operative vaginal deliveries" means

The indicated changes have been included in the revision

An English revision has been carried out by native

Abstract:

Background: Complicated operative vaginal deliveries are associated with high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a cesarean delivery is needed~~to complete fetal extraction~~. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination combined with the clinical expertise of the obstetrician ~~carrying out the delivery~~. Currently, there is no method for objectively quantifying the likelihood of successful delivery. Intrapartum ultrasound has been ~~the potential to improve precision in the assessment and management of operative deliveries~~ introduced in clinical practice to help predict the progression and final method of delivery. **Objective:** The aim of this study was to compare predictive models for identifying complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women. **Study design:** We performed a prospective cohort study in nulliparous women at term with singleton pregnancies and full dilatation who underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing

obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (angle of progression, progression distance, and midline angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters (estimated fetal weight, head circumference and biparietal diameter) was also carried out. An operative vaginal delivery was classified as 'complicated' when one or more of the following complications occurred: ≥3 tractions needed; 3rd-4th degree perineal tear; ~~substantial~~ severe bleeding during episiotomy repair (decrease of ≥2.5 g/dL in the hemoglobin level); or ~~substantial~~ significant traumatic neonatal lesion (subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).**Results:** We recruited 84 nulliparous patients, of ~~which~~ whom 5 ~~cases~~ were excluded due to the difficulty of adequately evaluating the biparietal diameter and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in the occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*p*=.001), biparietal diameter(93.2±2.1 versus 95.2±2.3 mm;*p*=0.001), head circumference(336±12 versus 348±6.4 mm;*p*=0.001), sex(female 62.5% versus 29.0%;*p*=0.010), newborn weight(3,258±472g versus 3,499±383g;*p*=0.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<0.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under the ROC curve between 0.863 and 0.876(95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on the angle of progression and head circumference; this model ~~which~~ has an area under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243; p<0.0005). **Conclusion:**The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

4) From title to manuscript, the authors use "complicated vaginal deliveries" - what does complicated mean? Does complicated mean the vaginal delivery was complicated by operative vaginal delivery or are the authors attempting to predict complications in case of operative vaginal delivery? This should be clarified throughout the manuscript.

The indicated changes have been included in the revision.

We have made an exact description and following the international bibliography.

Cuerva MJ, Bamberg C, Tobias P, Gil M, De la Calle M, Bartha JL. Intrapartum ultrasound, a predictive method for complicated operative forceps delivery in non-occiput posterior deliveries. Ultrasound Obstet Gynecol. 2014;43:687–92.

Kasbaoui S, Severac F, Aıssi G, Gaudineau A, Lecointre L, Akladios C, Favre R, Langer B, Sananes N. Predicting the difficulty of operative vaginal delivery by ultrasound measurement of fetal head station. *Am J Obstet Gynecol* 2017; **216**:507.e1–9.

Martins I, Silva R, Mendes S, Barros JG, Clode N. Correlation betwenn the angle of progression and complicated operative vaginal delivery after prolonged second stage of labour. *Ultrasound Obstet Gynecol* 2016**; 48:** 35 (OC18.05).

An operative vaginal delivery was classified as 'complicated' when one or more of the following complications occurred: ≥3 tractions needed; 3rd-4th degree perineal tear; severe bleeding during episiotomy repair (decrease of ≥2.5 g/dL in the hemoglobin level); or significant traumatic neonatal lesion (subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries).

5) I was surprised to read that the authors refer to midforceps deliveries. The latter have been abandoned in the U.S. and are not an option given the high rate of birth trauma associated with this. Introduction, line 12.

The indicated changes have been included in the revision.

According to standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged~~and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries~~ (14,15).

6) The authors say that few studies have evaluated the usefulness of transperineal intrapartum US, but then they cite 7 references.

The indicated changes have been included in the revision.

~~To date, few~~ Some studies have evaluated the usefulness of intrapartum transperineal ultrasound

for this purpose (23-30).

7) Page 7, authors refer to Sens, spec, PPV for predicting vacuum extraction failure in nulliparous women. In general, everytime a percentage is shown, the numerator and denominator should be shown between parentheses. Same applies any time authors refer to PPV or NPV since it depends on prevalence of the condition. Same applies to line 6, page 7.
The indicated changes have been included in the revision.

We present the data through ROC curve how the authors do it

Bultez et al. (25) reported ~~that an angle of progression less than 145.5° has a sensitivity of 86.2%, specificity of 49% and positive predictive value of 24% for the prediction of vacuum extraction failure in nulliparous women~~ that when using the optimal cutoff value of 145.5º for the angle of progression to predict vacuum extraction failure in nulliparous women, the calculated area under the receiver operating characteristics (ROC) curve (AUC) was 0.67 (95% CI, 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI, 16-34%). According to Kahrs et al. (29), ~~that a head-perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of unsuccessful vaginal delivery and the need for caesarean delivery.~~ when using a head-perineum distance > 35 mm as the cutoff, the sensitivity in predicting cesarean delivery was 56% (95% CI, 33-77%), the false-positive rate was 16% (95% CI, 11-21%), and the AUC was 0.83 (95% CI, 0.77-0.89).

Our group (30) has found that using an angle of progression with pushing < 153º when identifying complicated operative vaginal deliveries provides a sensitivity of 86.9% and a false-positive rate of 5.9% (AUC of 86.9% (95% CI, 80-91)). In that study, a complication was defined as the occurrence of one or more of the following situations: three or more tractions needed; a third or fourth degree perineal tear; ~~significant~~ severe bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion.

8) Don't use the word "significant bleeding" because significant should be used when there is a p-value. Also, what is significant bleeding? Line 9
The indicated changes have been included in the revision.

In that study, a complication was defined as the occurrence of one or more of the following situations: three or more tractions needed; a third or fourth degree perineal tear; ~~significant~~ severe bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion.

9) Line 12 - begins with "to date" - not necessary
10) Line 13 - should say estimated fetal weight, not just fetal weight
The indicated changes have been included in the revision.

~~To date,~~However, previous studies assessing predictive models for complicated vaginal deliveries did not include fetal characteristics, such as estimated fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

11) Many comments made above have been made by reviewers of this paper, and the authors have asserted they have made changes throughout the paper, but this has not happened. The authors should thus review the paper carefully.
We have made an important revision of the whole text and an English native has evaluated it

12) Line 22 - "listed" is not required.
The indicated changes have been included in the revision.

This was a prospective observational study in nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation~~who required the use of vacuum or forceps to complete fetal extraction~~. The study was performed between May 2016 and June 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

13) Page 9, fetal weight should be ESTIMATED fetal weight
14) Clean version of manuscript has a dash on page 9, in front of the word "fetal" but this should be the clean version of the manuscript.
The indicated changes have been included in the revision.

15) Authors have submitted a nice power point presentation. However, this article needs to have figures showing what is the angle of progression. For those who are not familiar they should see this in the manuscript without having to go to slides. So figures should be included in the manuscript and in figure 9.
The indicated changes have been included in the revision.

We include figures 1-4.

16) Significant bleeding used again on page 10
The indicated changes have been included in the revision.

17) Please explain what is C of Harrell? Most readers would not be familiar with this. In the initial review of the manuscript the authors were asked to describe this, and they replied to the reviewers but didn't add this information to the manuscript. This is not adequate.
The indicated changes have been included in the revision.

.Harrell's C-statistic (a statistical index used to evaluate the performance of a regression model that analyzes the ability of the model to discriminate between the presence and absence of the event)

18) Authors were asked to refer to ESTIMATED fetal weight, however they have ignored this. For example, in principal findings (page 14), they refer to fetal weight. It is not possible to know fetal weight. The best one can do is estimated fetal weight. Same applies to page 15, line 7.
The indicated changes have been included in the revision.

19) Principal findings are supposed to be a short paragraph listing main points of the study in 1 paragraph. The authors go on to describe strengths, etc. This should be in the appropriate section of the discussion (strengths and limitations of the study).
The indicated changes have been included in the revision.

The main finding of our study is that a model based on angle of progression and head circumference can predict 87.5% of complicated operative vaginal deliveries. As this model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference), we report an easy to implement model that provides rapid prediction. Finally, this model can be implemented in any labor and delivery unit.

20) Have the authors revised the paper carefully?
We have made an important revision of the whole text and an English native has evaluated it

21) Concept of fetal station is not owned by ACOG as implied on page 15, line 23. Station was introduced into obstetrics even before acog existed probably.
The indicated changes have been included in the revision.

Knowing that digital examination presents a high rate of error (20-75%) in identifying ~~the level of fetal presentation (ACOG~~ the fetal station and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the delivery room to improve assessments of the progression and final method of delivery.

22) The term perineal skull distance is used, vs. head perineum distance. Why use a different term?
The indicated changes have been included in the revision.

In addition, Kasbaoui et al. (~~47~~, 43) carried out a prospective cohort study including 659 women, in which the head-perineum distance ~~(in this study referred to as the perineum–skull distance)~~ was measured prior to operative vaginal delivery.

23) Some constructions don't make sense - example, page 17 "their work has mainly associated different maternal and fetal parameters with sonographic parameters that have only been taken into account in recent studies."
24) What is a misclassification rate of 0.21 page 17?
The indicated changes have been included in the revision.

Several authors have expressed interest in predicting the type of vaginal operative delivery they will encounter and the risk for cesarean delivery (~~49-51,~~ 45-47). ~~Their work has mainly associated different maternal and fetal parameters with sonographic parameters not considered until recently.~~ Their efforts have been focused on predicting the outcome of labor, that is, vaginal versus cesarean delivery, by assessing the first stage of labor. Thus, Burker et al. ~~(50)~~ (46) presented a predictive model of cesarean risk based on five parameters (maternal age, BMI, height, fetal abdominal circumference, and fetal head circumference) that were evaluated in the first stage of labor and found excellent calibration and discriminative ability (Kolmogorov-Smirnov, D-statistic, 0.29; 95% CI, 0.28 to 0.30)~~and a misclassification rate of 0.21.~~

25) Line 14 - Eggebo should be in past tense "introduced intrapartum..." and applies to rest of sentence.
26) What does ARC stand for page 17? If this is area under the curve, what are the CI and p-value?
The indicated changes have been included in the revision.

With the same purpose of predicting the probability of vaginal delivery versus required cesarean delivery, Eggebø et al. (47) ~~(51)~~ introduced intrapartum transperineal ultrasound in his evaluation and presented a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal BMI), which were all evaluated during the first stage of labor, and obtained an AUC of 0.853% (95% CI, 0.678-1.000)~~ARC of 0.853.~~

27) Page 18, line 5, why do the authors say the model is easy to perform? This doesn't apply to the model, but to the measurement taken by US or the computation of the model.

The indicated changes have been included in the revision.

Nonetheless, unlike previously published models (25,46,47 ~~50, 51~~) for predicting complicated or difficult operative deliveries, our predictive model presents the following characteristics: 1. the model can be used in the delivery room; 2. the model provides a quick evaluation because only 2 ultrasound parameters are involved; and 3. the echographic measurements used in the model appear to be easy to perform.~~3. The model appears to be easy to perform.~~

28) Why did the authors not evaluate head to perineum distance? This parameter is well known. What do the authors mean with "This parameter should be designed for this purpose"?

The indicated changes have been included in the revision.

We consider the following to be limitations of our work: in our predictive model, we did not evaluate the head-perineum distance, an ultrasound parameter that appears to be very useful in predicting the difficulty of vaginal delivery, though our group has not achieved adequate reproducibility of this parameter (interobserver correlation of 0.53 (95% CI, 0.1-0.9) (36).~~ this parameter should be designed for this purpose.~~

29) Authors say they included a large number of patients as strengths and then in same section, they say the study was underpowered to study neonatal and maternal

morbidity and further studies are needs. This is contradictory.
The indicated changes have been included in the revision.

Lastly, we consider that including other types of forceps instead of only Kielland's forceps and using additional objective parameters to classify a delivery as a "complicated operative vaginal delivery", such as the need for maternal blood transfusion, traumatic fetal lesion or cup detachment, should be considered in future studies.~~Lastly, we believe that, as our study was underpowered to detect neonatal and maternal morbidity, further studies for the assessment of these parameters should be carried out.~~

30) The power point presentation needs to be reviewed by the authors. Hypothesis should be in a single slide. It is not appropriate to say "we ask ourselves would it be possible to develop...."
The indicated changes have been included in the revision.

HYPOTHESIS: Is it possible to develop a simple model to predict complicated operative vaginal deliveries (based on only a few parameters) that can be used in any labor ward?

31) Some slides are too crowded and they should be numbered.
The indicated changes have been included in the revision.

32) If the authors have used figures or images from other published papers, they must give credit.
All the figures are own

33) THe last slide is too complicated and must be improved. It is hard to read and interpret.
The indicated changes have been included in the revision.

In summary, the authors have improved the manuscript somewhat, but needs more work to comply with recommendations of reviewers and a careful review of language.
The indicated changes have been included in the revision.

A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS.

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Conflict of interest. The authors declare no conflicts of interest.

Any sources of financial support for the research

Sources of support for the study. This study was supported by the authors as practicing physicians in the hospital and faculty members of the University of Seville, Spain.

- **CONDENSATION, AJOG AT A GLANCE, SHORT VERSION OF TITLE**

- **CONDENSATION.**

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries.

- **AJOG AT A GLANCE**

- A. Why was this study conducted?

- Operative vaginal deliveries are associated with a high maternal and neonatal morbidity.
- We sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature

- B. What are the key findings?

A predictive model based on the angle of progression and head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?

- We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference).
- The predictive ability of the model is superior to other models previously reported (87% vs a range of 56-67%).
- This model can be implemented in any labor and delivery unit.

- **Short version of title.**

A simple predictive model for complicated operative vaginal deliveries.

Abstract:

Background:

Complicated operative vaginal deliveries are associated with high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a cesarean delivery is neededto complete fetal extraction. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination combined with the clinical expertise of the obstetrician carrying out the delivery. Currently, there is no method for objectively quantifying the likelihood of successful delivery. Intrapartum ultrasound has been the potential to improve precision in the assessment and management of operative deliveries introduced in clinical practice to help predict the progression and final method of delivery.

Objective: The aim of this study was to compare predictive models for identifying complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.

Study design: We performed a prospective cohort study in nulliparous women at term with singleton pregnancies and full dilatation who underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (angle of progression, progression distance, and midline angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters (estimated fetal weight, head circumference and biparietal diameter) was also carried out. An operative vaginal delivery was classified as 'complicated' when

one or more of the following complications occurred: ≥3 tractions needed; 3rd-4th degree perineal tear; ~~substantial~~ severe bleeding during episiotomy repair (decrease of ≥2.5 g/dL in the hemoglobin level); or ~~substantial~~ significant traumatic neonatal lesion (subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).

Results: We recruited 84 nulliparous patients, of ~~which~~ whom 5 ~~cases~~ were excluded due to the difficulty of adequately evaluating the biparietal diameter and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in the occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*p*=.001), biparietal diameter(93.2±2.1 versus 95.2±2.3 mm;*p*=0.001), head circumference(336±12 versus 348±6.4 mm;*p*=0.001), sex(female 62.5% versus 29.0%;*p*=0.010), newborn weight(3,258±472g versus 3,499±383g;*p*=0.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<0.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under the ROC curve between 0.863 and 0.876(95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on the angle of progression and head circumference; this model ~~which~~ has an area under the ROC curve of 0.876(95% CI 0.790-

0.963;p<0.0005) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243; p<0.0005).

Conclusion:

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Keywords: Labor; complication; operative vaginal delivery; vacuum extraction; cesarean delivery; biomarker; birth trauma; neonatal injury; perineal laceration; postpartum hemorrhage.

Introduction:

Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult operative vaginal deliveries and cesarean deliveries performed after failed operative vaginal delivery (8-13). Indeed, the reported incidence of postpartum intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, which is 5.7 times greater than the incidence associated with spontaneous vaginal birth (8).

According to standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged~~and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries~~ (14,15). Thus far, the decision to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on digital examination (14,15). However, digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to help predict the progression and final method of delivery [spontaneous vaginal delivery versus operative vaginal delivery ~~to complete fetal extraction~~ (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative vaginal deliveries and to identify cases with a high probability of requiring cesarean delivery due to failed operative vaginal delivery (22-30). ~~To date, few~~ Some studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).

Bultez et al. (25) reported ~~that an angle of progression less than 145.5° has a sensitivity of~~

~~86.2%, specificity of 49% and positive predictive value of 24% for the prediction of vacuum extraction failure in nulliparous women~~

that when using the optimal cutoff value of 145.5º for the angle of progression to predict vacuum extraction failure in nulliparous women, the calculated area under the receiver operating characteristics (ROC) curve (AUC) was 0.67 (95% CI, 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI, 16-34%).

According to Kahrs et al. (29), ~~that a head-perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of unsuccessful vaginal delivery and the need for caesarean delivery.~~ when using a head-perineum distance > 35 mm as the cutoff, the sensitivity in predicting cesarean delivery was 56% (95% CI, 33-77%), the false-positive rate was 16% (95% CI, 11-21%), and the AUC was 0.83 (95% CI, 0.77-0.89).

Our group (30) has found that using an angle of progression with pushing < 153º when identifying complicated operative vaginal deliveries provides a sensitivity of 86.9% and a false-positive rate of 5.9% (AUC of 86.9% (95% CI, 80-91)). In that study, a complication was defined as the occurrence of one or more of the following situations: three or more tractions needed; a third or fourth degree perineal tear; ~~significant~~ severe bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion.

~~To date,~~However, previous studies assessing predictive models for complicated vaginal deliveries did not include fetal characteristics, such as estimated fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

Taking this information into account, we sought to develop a model to predict complicated

operative vaginal deliveries (vacuum and forceps) in nulliparous women.

Materials and Methods:

This was a prospective observational study in nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation~~who required the use of vacuum or forceps to complete fetal extraction~~. The study was performed between May 2016 and June 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

The inclusion criteria were at term nulliparous women with uncomplicated pregnancies who required operative vaginal delivery (forceps or vacuum) ~~to complete fetal extraction~~. The indications for operative delivery were nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in cases of prolonged fetal bradycardia or late heart-rate decelerations with absent fetal heart-rate variability. Operative deliveries were performed by obstetricians with more than 4 years of experience in operative vaginal deliveries. All forceps deliveries were performed using Kielland's forceps, while for all vacuum-assisted deliveries, the same model of a rigid metal vacuum was used (Bird´s cup n° 5). The fetal head station was assessed by digital examination for low or outlet operative vaginal deliveries, as defined by the American College of Obstetricians and Gynecologists (14). Subsequently, a transabdominal ultrasound was performed to monitor the fetal head position. The managing obstetricians were different from those performing the intrapartum transperineal ultrasound and were blinded to the recorded sonographic data. The intrapartum transperineal ultrasound was performed exclusively by a group of five obstetricians (J.S., C.B., P.F., A.A., and J.G-M.)

who had demonstrated competency for this type of ultrasound examination (30).

Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide informed consent before being enrolled in the study. Once the patient provided signed informed consent, an intrapartum transperineal ultrasound was performed as described below. In the presence of one of the abovementioned indications for operative vaginal delivery, the managing obstetrician chose the instrument that was considered most appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while ~~fetal~~ biparietal diameter (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in a semirecumbent position, with an empty bladder and ruptured membranes. The probe was placed between the labia below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (**Table 1. Figures 2, 3 and 4)**: angle of progression (AoP) and progression distance (PD) evaluated on the longitudinal plane and midline angle (MLA) assessed on the transverse plane. Furthermore, the angle of progression, progression distance and midline angle were assessed at rest (AoP1, PD1, and MLA1, respectively) and concurrently with contraction and active pushing (AoP2, PD2, and MLA2, respectively). Angle of progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading

edge of the bony part of the fetal head. Progression distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline angle is defined as the angle between the anteroposterior axis of the pelvis and the fetal brain midline. Intrapartum transperineal ultrasound measurements were performed according to a previously published technique (20,36).

The following demographic and obstetric data were recorded: maternal age; gestational age at delivery; body mass index (BMI); obstetric history; duration of the first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight; and sex. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (37) and postpartum hemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial hemorrhage, clavicle fracture or peripheral and cranial nerve injuries) and admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, or risk of neonatal sepsis).

An operative delivery was classified as "complicated" when one or more of the following situations occurred (30,38): three or more tractions were required to complete fetal extraction (39); failed operative vaginal delivery; third or higher degree perineal tear according to Sultan's classification (37); major tear reported by the obstetrician; ~~significant~~ severe bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin

level of ≥2.5 g/dL following delivery (40); or a significant traumatic neonatal lesion (subdural and intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries) (30,38).

Statistical analyses.

We determined the mean and standard deviation for numeric variables and the percentage for qualitative variables. Comparisons of the numeric variables between complicated and uncomplicated operative vaginal deliveries were performed using Student's t-test. Comparison of qualitative variables between study groups was performed using a chi-square test. Individual predictive capabilities were evaluated using a ROC curve and the AUC. All statistical comparisons were performed using a two-sided test, and $p<0.005$ was considered statistically significant for all comparisons. Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY).

Evaluation of logistic regression models.

We generated different multivariate binary logistic regression models using nonautomated methods to predict complicated operative vaginal delivery, including intrapartum transperineal ultrasound parameters, estimated fetal weight, biparietal diameter and head circumference. These parameters were added progressively according to the simplicity of their evaluation and their predictive capacity for identifying complicated operative delivery. We implemented and compared 6 binary logistic regression models (**Table 2)**. We performed a goodness-of-fit test (-2 log likelihood) and the Hosmer and Lemeshow test for each model. Harrell's C-statistic (a statistical index used to evaluate the performance of a regression model that analyzes the ability of the model to discriminate between the

presence and absence of the event) was then determined for those models with an adequate fit to evaluate their discriminatory capacity (obtained as the AUC of the predicted probabilities given by the model), and the slope and calibration graphic were also obtained. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform shrinkage factor. Once the definite multivariate binary regression model was identified, we developed software to predict complicated operative vaginal deliveries (vacuum and forceps) with the aim of making the model applicable to clinical practice.

Results:

Study population.

We recruited 84 nulliparous patients, 5 of whom were excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. In total, we evaluated 79 nulliparous patients who required operative vaginal assistance ~~to complete the fetal extraction~~ (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).

Forty-eight cases were classified as 'uncomplicated operative vaginal deliveries' (28 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 were classified as 'complicated operative vaginal deliveries' (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Of the 31 cases of complicated operative vaginal deliveries, a third-degree perineal tear occurred in 6 cases (19.35%). In 7 cases (22.5%), severe bleeding was noted while repairing the episiotomy and was confirmed by a decrease of ≥ 2.5 g/dL in the maternal hemoglobin level. Three or more tractions were performed in 18 cases (58.06%).

Regarding maternal and neonatal demographic data, significant differences were noted between uncomplicated and complicated operative vaginal deliveries in estimated fetal weight, biparietal diameter, head circumference, gender and birth weight **(Table 3).**

The proportion of cases with the occiput posterior position was 13.6% (13 cases); the main indication for operative vaginal delivery was failure to progress in labor (60.75%, 48 cases), and 76.2% (74 cases) required mediolateral episiotomy. Four cases (12.9%) in the group of complicated operative vaginal deliveries required a cesarean delivery~~to complete fetal extraction.~~ One newborn required admission to the neonatal unit (mild respiratory distress).

Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal deliveries.

Significant differences were observed between the uncomplicated and complicated operative vaginal delivery cases regarding the angle of progression at rest, progression distance at rest, midline angle at rest, angle of progression with pushing and progression distance with pushing, with no statistically significant difference found in the midline angle with pushing **(Table 4)**. The complicated operative vaginal delivery group required a significantly higher number of tractions (4 tractions) than the uncomplicated operative vaginal delivery group (1 traction).

Predictive models of complicated deliveries.

We used several binary logistic regression models to predict and explain complicated operative vaginal deliveries. The Harrell's C-statistic values of the models oscillated between 0.863 and 0.876, as determined as the AUC of the predicted probabilities. The

binary logistic regression model that identified the variables "angle of progression with pushing" and "head circumference" as predictors of complicated operative vaginal delivery was chosen because these variables were included in the final multivariate analysis, which is shown in **Table 5**. Harrell's C-statistic, which was obtained from the AUC of the predicted probabilities by the model, was 0.876 (95% CI 0.790-0.963; p<0.0005), i.e., an initial discriminatory capacity >0.75, which is the same as the values obtained for the model adjusted by the Shrinkage uniform model, in which the C-statistic values were 0.876 (95% CI 0.790-0.963; p<0.0005) (**Figures 5 and 6)**. The calibration of the selected model was evaluated by calculating the calibration slope B, which was 0.984 (95% CI 0.726-1.243; p<0.0005). Pearson linear correlation coefficients were also calculated (0.906 and 0.849) (**Figures 7 and 8).**

Comment.

Principal findings.

The main finding of our study is that a model based on angle of progression and head circumference can predict 87.5% of complicated operative vaginal deliveries. As this model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference), we report an easy to implement model that provides rapid prediction. Finally, this model can be implemented in any labor and delivery unit.

~~the identification of a predictive model for complicated operative vaginal deliveries~~

~~(vacuum and forceps) in nulliparous women that includes both fetal (ESTIMATED fetal weight, biparietal diameter, head circumference) and intrapartum transperineal ultrasound (Angle of Progression, Progression Distance, Midline Angle) parameters and that is easy to use in the delivery room. This multivariate study, which follows principles of "interpretability" and "parsimony" (simplicity), has allowed us to identify a binary model based on progression angle with pushing and head circumference, which has been proven to predict complicated operative vaginal delivery (87.6%). We observed a significant association between this binary model and the need for three or more tractions to complete fetal extractions, failed attempts at operative vaginal delivery, third or higher degrees of perineal tears, significant bleeding during episiotomy or a significant traumatic neonatal lesion.~~

~~We propose that one of the strengths of this study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that is frequently found in most delivery units worldwide. Thus, this technique is generalizable. The Angle of Progression has proven to be easy to evaluate and is very useful for this purpose (30). The fetal weight and head circumference are risk factors for caesarean and operative deliveries (31-33); therefore, the evaluation of these parameters should be included in the assessment for the prediction of the success of instrumentation. Head circumference presents an adequate correlation with the difficulty of an instrumental delivery, the probability of failure and the need for caesarean delivery (31,33,41). The evaluation of head circumference in the delivery room seems to be feasible, although we believe that the reproducibility of its measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) should be assessed in future~~

~~studies.~~

~~However, fetal weight is more difficult to evaluate and presents a higher error rate (42-44).~~

~~We propose that new studies, which will include a larger number of cases, should be conducted to evaluate the usefulness of our binary model for the prediction of complicated operative vaginal deliveries.~~

Clinical Implications.

By applying the proposed predictive model, any obstetrician can easily predict the type of operative vaginal delivery that he or she will encounter in the delivery room, as a variation in head circumference can shift the situation from an uncomplicated operative vaginal delivery. In such cases, 1 or 2 tractions are needed (when an angle of progression with pushing of 146° is identified by intrapartum transperineal ultrasound) for a complicated operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an angle of progression with pushing of 115° is identified) **(Figure 9) (video 1).**

Research Implications.

Knowing that digital examination presents a high rate of error (20-75%) in identifying ~~the level of fetal presentation (ACOG~~ the fetal station and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the delivery room to improve assessments of the progression and final method of delivery. Accordingly, Kalache et al. (~~45,~~ 41) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, whereas Ramphulm et al. (~~46~~, 42) discussed the utility of intrapartum ultrasound for evaluating fetal head position before operative vaginal delivery.

Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13), especially when a cesarean delivery is required due to a failed operative vaginal delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to enable the prediction of the difficulty and possible complications of operative vaginal deliveries. ~~Bultez et al. (25) observed that an angle of progression <145° (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated with a higher rate of failed vacuum delivery~~Bultez et al. (25) reported that the optimal cutoff for angle of progression was 145.5° for predicting vacuum extraction failure in nulliparous women; the calculated AUC was 0.67 (95% CI, 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI, 16-34%). Kahrs et al. (29) found that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% (9/41) risk of an emergency cesarean delivery.

In addition, Kasbaoui et al. (~~47~~, 43) carried out a prospective cohort study including 659 women, in which the head-perineum distance ~~(in this study referred to as the perineum-skull distance)~~ was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (~~48~~, 44) found that a cutoff of 142° for the angle of progression was a

predictor for complicated operative vaginal deliveries. This is consistent with the results of our study (30), which identified an angle of progression with pushing <153.5° as a predictor of complicated operative deliveries (sensitivity of 86.9% and false-positive rate of 5.9% (AUC of 86.9% (95% CI, 80-91).

Several authors have expressed interest in predicting the type of vaginal operative delivery they will encounter and the risk for cesarean delivery (~~49-51,~~ 45-47). ~~Their work has mainly associated different maternal and fetal parameters with sonographic parameters not considered until recently.~~ Their efforts have been focused on predicting the outcome of labor, that is, vaginal versus cesarean delivery, by assessing the first stage of labor. Thus, Burker et al. ~~(50)~~ (46) presented a predictive model of cesarean risk based on five parameters (maternal age, BMI, height, fetal abdominal circumference, and fetal head circumference) that were evaluated in the first stage of labor and found excellent calibration and discriminative ability (Kolmogorov-Smirnov, D-statistic, 0.29; 95% CI, 0.28 to 0.30)~~and a misclassification rate of 0.21~~. With the same purpose of predicting the probability of vaginal delivery versus required cesarean delivery, Eggebø et al. (47) ~~(51)~~ introduced intrapartum transperineal ultrasound in his evaluation and presented a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal BMI), which were all evaluated during the first stage of labor, and obtained an AUC of 0.853% (95% CI, 0.678-1.000)~~ARC of 0.853.~~

We observed a significant difference in fetal sex between study groups (62.5% female fetuses in the uncomplicated operative vaginal deliveries versus 29% in the complicated operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head

circumference during the second stage of labor as the fetal head was already engaged in the maternal pelvis.

Nonetheless, unlike previously published models (25,46,47 ~~50, 51~~) for predicting complicated or difficult operative deliveries, our predictive model presents the following characteristics: 1. the model can be used in the delivery room; 2. the model provides a quick evaluation because only 2 ultrasound parameters are involved; and 3. the echographic measurements used in the model appear to be easy to perform.~~3. The model appears to be easy to perform.~~

Strengths and limitations.

This study has several strengths. First, our study includes a large series of deliveries at high risk of resulting in complicated operative vaginal deliveries (i.e., nulliparous women and occiput posterior position) (48-49)(~~52,53~~), the use of two types of instruments (vacuum and forceps), and an evaluation by intrapartum transperineal ultrasound. Moreover, the population included in this study is representative of pregnant women who require operative vaginal delivery to complete fetal extraction, including cases with the main indications for operative vaginal deliveries, such as nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Regarding the method, operative vaginal deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice.~~Intrapartum transperineal ultrasound was performed by experienced sonographers with specific training in pelvic floor and intrapartum transperineal ultrasound~~. ~~Lastly,~~We identified an adequate predictive model for complicated operative vaginal deliveries that we consider easy to apply in the delivery room because it involves only 2

variables, a fetal ultrasound parameter (head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proven to be useful in the identification of difficult or complicated operative vaginal deliveries (24-30).

Lastly, this study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that is frequently found in most delivery units worldwide. Therefore, this technique is generalizable. Angle of progression has proven to be easy to evaluate and is very useful for this purpose (30). Estimated fetal weight and head circumference are risk factors for cesarean and operative deliveries (31-33); accordingly, these parameters should be considered when assessing and predicting the success of instrumentation. Head circumference presents an adequate correlation with the difficulty of instrumental delivery, the probability of failure and the need for cesarean delivery (31,33,~~41~~, 50). However, estimated fetal weight is more difficult to evaluate and presents a higher error rate than does head circumference (51-53).~~42-44)~~

We consider the following to be limitations of our work: in our predictive model, we did not evaluate the head-perineum distance, an ultrasound parameter that appears to be very useful in predicting the difficulty of vaginal delivery, though our group has not achieved adequate reproducibility of this parameter (interobserver correlation of 0.53 (95% CI, 0.1-0.9) (36). ~~this parameter should be designed for this purpose.~~

~~We consider the omission of the head-perineum distance to be the main limitation of our work.~~ In addition, we believe that the reproducibility of head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proven. External validation of the predictive model should also be carried out. Lastly, we consider that including other types of forceps instead of only Kielland's

forceps and using additional objective parameters to classify a delivery as a "complicated operative vaginal delivery", such as the need for maternal blood transfusion, traumatic fetal lesion or cup detachment, should be considered in future studies.~~Lastly, we believe that, as our study was underpowered to detect neonatal and maternal morbidity, further studies for the assessment of these parameters should be carried out.~~

Conclusion.

The combination of angle of progression and head circumference can predict 87% of complicated operative vaginal deliveries, and such prediction can be performed in the delivery room.

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A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS.

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- **CONDENSATION, AJOG AT A GLANCE, SHORT VERSION OF TITLE**

- **CONDENSATION.**

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries.

- **AJOG AT A GLANCE**

- A. Why was this study conducted?

- Operative vaginal deliveries are associated with a high maternal and neonatal morbidity.
- We sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature

- B. What are the key findings?

A predictive model based on the angle of progression and head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?

- We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference).
- The predictive ability of the model is superior to other models previously reported (87% vs a range of 56-67%).
- This model can be implemented in any labor and delivery unit.

- **Short version of title.**

A simple predictive model for complicated operative vaginal deliveries.

Abstract:

Background:

Complicated operative vaginal deliveries are associated with high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a cesarean delivery is needed. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination combined with the clinical expertise of the obstetrician. Currently, there is no method for objectively quantifying the likelihood of successful delivery. Intrapartum ultrasound has been introduced in clinical practice to help predict the progression and final method of delivery.

Objective: The aim of this study was to compare predictive models for identifying complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.

Study design: We performed a prospective cohort study in nulliparous women at term with singleton pregnancies and full dilatation who underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (angle of progression, progression distance, and midline angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters (estimated fetal weight, head circumference and biparietal diameter) was also carried out. An operative vaginal delivery was classified as 'complicated' when one or more of the following complications occurred: ≥3 tractions needed; 3^{rd}-4^{th} degree perineal tear; severe bleeding during episiotomy repair (decrease of ≥2.5 g/dL in the

hemoglobin level); or significant traumatic neonatal lesion (subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).

Results: We recruited 84 nulliparous patients, of whom 5 were excluded due to the difficulty of adequately evaluating the biparietal diameter and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in the occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight (3,243±425g versus 3,565±330g;*P*=.001), biparietal diameter (93.2±2.1 versus 95.2±2.3 mm;*p*=0.001), head circumference (336±12 versus 348±6.4 mm;*p*=0.001), sex (female 62.5% versus 29.0%;*p*=0.010), newborn weight (3,258±472g versus 3,499±383g;*p*=0.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<0.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under the ROC curve between 0.863 and 0.876(95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on the angle of progression and head circumference; this model has an area under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243; p<0.0005).

Conclusion:

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Keywords: Labor; complication; operative vaginal delivery; vacuum extraction; cesarean delivery; biomarker; birth trauma; neonatal injury; perineal laceration; postpartum hemorrhage.

Introduction:

Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult operative vaginal deliveries and cesarean deliveries performed after failed operative vaginal delivery (8-13). Indeed, the reported incidence of postpartum intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, which is 5.7 times greater than the incidence associated with spontaneous vaginal birth (8).

According to standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged (14,15). Thus far, the decision to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on digital examination (14,15). However, digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to help predict the progression and final method of delivery [spontaneous vaginal delivery versus operative vaginal delivery (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative vaginal deliveries and to identify cases with a high probability of requiring cesarean delivery due to failed operative vaginal delivery (22-30). Some studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).

Bultez et al. (25) reported that when using the optimal cutoff value of 145.5º for the angle of progression to predict vacuum extraction failure in nulliparous women, the calculated area under the receiver operating characteristics (ROC) curve (AUC) was 0.67 (95% CI,

0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI, 16-34%).

According to Kahrs et al. (29) when using a head-perineum distance > 35 mm as the cutoff, the sensitivity in predicting cesarean delivery was 56% (95% CI, 33-77%), the false-positive rate was 16% (95% CI, 11-21%), and the AUC was 0.83 (95% CI, 0.77-0.89).

Our group (30) has found that using an angle of progression with pushing < 153º when identifying complicated operative vaginal deliveries provides a sensitivity of 86.9% and a false-positive rate of 5.9% (AUC of 86.9% (95% CI, 80-91)). In that study, a complication was defined as the occurrence of one or more of the following situations: three or more tractions needed; a third or fourth degree perineal tear; severe bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion.

However, previous studies assessing predictive models for complicated vaginal deliveries did not include fetal characteristics, such as estimated fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

Taking this information into account, we sought to develop a model to predict complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women.

Materials and Methods:

This was a prospective observational study in nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation. The study was performed between May 2016 and June 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

The inclusion criteria were at term nulliparous women with uncomplicated pregnancies who required operative vaginal delivery (forceps or vacuum). The indications for operative delivery were nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in cases of prolonged fetal bradycardia or late heart-rate decelerations with absent fetal heart-rate variability. Operative deliveries were performed by obstetricians with more than 4 years of experience in operative vaginal deliveries. All forceps deliveries were performed using Kielland's forceps, while for all vacuum-assisted deliveries, the same model of a rigid metal vacuum was used (Bird´s cup n° 5). The fetal head station was assessed by digital examination for low or outlet operative vaginal deliveries, as defined by the American College of Obstetricians and Gynecologists (14). Subsequently, a transabdominal ultrasound was performed to monitor the fetal head position. The managing obstetricians were different from those performing the intrapartum transperineal ultrasound and were blinded to the recorded sonographic data. The intrapartum transperineal ultrasound was performed exclusively by a group of five obstetricians (J.S., C.B., P.F., A.A., and J.G-M.) who had demonstrated competency for this type of ultrasound examination (30).

Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide informed consent before being enrolled in the study. Once the patient provided signed informed consent, an intrapartum transperineal ultrasound was performed as described below. In the presence of one of the abovementioned indications for operative vaginal delivery, the managing obstetrician chose the instrument that was considered most

appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while biparietal diameter (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in a semirecumbent position, with an empty bladder and ruptured membranes. The probe was placed between the labia below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (**Table 1. Figures 2, 3 and 4)**: angle of progression (AoP) and progression distance (PD) evaluated on the longitudinal plane and midline angle (MLA) assessed on the transverse plane. Furthermore, the angle of progression, progression distance and midline angle were assessed at rest (AoP1, PD1, and MLA1, respectively) and concurrently with contraction and active pushing (AoP2, PD2, and MLA2, respectively). Angle of progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading edge of the bony part of the fetal head. Progression distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline angle is defined as the angle between the anteroposterior axis of the pelvis and the fetal brain midline. Intrapartum transperineal ultrasound measurements were performed according to a previously published technique (20,36).

The following demographic and obstetric data were recorded: maternal age; gestational age at delivery; body mass index (BMI); obstetric history; duration of the first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight; and sex. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (37) and postpartum hemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial hemorrhage, clavicle fracture or peripheral and cranial nerve injuries) and admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, or risk of neonatal sepsis).

An operative delivery was classified as "complicated" when one or more of the following situations occurred (30,38): three or more tractions were required to complete fetal extraction (39); failed operative vaginal delivery; third or higher degree perineal tear according to Sultan's classification (37); major tear reported by the obstetrician; severe bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin level of ≥2.5 g/dL following delivery (40); or a significant traumatic neonatal lesion (subdural and intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries) (30,38).

Statistical analyses.

We determined the mean and standard deviation for numeric variables and the percentage for qualitative variables. Comparisons of the numeric variables between complicated and uncomplicated operative vaginal deliveries were performed using Student's t-test.

Comparison of qualitative variables between study groups was performed using a chi-square test. Individual predictive capabilities were evaluated using a ROC curve and the AUC. All statistical comparisons were performed using a two-sided test, and $p<0.005$ was considered statistically significant for all comparisons. Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY).

Evaluation of logistic regression models.

We generated different multivariate binary logistic regression models using nonautomated methods to predict complicated operative vaginal delivery, including intrapartum transperineal ultrasound parameters, estimated fetal weight, biparietal diameter and head circumference. These parameters were added progressively according to the simplicity of their evaluation and their predictive capacity for identifying complicated operative delivery. We implemented and compared 6 binary logistic regression models (**Table 2)**. We performed a goodness-of-fit test (-2 log likelihood) and the Hosmer and Lemeshow test for each model. Harrell's C-statistic (a statistical index used to evaluate the performance of a regression model that analyzes the ability of the model to discriminate between the presence and absence of the event) was then determined for those models with an adequate fit to evaluate their discriminatory capacity (obtained as the AUC of the predicted probabilities given by the model), and the slope and calibration graphic were also obtained. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform shrinkage factor. Once the definite multivariate binary regression model was identified, we developed software to

predict complicated operative vaginal deliveries (vacuum and forceps) with the aim of making the model applicable to clinical practice.

Results:

Study population.

We recruited 84 nulliparous patients, 5 of whom were excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. In total, we evaluated 79 nulliparous patients who required operative vaginal assistance (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).

Forty-eight cases were classified as 'uncomplicated operative vaginal deliveries' (28 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 were classified as 'complicated operative vaginal deliveries' (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Of the 31 cases of complicated operative vaginal deliveries, a third-degree perineal tear occurred in 6 cases (19.35%). In 7 cases (22.5%), severe bleeding was noted while repairing the episiotomy and was confirmed by a decrease of ≥ 2.5 g/dL in the maternal hemoglobin level. Three or more tractions were performed in 18 cases (58.06%).

Regarding maternal and neonatal demographic data, significant differences were noted between uncomplicated and complicated operative vaginal deliveries in estimated fetal weight, biparietal diameter, head circumference, gender and birth weight **(Table 3).**

The proportion of cases with the occiput posterior position was 13.6% (13 cases); the main indication for operative vaginal delivery was failure to progress in labor (60.75%, 48 cases), and 76.2% (74 cases) required mediolateral episiotomy. Four cases (12.9%) in the group of complicated operative vaginal deliveries required a cesarean delivery. One newborn required admission to the neonatal unit (mild respiratory distress).

Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal deliveries.

Significant differences were observed between the uncomplicated and complicated operative vaginal delivery cases regarding the angle of progression at rest, progression distance at rest, midline angle at rest, angle of progression with pushing and progression distance with pushing, with no statistically significant difference found in the midline angle with pushing **(Table 4)**. The complicated operative vaginal delivery group required a significantly higher number of tractions (4 tractions) than the uncomplicated operative vaginal delivery group (1 traction).

Predictive models of complicated deliveries.

We used several binary logistic regression models to predict and explain complicated operative vaginal deliveries. The Harrell's C-statistic values of the models oscillated between 0.863 and 0.876, as determined as the AUC of the predicted probabilities. The binary logistic regression model that identified the variables "angle of progression with pushing" and "head circumference" as predictors of complicated operative vaginal delivery was chosen because these variables were included in the final multivariate analysis, which is shown in **Table 5**. Harrell's C-statistic, which was obtained from the AUC of the predicted probabilities by the model, was 0.876 (95% CI 0.790-0.963; $p<0.0005$), i.e., an initial discriminatory capacity >0.75, which is the same as the values obtained for the model adjusted by the Shrinkage uniform model, in which the C-statistic values were 0.876 (95% CI 0.790-0.963; $p<0.0005$) (**Figures 5 and 6)**. The calibration of the selected model was evaluated by calculating the calibration slope B, which was 0.984 (95% CI 0.726-

1.243; p<0.0005). Pearson linear correlation coefficients were also calculated (0.906 and 0.849) (**Figures 7 and 8).**

Comment.

Principal findings.

The main finding of our study is that a model based on angle of progression and head circumference can predict 87.5% of complicated operative vaginal deliveries. As this model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference), we report an easy to implement model that provides rapid prediction. Finally, this model can be implemented in any labor and delivery unit.

Clinical Implications.

By applying the proposed predictive model, any obstetrician can easily predict the type of operative vaginal delivery that he or she will encounter in the delivery room, as a variation in head circumference can shift the situation from an uncomplicated operative vaginal delivery. In such cases, 1 or 2 tractions are needed (when an angle of progression with pushing of 146° is identified by intrapartum transperineal ultrasound) for a complicated operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an angle of progression with pushing of 115° is identified) **(Figure 9) (video 1).**

Research Implications.

Knowing that digital examination presents a high rate of error (20-75%) in identifying the

fetal station and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the delivery room to improve assessments of the progression and final method of delivery. Accordingly, Kalache et al. (41) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, whereas Ramphulm et al. (42) discussed the utility of intrapartum ultrasound for evaluating fetal head position before operative vaginal delivery.

Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13), especially when a cesarean delivery is required due to a failed operative vaginal delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to enable the prediction of the difficulty and possible complications of operative vaginal deliveries. Bultez et al. (25) reported that the optimal cutoff for angle of progression was 145.5° for predicting vacuum extraction failure in nulliparous women; the calculated AUC was 0.67 (95% CI, 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI, 16-34%). Kahrs et al. (29) found that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% (9/41) risk of an emergency cesarean delivery.

In addition, Kasbaoui et al. (43) carried out a prospective cohort study including 659 women, in which the head-perineum distance was measured prior to operative vaginal

delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (44) found that a cutoff of 142° for the angle of progression was a predictor for complicated operative vaginal deliveries. This is consistent with the results of our study (30), which identified an angle of progression with pushing <153.5° as a predictor of complicated operative deliveries (sensitivity of 86.9% and false-positive rate of 5.9% (AUC of 86.9% (95% CI, 80-91).

Several authors have expressed interest in predicting the type of vaginal operative delivery they will encounter and the risk for cesarean delivery (45-47). Their efforts have been focused on predicting the outcome of labor, that is, vaginal versus cesarean delivery, by assessing the first stage of labor. Thus, Burker et al. (46) presented a predictive model of cesarean risk based on five parameters (maternal age, BMI, height, fetal abdominal circumference, and fetal head circumference) that were evaluated in the first stage of labor and found excellent calibration and discriminative ability (Kolmogorov-Smirnov, D-statistic, 0.29; 95% CI, 0.28 to 0.30). With the same purpose of predicting the probability of vaginal delivery versus required cesarean delivery, Eggebø et al. (47) introduced intrapartum transperineal ultrasound in his evaluation and presented a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal BMI), which were all evaluated during the first stage of labor, and obtained an AUC of 0.853% (95% CI, 0.678-1.000).

We observed a significant difference in fetal sex between study groups (62.5% female fetuses in the uncomplicated operative vaginal deliveries versus 29% in the complicated

operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head circumference during the second stage of labor as the fetal head was already engaged in the maternal pelvis.

Nonetheless, unlike previously published models (25,46,47) for predicting complicated or difficult operative deliveries, our predictive model presents the following characteristics: 1. the model can be used in the delivery room; 2. the model provides a quick evaluation because only 2 ultrasound parameters are involved; and 3. the echographic measurements used in the model appear to be easy to perform

Strengths and limitations.

This study has several strengths. First, our study includes a large series of deliveries at high risk of resulting in complicated operative vaginal deliveries (i.e., nulliparous women and occiput posterior position) (48-49), the use of two types of instruments (vacuum and forceps), and an evaluation by intrapartum transperineal ultrasound. Moreover, the population included in this study is representative of pregnant women who require operative vaginal delivery to complete fetal extraction, including cases with the main indications for operative vaginal deliveries, such as nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Regarding the method, operative vaginal deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice. We identified an adequate predictive model for complicated operative vaginal deliveries that we consider easy to apply in the delivery room because it involves only 2 variables, a fetal ultrasound parameter (head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proven

to be useful in the identification of difficult or complicated operative vaginal deliveries (24-30).

Lastly, this study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that is frequently found in most delivery units worldwide. Therefore, this technique is generalizable. Angle of progression has proven to be easy to evaluate and is very useful for this purpose (30). Estimated fetal weight and head circumference are risk factors for cesarean and operative deliveries (31-33); accordingly, these parameters should be considered when assessing and predicting the success of instrumentation. Head circumference presents an adequate correlation with the difficulty of instrumental delivery, the probability of failure and the need for cesarean delivery (31,33, 50). However, estimated fetal weight is more difficult to evaluate and presents a higher error rate than does head circumference (51-53).

We consider the following to be limitations of our work: in our predictive model, we did not evaluate the head-perineum distance, an ultrasound parameter that appears to be very useful in predicting the difficulty of vaginal delivery, though our group has not achieved adequate reproducibility of this parameter (interobserver correlation of 0.53 (95% CI, 0.1-0.9) (36). In addition, we believe that the reproducibility of head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proven. External validation of the predictive model should also be carried out. Lastly, we consider that including other types of forceps instead of only Kielland's forceps and using additional objective parameters to classify a delivery as a "complicated operative vaginal delivery", such as the need for maternal blood transfusion, traumatic fetal lesion or cup detachment, should be considered in future studies.

Conclusion.

The combination of angle of progression and head circumference can predict 87% of complicated operative vaginal deliveries, and such prediction can be performed in the delivery room.

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Table(s)

Intrapartum Transperineal Ultrasound	
Longitudinal plane	
Angle of progression at rest	**AoP 1 (º)**
Angle of progression with active pushing	**AoP 2(º)**
Progression distance at rest	**PD 1 (mm)**
Progression distance with active pushing	**PD 2 (mm)**
Transverse plane	
Midline angle at rest	**MLA 1 (º)**
Midline with active pushing	**MLA 2 (º)**

Table 1. Ecographic parameters evaluated in the Intrapartum Transperineal ultrasound

Table(s)

Model	Parameters included in the predictor model
Model 1	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression (rest)
Model 2	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression + Midline-Angle (rest)
Model 3	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression + Midline-Angle + Progression Distance (rest)
Model 4	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression + Midline-Angle + Progression Distance (rest) + Angle of Progression (push)
Model 5	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression + Midline-Angle + Progression Distance (rest) + Angle of Progression + Progression Distance (push).
Model 6	Estimated Fetal Weight + Biparietal Diameter + Fetal Head Circumference + Angle of Progression + Midline-Angle + Progression Distance (rest) + Angle of Progression + Progression Distance + Midline-Angle (push).

Table 2. Predictive models evaluated by binary logistic regression

Table(s)

	Complete study population (n=79)		
	Uncomplicated operative delivery (n= 48)	**Complicated operative delivery (n=31)**	**P**
Maternal age (years)	28.6±5.8	30.4±4.3	0.148
Maternal BMI(Kg/m^2)	23.3± 2.1	23.8± 1.9	0.620
Gestational pathology	7 (14.6%)	3 (9.7%)	0.769
Gestational age at delivery (weeks)	39.4±1.3	39.7±1.3	0.930
Cause of operative delivery **Failure to Progress in Labor** **Maternal Exhaustion** **Non-reassuring fetal heart rate**	 36 (75%) 4 (8.3%) 8 (16.6%)	 22 (70.9%) 3 (9.6%) 6 (19.3%)	0.585
Estimated Fetal Weight (g)	3,243±425	3,565±330	0.001
Head Circumference (mm)	336±12	348±6.4	0.001
Fetal Biparietal Diameter (mm)	93.2±2.1	95.2±2.3	0.001
Duration of 1st stage of labor (minutes)	398±142	402±154	0.868
Duration of 2nd stage of labor (minutes)	136±54	155±54	0.162
Mediolateral episiotomy	44 (93.7%)	30 (96.7%)	0.655
Occiput posterior position	5 (10.4%)	8 (25.8%)	0.085
Forceps Operative Delivery	20 (62.5%)	12 (37.5%)	0.979
Caesarean section after failed attempt at vaginal delivery	0 (0%)	4 (12.9%)	0.108
Gender (females)	30 (62.5%)	9 (29.0%)	0.010
Birth Weight(g)	3,258±472	3,499±383	0.027
APGAR 1 minute	8.9±1.0	8.7±0.7	0.165
APGAR 5 minutes	9.9±0.8	9.8±0.8	0.118

Umbilical cord artery pH	7.27±0.06	7.24±0.07	0.121

Table 3. Maternal and neonatal characteristics in 79 nulliparous requiring operative delivery to complete fetal extraction.

Table(s)

Intrapartum Transperineal Ultrasound	**Uncomplicated operative delivery (n= 48)**	**Complicated operative delivery (n=31)**	**P**
AoP 1 (º)	138.12±13.4	119.1±16.8	P<0.0005
AoP 2(º)	149.5±15.2	126.2±13.3	P<0.0005
PD 1 (mm)	45.0±11.5	36.4±13.7	P=0.004
PD 2 (mm)	52.2±14.0	41.7±13.3	P=0.002
MLA 1 (º)	37.8±28.9	49.0±23.1	P=0.036
MLA 2 (º)	37.3±31.1	40.5±19.5	P=0.537
Number of instrumental tractions (median and IQR)	1 (1-2)	4 (3-5)	P<0.0005

Table 4. Intrapartum Transperineal ultrasound data from 79 nulliparous requiring operative delivery to complete fetal extraction. AoP1. Angle of progression at rest. AoP2. Angle of progression with active pushing. PD1. Progression distance at rest. PD2. Progression distance with active pushing. MLA 1. Midline angle at rest. MLA 2. Midline with active pushing. IQR. Interquartile range

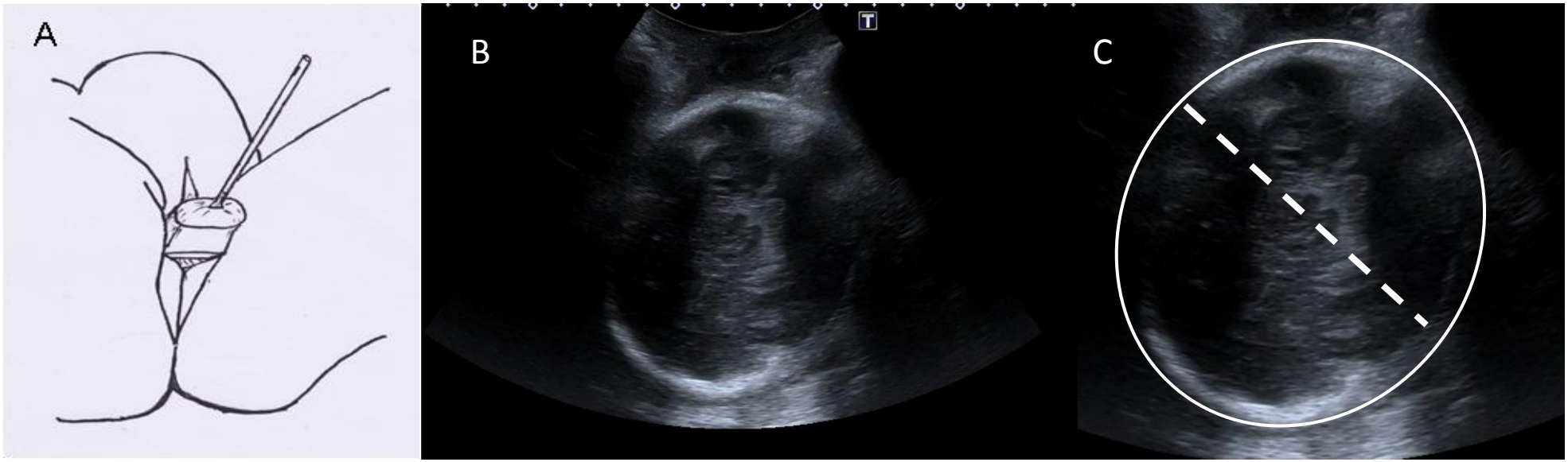
Table(s)

Tabla 5. Final logistic regression model obtained with the angle of progression with pushing and Head Circumference.

Variables in the equation		IC 95%	
	Exp (B)	lower	Upper
Angle of Progression(AoP) with pushing (per 5°)	0.698	0.568	0.855
Head Circumference (per 5 mm.)	1.665	1.111	2.484
Constant	-25.376		
Prob.COD= Probability for the identification of complicated operative deliveries Prob.= $1/\ 1+e^{(-(-25.376-0.36\ \text{Angle of Progression} + 0.508\ \text{Head Circumference})}$			

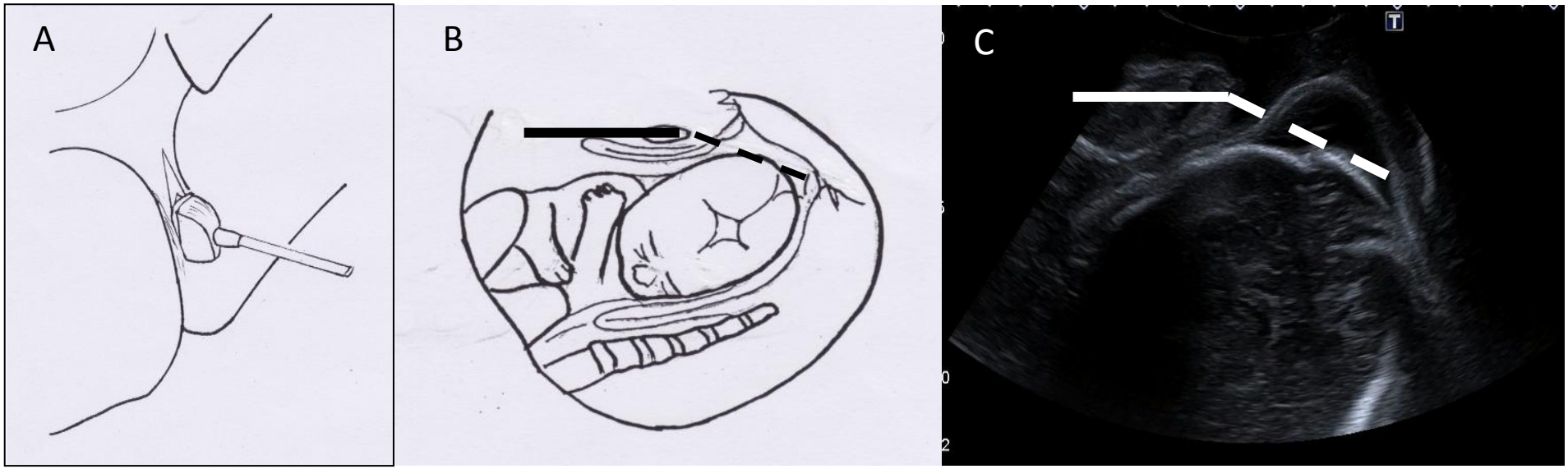
Figure(s)

Figure 1. A and B. Acquisition of fetal head image using transperineal ultrasound. C. Evaluation of biparietal diameter and fetal head circumference (using the transthalamic plane of the fetal head).



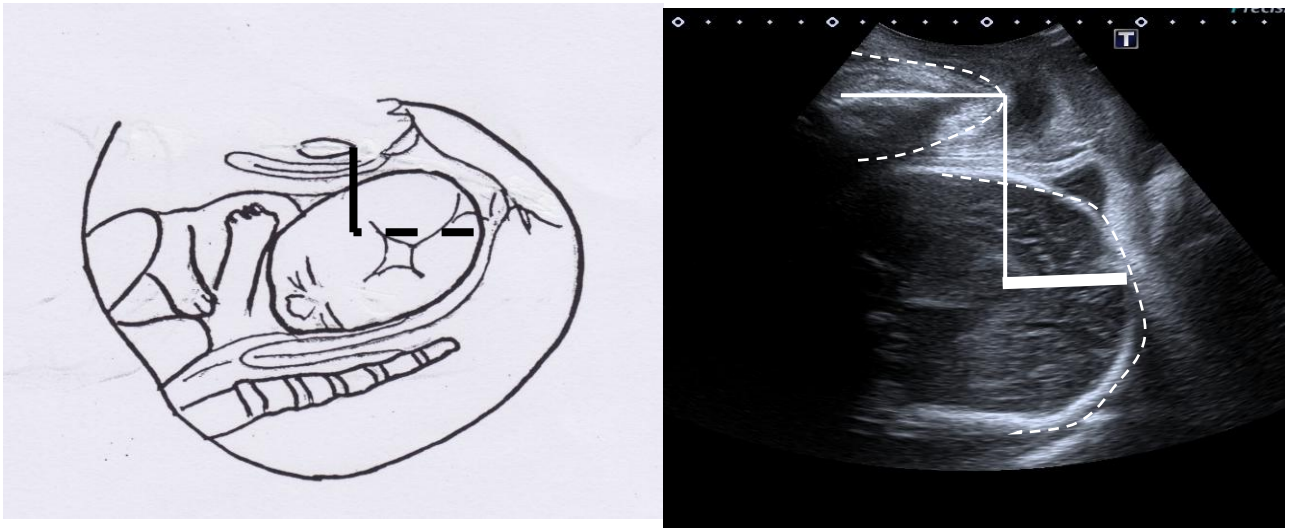
Figure(s)

Figure 2. Transperineal longitudinal plane at rest (A)..Angle of Progression (AoP) (B and C).



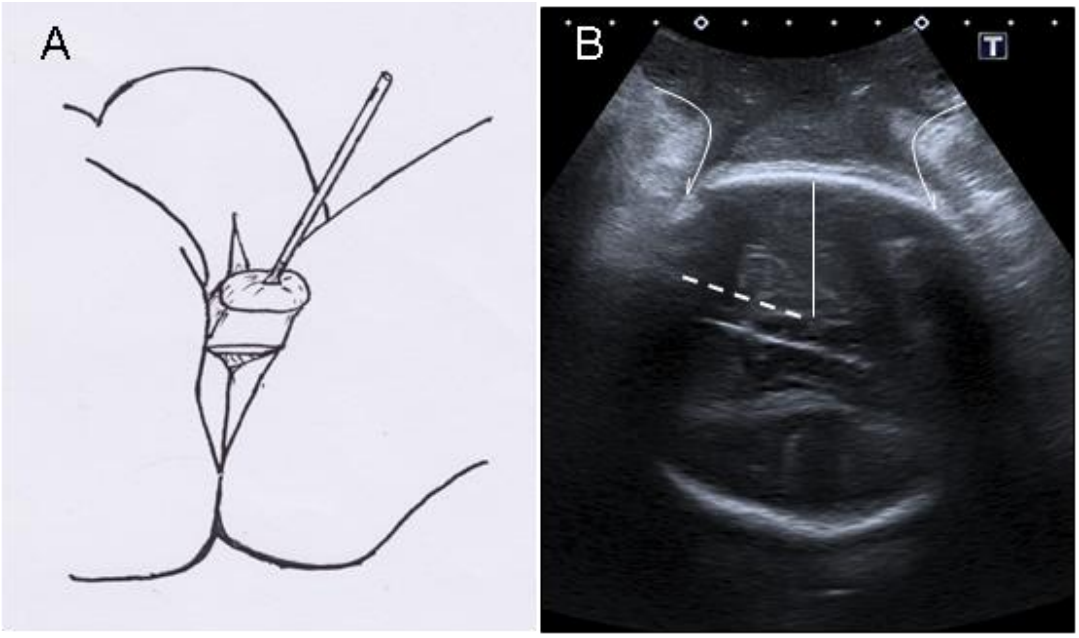
Figure(s)

Figure 3. Transperineal longitudinal plane (A).. Progression Distance (PD) (B)



Figure(s)

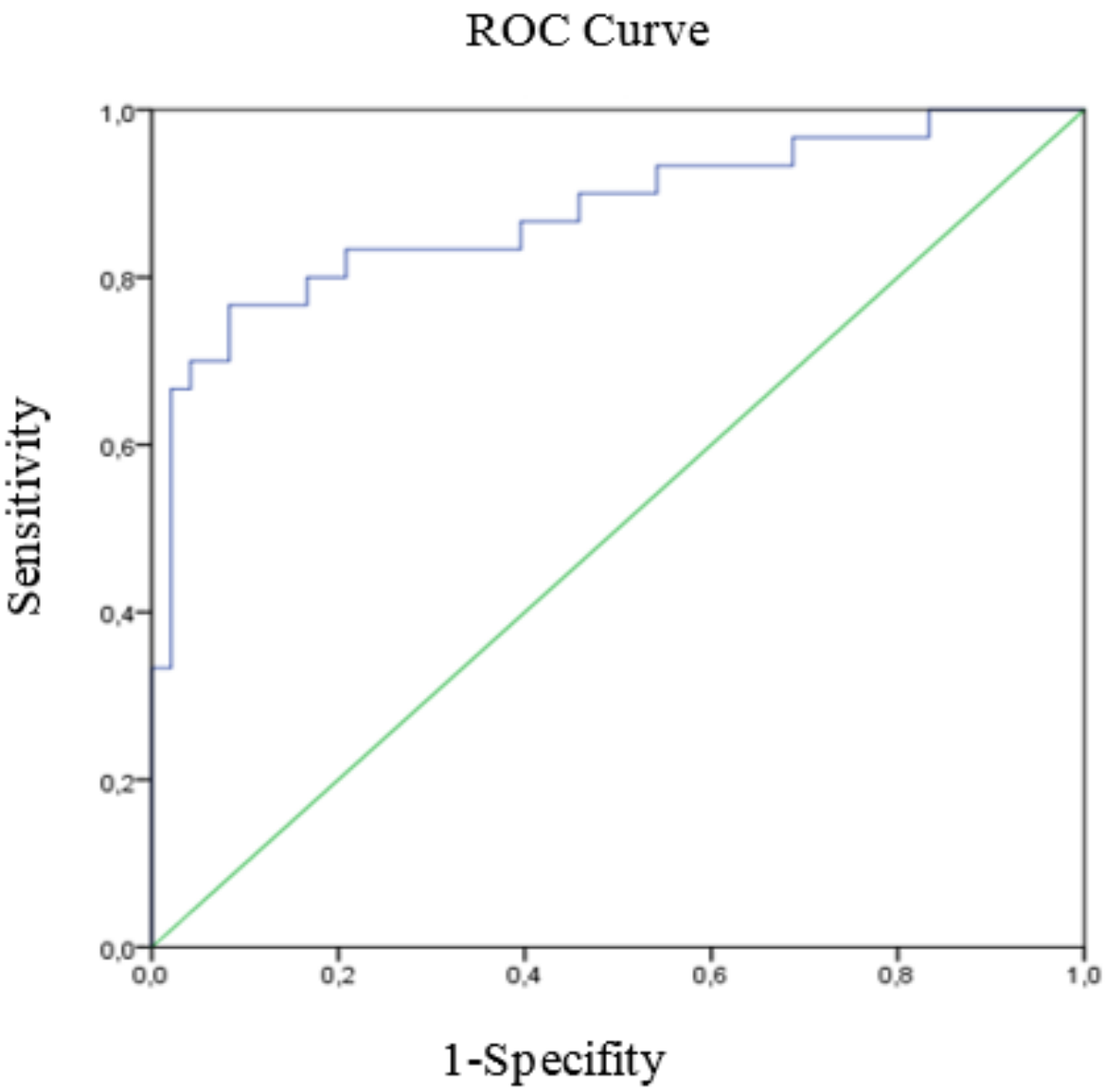
Figure 4. Transperineal axial plane at rest (A). Midline Angle (MLA) (B)



Figure(s)

Figure 5. ROC curve for logistic regression model obtained from the association between Angle of Progression with pushing and Head Circumference

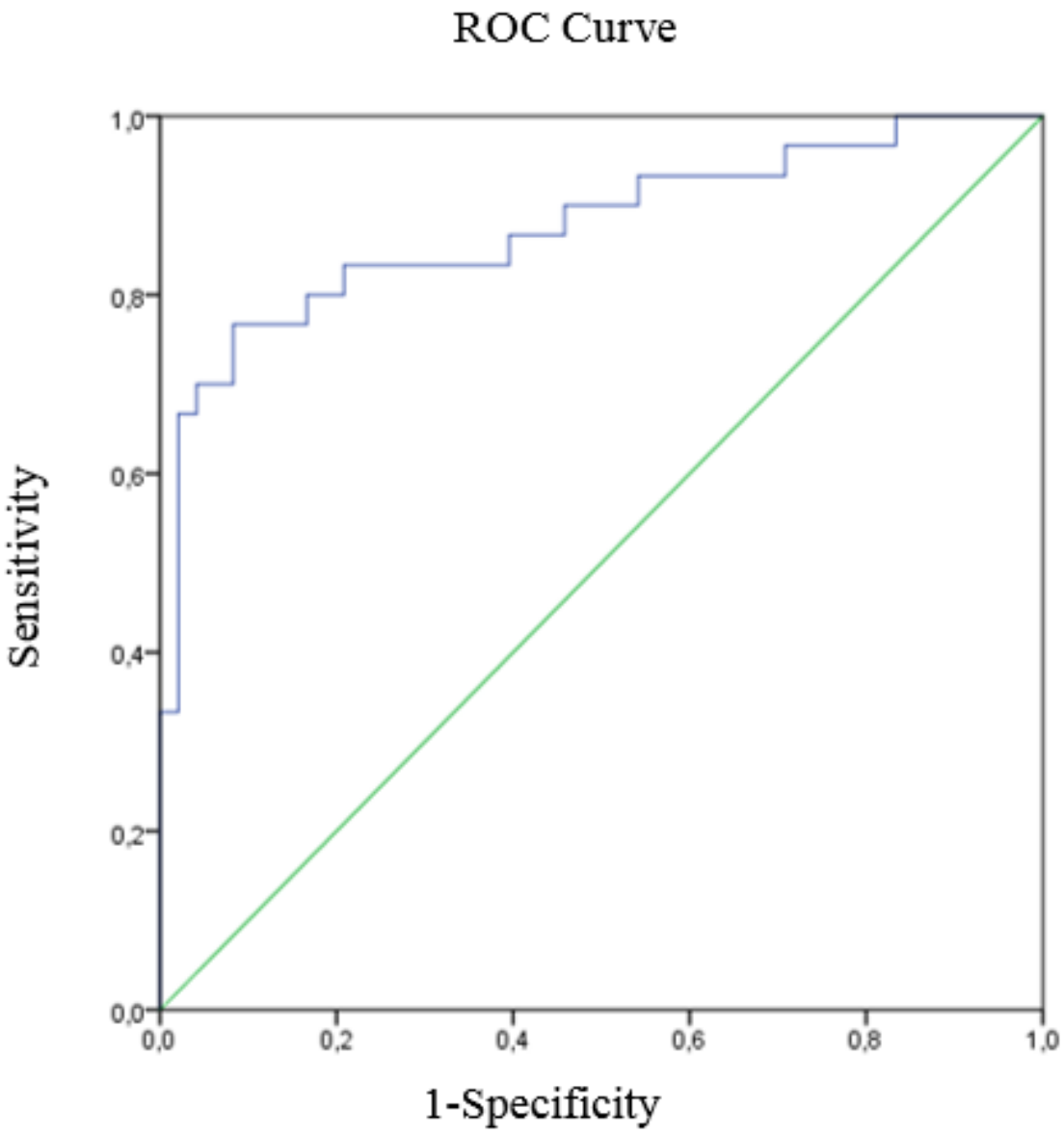
Area under ROC curve = 0.876 (95% CI 0.790-0.963; p<0.0005)



Figure(s)

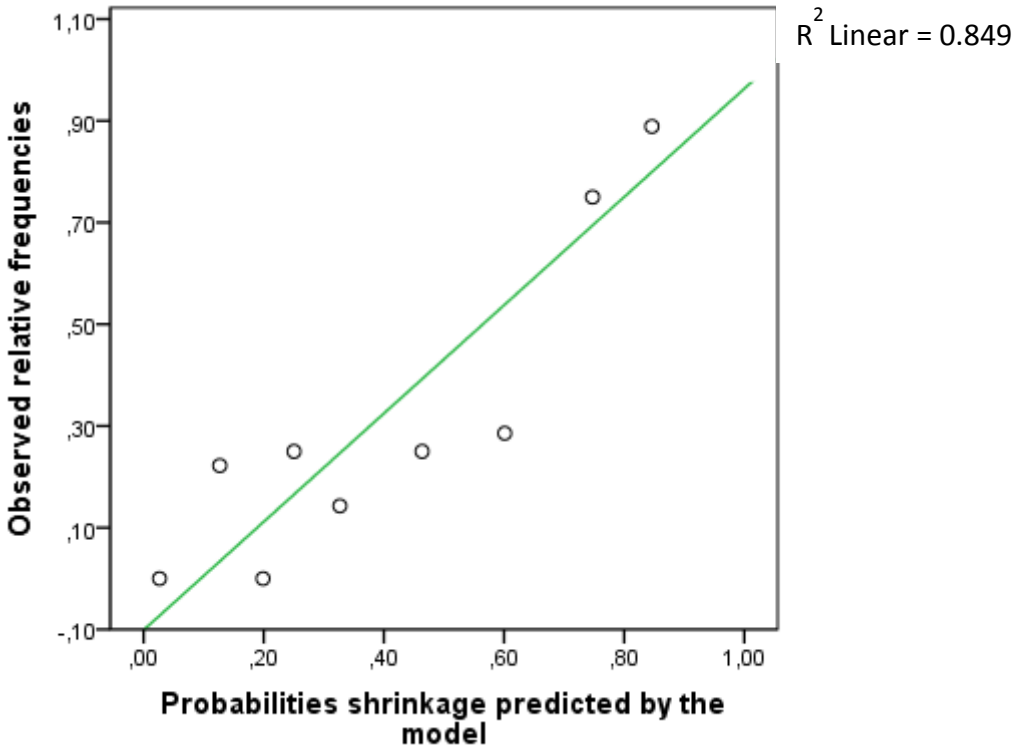
Figure 6. ROC curve for logistic regression model adjusted by Shrinkage method obtained from the association between Angle of Progression with pushing and Head Circumference

Area under ROC curve = 0.876 (95% CI 0.790-0.963; p<0.0005



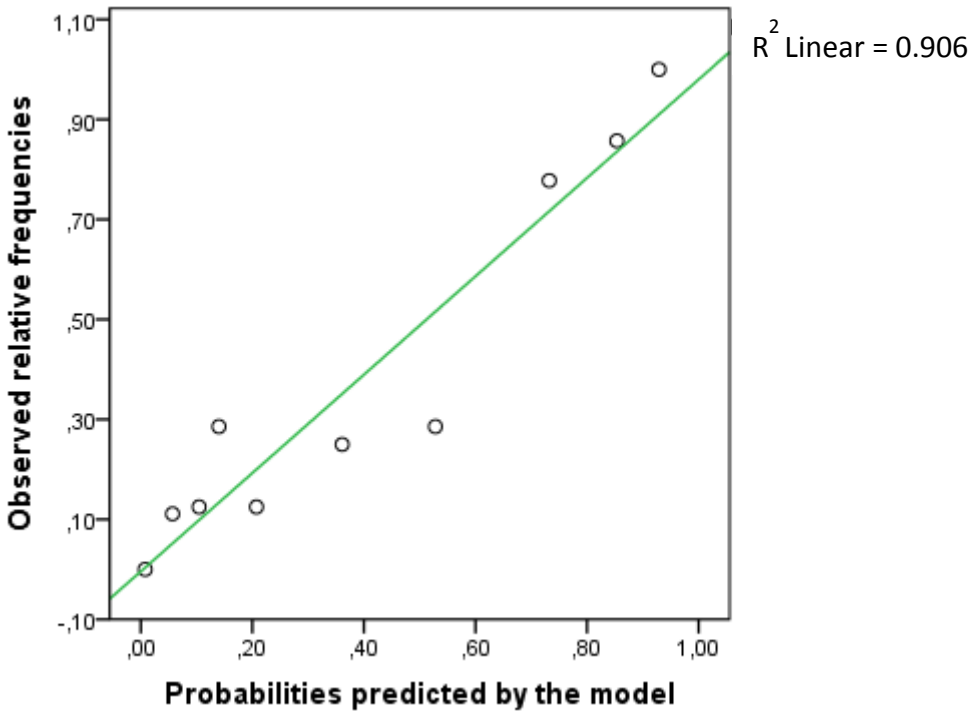
Figure(s)

Figure 7. Calibration graphic of original logistic regression model adjusted by Shrinkage method obtained from the association between Angle of Progression with pushing and Head Circumference



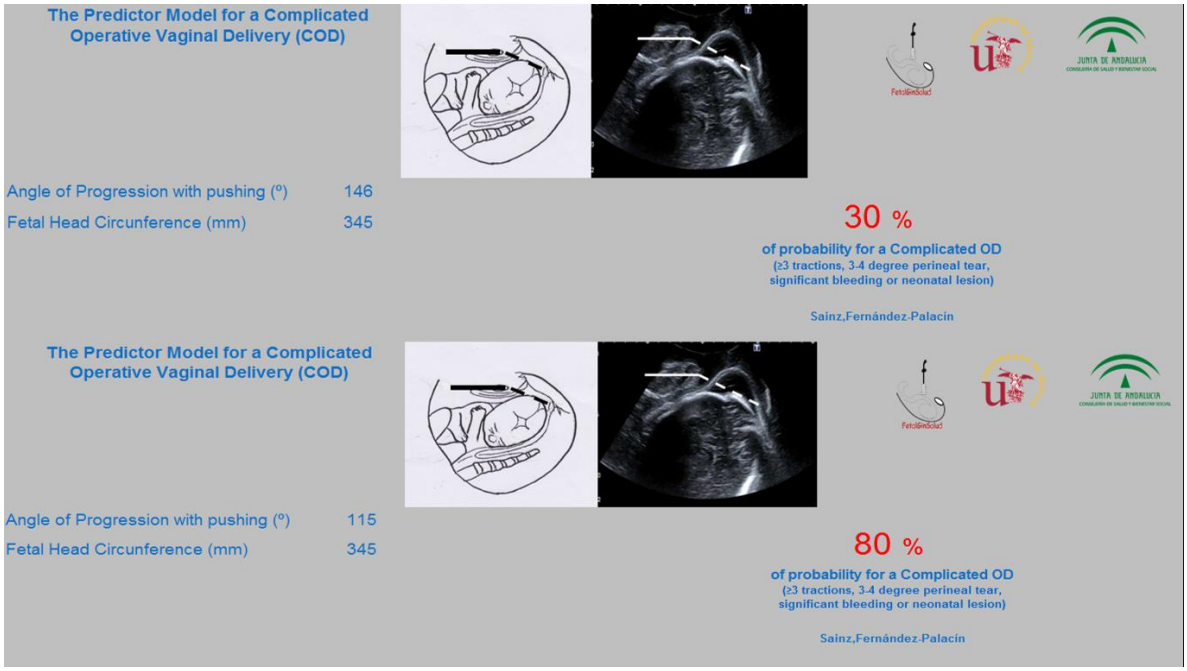
Figure(s)

Figure 8. Calibration graphic of original logistic regression model obtained from the association between Angle of Progression with pushing and Head Circumference



Figure(s)

Figure 9. Example of using the binary model based on angle of progression with pushing and head circumference as predictor for a complicated operative vaginal delivery.



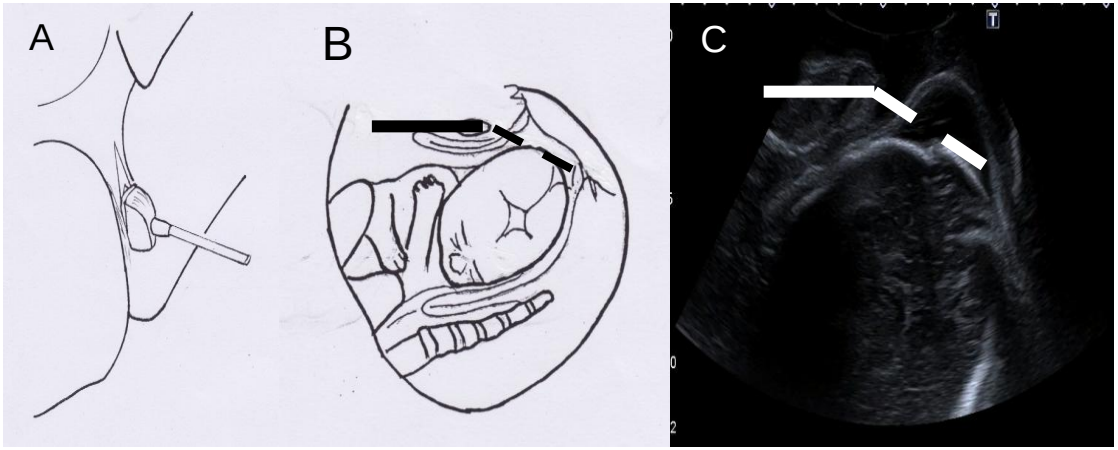
SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS

JA Sainz, JA García-Mejido, A Aquise, C Borrero, MJ Bonomi, A Fernández-Palacín

American Journal of Obstetrics & Gynecology

- The digital examination presents a high rate of error (20-75%) for the identification of the level of the fetal presentation (ACOG fetal station) and its degree of engagement (Dupuis O, Am J Obstet Gynecol 2005)

Figure 1. Transperineal longitudinal plane (A).. Angle of Progression (AoP) (B, C)



- Intrapartum transperineal ultrasound has been introduced in clinical practice to help predict the progression and finalization of the delivery (spontaneous versus operative vaginal delivery) (Ghi T, Am J Obstet Gynecol 2016)

- Operative vaginal deliveries are associated with a high maternal and neonatal morbidity. (Gimovsky AC, Am J Obstet Gynecol 2016).

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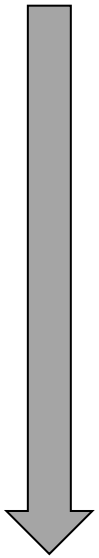
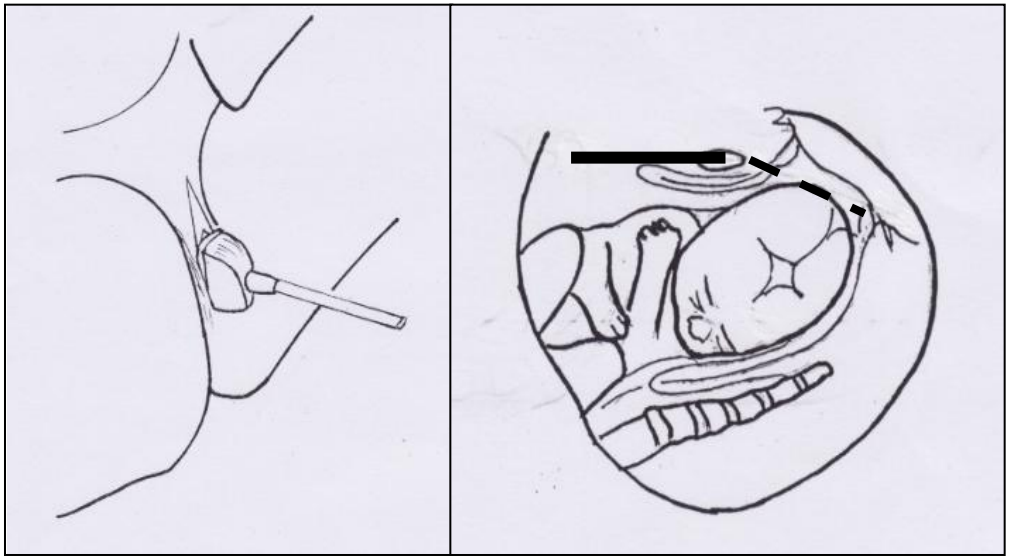




- Intrapartum Transperineal Ultrasound is useful to predict cases of complicated operative vaginal deliveries and to identify cases with high probability of requiring caesarean delivery due to failure of operative vaginal delivery.

Intrapartum Transperineal Ultrasound

Figure 1. Transperineal longitudinal plane (A). Angle of Progression (B, C)

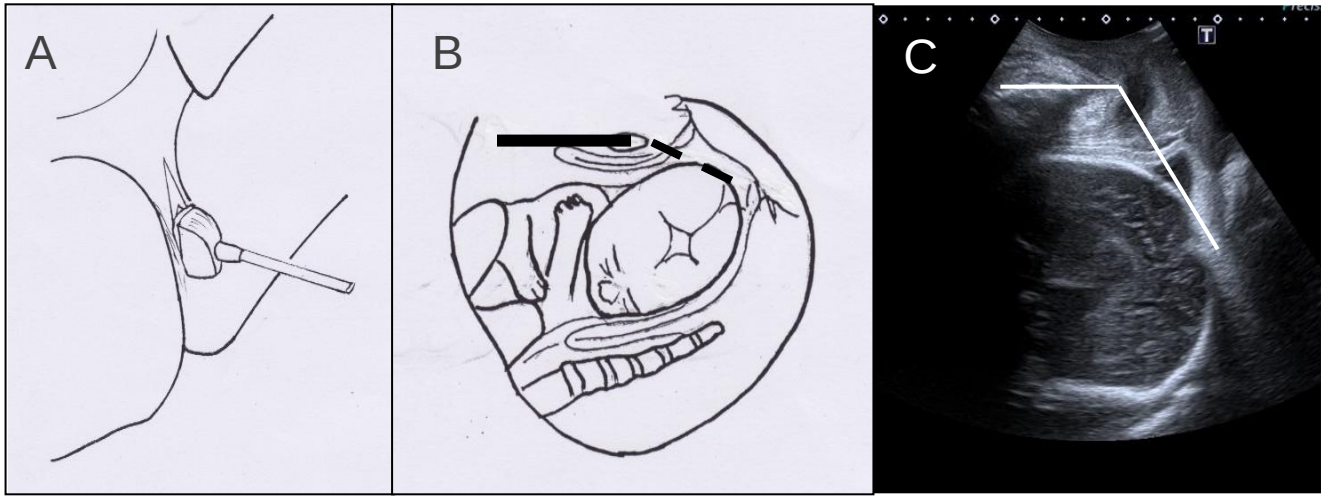
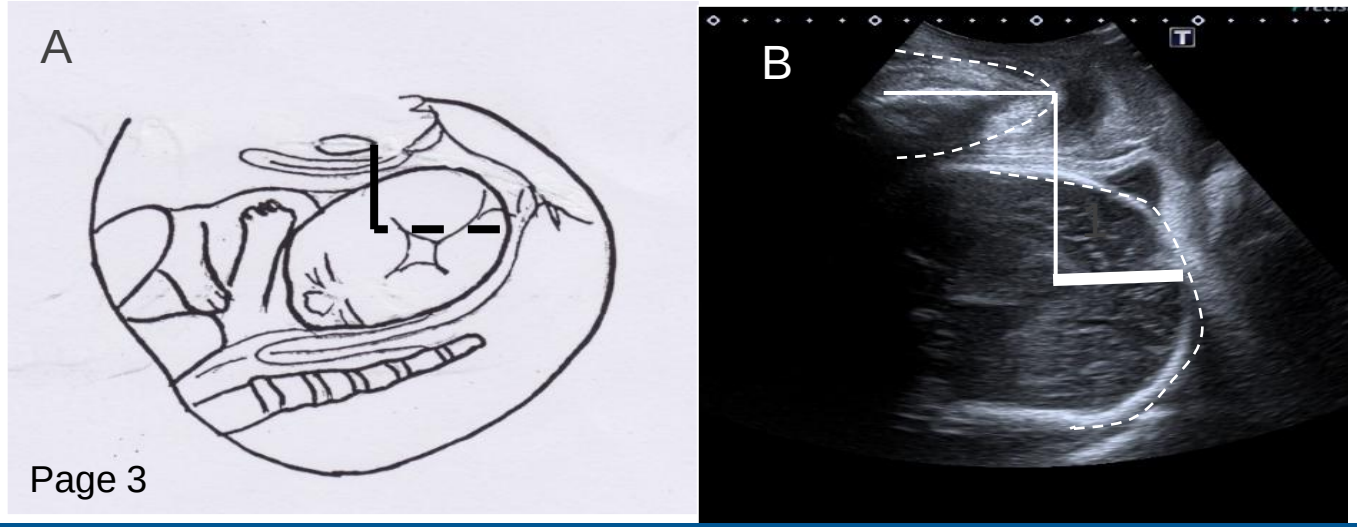


Figure 2. Transperineal longitudinal plane (A). Progression Distance (B)



Intrapartum Transperineal Ultrasound

Figure 3. Transperineal axial plane at rest (A). Midline Angle (MLA) (B)

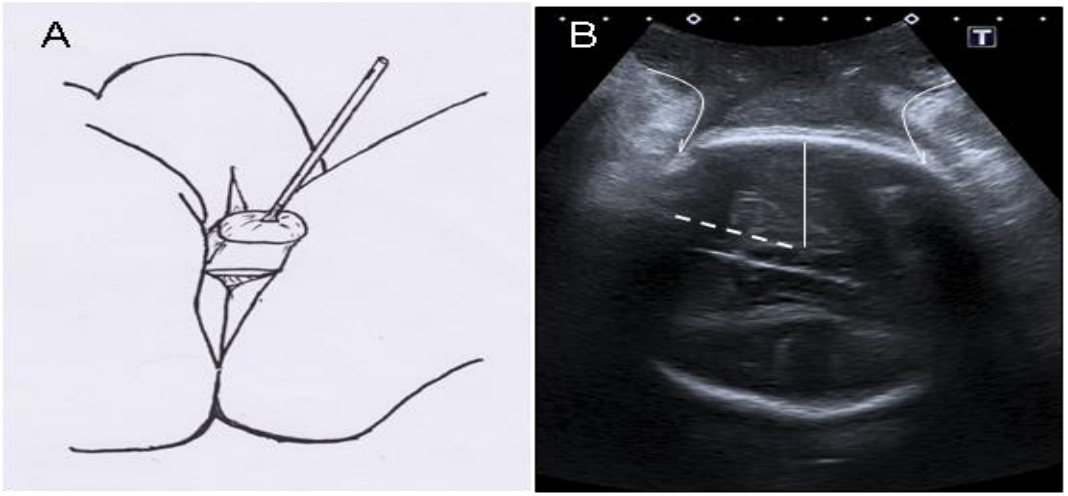
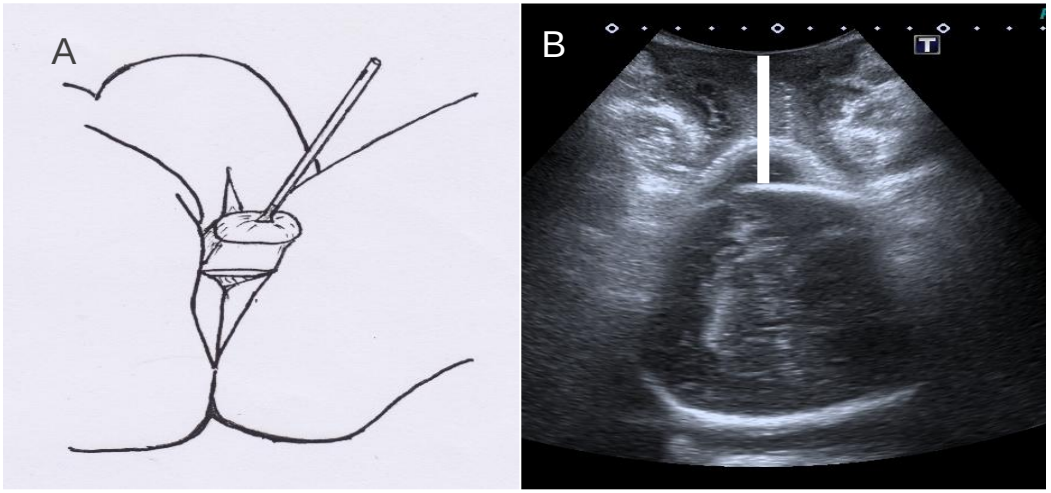
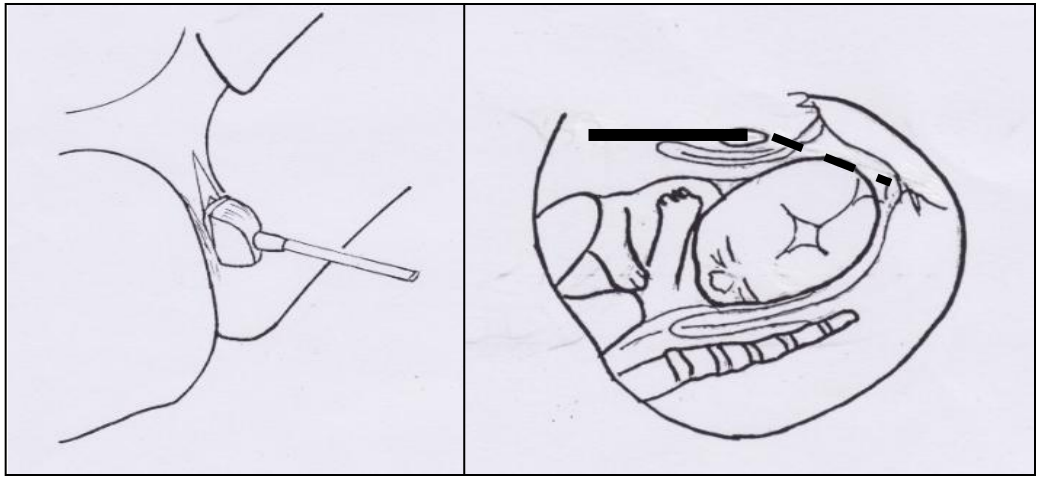


Figure 4. Transperineal axial plane at rest (A). Head-Perineum Distance(B)

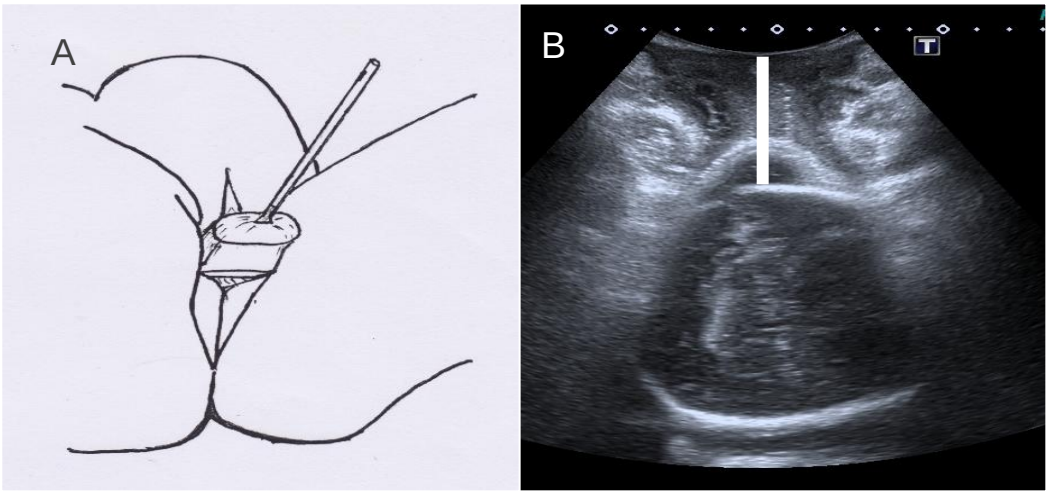


- Intrapartum transperineal ultrasound is useful to predict cases of complicated operative vaginal deliveries.
    - Angle of progression < 145º presents a higher risk of failure in cases of vacuum assisted deliveries (Bultez, Ultrasound Obstet Gynecol 2016)
    - Head Perineum distance > 45 mm is a predictor of unsuccessful vaginal delivery and need for caesarean delivery (Kahrs, Am J Obstet Gynecol 2017)



Several authors have expressed their interest in predicting the kind of vaginal delivery they will encounter and the risk for caesarean delivery:

•Eggebo reported a model based on six parameters (head-perineal distance, caput succedaneum, occiput posterior position, maternal age, gestational age and maternal body mass index) all evaluated during the first stage of labor with an area under the curve of 0.853 (Eggebo , Am J Obstet Gynecol 2015)



HYPOTHESIS:

Is it possible to develop a simple model to predict complicated operative vaginal deliveries (based on only a few parameters) that can be used in any labor ward?

SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS (Sainz, Am J Obstet Gynecol 2018)

•Objetive: To compare predictive models for the identification of complicated operative vaginal deliveries based on Intrapartum Transperineal Ultrasound(ITU).

•Study design:

- A prospective cohort study in nulliparous women at term, with singleton pregnancies, at full dilatation.
- ITU was performed immediately before the operative vaginal delivery
- Intrapartum evaluation of fetal biometric parameters was also carried out (fetal weight, head circumference and biparietal diameter).

•Study design:

- An operative vaginal delivery was classified as ‘complicated’ when one or more of the following situations occurred:

  ≥3 tractions needed to complete fetal extraction

  3-4th degree perineal tear

  Severe bleeding during the episiotomy repair

  Significant traumatic neonatal lesion.

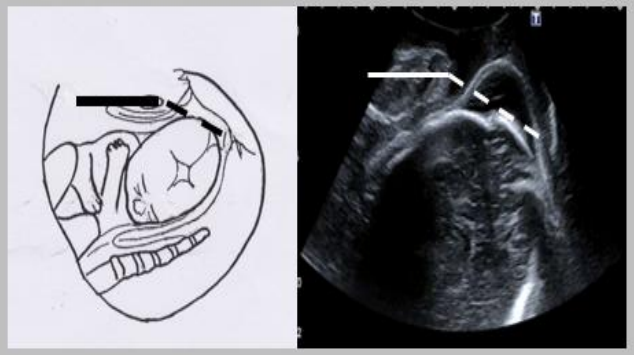
•Results:

- 79 nulliparous were studied (47 vacuum-deliveries, 32 forceps-deliveries).31 cases of complicated operative vaginal deliveries.

- We have identified a binary logistic regression model based on Angle of Progression and fetal head circumference, which presents an area-under ROC curve of 0.876 (95% CI0.790-0.963)

- We report a simple and quick predictive model for complicated operative vaginal deliveries.
- Including only two parameters (Angle of progression and head circumference).
- Easy to implement in any labor and delivery unit.

The Predictor Model for a Complicated Operative Vaginal Delivery (COD)



Angle of Progression with pushing (º)	152
Fetal Head Circunference (mm)	348

28 %

of probability for a Complicated OD
(≥3 tractions, 3-4 degree perineal tear, significant bleeding or neonatal lesion)

Sainz,Fernández-Palacín

- Case that presents an Angle of Progression of 152 º and a Head Circunference of 348 mm. This situation associates a 28% of probability for Complicated operative vaginal delivery

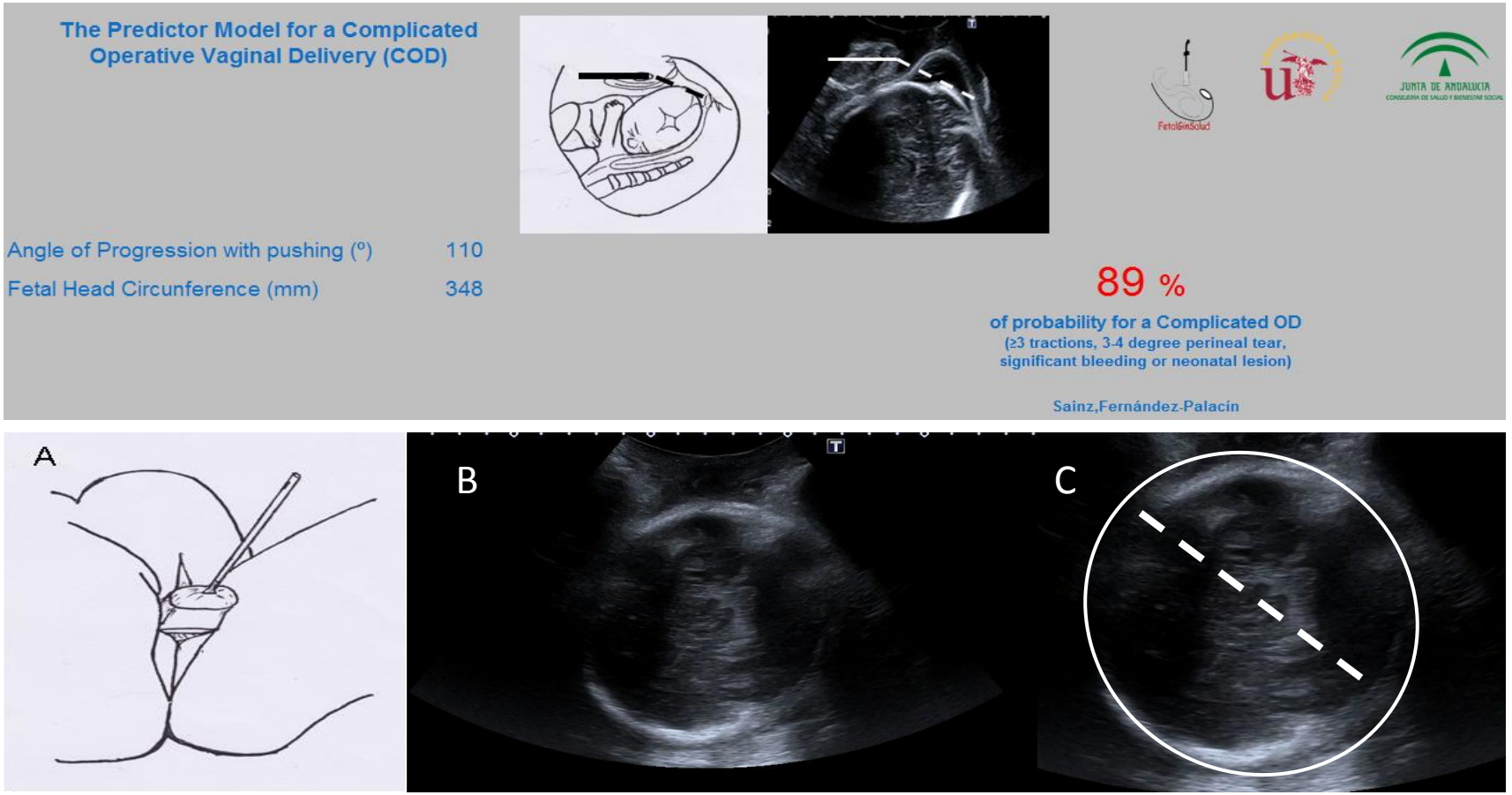


Figure 5. A and B. Acquisition of fetal head image using transperineal ultrasound. C. Evaluation of biparietal diameter and fetal head circumference (using the transthalamic plane of the fetal head).

- Case that presents an Angle of Progression of 110 º and a Head Circunference of 348 mm. This situation associates a 89% of probability for Complicated operative vaginal delivery

Video

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Corresponding author: José Antonio Sainz

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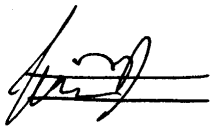

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Que esta Comisión, en reunión celebrada el 6 de septiembre de 2007, ha informado favorablemente sobre el proyecto titulado:

Ecografia Transperial intraparto para la instrumentación con vacuum

Cuyo investigador principal en este Centro es:

José Antonio Sainz Bueno

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A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS.

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Conflict of interest:

The authors have stated explicitly that there is no conflict of interest between this article and any type of economic support for the research.

Any sources of financial support for the research

CONDENSATION, IMPLICATIONS AND CONTRIBUTION, SHORT VERSION OF TITLE

- **CONDENSATION.**

We propose a simple model to predict the implications of an operative vaginal delivery.

- **IMPLICATIONS AND CONTRIBUTIONS.**

- A. Why was this study conducted?

Instrumental deliveries are associated with higher maternal and neonatal morbidity. Identifying the cases at high risk for complicated operative deliveries is important to improve obstetric assistance in the labor ward.

Intrapartum ultrasound can become a useful tool in the delivery room. Therefore, we believe the development of a predictive model for complicated operative deliveries based on intrapartum parameters (angle of progression and fetal head circumference), could be of great utility for obstetricians assisting instrumental deliveries.

- B. What are the key findings?

A predictive model that includes angle of progression and fetal head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?

Previous predictive models for difficult vaginal deliveries or need for cesarean section required the combination of multiple parameters (up to 6 parameters), which were evaluated during the first stage of labor.
We present a simple and quick predictive model for complicated operative deliveries (requiring only 2 ultrasound parameters) which can be performed during second stage of labor.

- **Short version of title.**

Predictive model for complicated operative vaginal deliveries.

Abstract:

BACKGROUND:

Complicated operative deliveries are associated a greater neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a caesarean section is needed to complete fetal extraction. The decision to perform an instrumental delivery has traditionally been based on a subjective assessment by digital vaginal examination, combined with the clinical expertise of the obstetrician carrying out the delivery. To date, there is no method of objectively quantifying the likelihood of a successful delivery. Intrapartum ultrasound has a potential to improve the precision in assessing and managing instrumental deliveries.

OBJECTIVE: The aim of the study is to compare predictive models for the identification of complicated operative deliveries (vacuum or forceps) based on intrapartum-transperineal-ultrasound in nulliparous women.

Study design: We performed a prospective cohort study in nulliparous women at term, with singleton pregnancies, at full dilatation that underwent intrapartum-transperineal-ultrasound evaluation prior to operative delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (Angle of Progression, Progression-Distance, Midline-Angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters was also carried out (estimated fetal weight, fetal head circumference and biparietal diameter). An operative delivery was classified as 'complicated' when one or more of the following situations occurred: ≥3 tractions needed to complete fetal extraction; 3-4th degree perineal tear; substantial bleeding during the episiotomy repair; or substantial

traumatic neonatal lesion. Six predictive models were evaluated (information available in table 1).

Results: We recruited 84 nulliparous, out of which 5 cases have been excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. 79 nulliparous were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in occiput-posterior position. We identified 31 cases of complicated operative deliveries (19 vacuum-deliveries or 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated delivery versus operative complicated delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*P*=.001), fetal biparietal diameter(93.2±2.1 versus 95.2±2.3mm;*P*=.001), fetal head circumference(336±12 versus 348±6.4mm;*P*=.001), gender(female 62.5% versus 29.0%;*P*=.010), newborn weight(3,258±472g versus 3,499±383g;*P*=.027) and number of tractions(1.4±0.5 vs 4.2±1.0;*P*<.0005). In order to predict complicated operative deliveries, all 6 models studied presented an area-under-ROC-curve between 0.863 and 0.876. This multivariate study, which follows principles of "interpretability" and "parsimony"(simplicity), has allowed us to identify a binary logistic regression model based on angle of progression and fetal head circumference, which presents an area-under-ROC-curve of 0.876 (95% CI0.790-0.963) and a calibration slope B-0.906.

Conclusion: The predictive model including angle of progression and fetal head circumference has adequate predictive capacity of complicated operative deliveries (87.5%), and can be performed in the delivery room.

Keywords: angle of progression; forceps; intrapartum ultrasound; labor; operative

delivery; progression distance; translabial ultrasound; transperineal ultrasound; vacuum

Introduction

Operative deliveries are associated with an increased neonatal (subdural or cerebral haemorrhage, convulsions, mechanical ventilation) (1-3) and maternal morbidity (haemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult instrumentation and caesarean section performed after a failed attempt of operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum intracranial haemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than the rate associated with spontaneous vaginal birth (8).

According to the standard clinical practice guidelines, operative deliveries must only be performed if the fetal head is engaged and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries (14,15). Thus far, the decision to attempt operative delivery, as well as the evaluation of its potential difficulty, has relied on digital vaginal exploration (14,15). However, it is well known that digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound (ITU) has been introduced in clinical practice to help predict the progression and finalization of the delivery [spontaneous vs. need for instrumentation to complete fetal extraction (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative deliveries and to identify cases with high probability of requiring caesarean section due to failure of instrumentation (22-30). To date, few studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).

Bultez et al (25) observed that cases of vacuum assisted deliveries with an angle of progression less than 145º presented a higher risk of failure. Kahrs et al (29) identifies, a

head-perineum distance > 35 mm, as predictor of unsuccessful vaginal delivery and need for cesarean section. Our group (30) notes that an angle of progression with pushing of 153º is an adequate cut-off point to identify complicated operative deliveries (vacuum and forceps). To the date, previous studies assessing predictive models for complicated deliveries have not included fetal characteristics, such as estimated fetal weight or head circumference, which are known independent risk factors for operative and cesarean deliveries (31-33). Taking this into account, we propose an evaluation of the predictive capacity of intrapartum transperineal ultrasound parameters associated with fetal characteristics for the identification of complicated operative deliveries (vacuum and forceps) in nulliparous women.

Material and Methods:

This was a prospective observational study of nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation, who required the use of vacuum or forceps to complete the fetal extraction. The study was performed between May 2016 and June 2017 in Valme's University Hospital Maternity Unit in Seville, Spain. The study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

Inclusion criteria were: at term nulliparous women with uncomplicated pregnancies who required instrumentation (forceps or vacuum) to complete fetal extraction. Indications for operative delivery were: non-reassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in cases of prolonged fetal bradycardia or late heart-rate decelerations with absent fetal heart-rate variability. Operative deliveries were performed by obstetricians with more than 4 years of experience in

instrumental deliveries. All forceps deliveries were performed using Kielland's forceps, while for all vacuum assisted deliveries the same model of rigid metal vacuum was used (Bird´s cup n° 5). The fetal head station was assessed by transvaginal digital examination for low or outlet instrumental deliveries, as defined by the American College of Obstetricians and Gynecologists (14). Subsequently, a transabdominal ultrasound was performed to monitor the fetal head position. Managing obstetricians were different from those performing the intrapartum transperineal ultrasound and were blinded to the sonographic data registered. The intrapartum transperineal ultrasound was performed exclusively by a group of five obstetricians (J.S, C.B, P.F, A.A, J.G-M) who had demonstrated competency for this type of ultrasound examination (30).

Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide an informed consent before being enrolled in the study. Once the patient had signed the informed consent, the intrapartum transperineal ultrasound was performed as described below. When one of the listed indications for the operative delivery occurred, the managing obstetrician chose the instrument that considered most appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokio, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while fetal biparietal diameter (BPD) and fetal head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in semirecumbent

position, with an empty bladder and ruptured membranes. The probe was placed between the labia, below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (**Figures 2, 3 and 4)**: Angle of Progression (AoP) and Progression-Distance (PD), evaluated on the longitudinal plane, and Midline-Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression, Progression-Distance and Midline-Angle were assessed at rest (AoP1, PD1, MLA1) and concurrently with contraction and active pushing (AoP2, PD2, MLA2). Angle of Progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading edge of the bony part of the fetal head. Progression-Distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline-Angle is defined as the angle between the anteroposterior axis of the pelvis and foetal brain midline. Intrapartum transperineal ultrasound measurements were obtained according to previously published technique.

The following demographic and obstetric data were recorded: maternal age, gestational age at delivery; body mass index (BMI); obstetric history; duration of first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight and gender. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (30) and postpartum haemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial haemorrhage, clavicle fracture) and admission of the

newborn to the neonatal unit (respiratory distress, neonatal jaundice, risk of neonatal sepsis).

An operative delivery was classified as complicated when one or more of the following situations occurred (30): three or more tractions were required to complete fetal extraction, failed attempt at operative vaginal delivery, third or higher degree perineal tear according to Sultan's classification, major tear reported by the obstetrician, significant bleeding during the episiotomy repair confirmed by a decrease in the haemoglobin level of ≥2.5 g/dL following the delivery, or a significant traumatic neonatal lesion.

Statistical analyses.

Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY). We determined the mean and standard deviations for numeric variables, and the percentage for qualitative variables. Comparisons of numeric variables between complicated and uncomplicated operative delivery were performed using Student´s t-test. Comparison of qualitative variables between study groups was performed using a chi-squared test. Individual predictive capabilities were evaluated using the receiver–operating characteristics (ROC) curve and the area under the curve (AUC). The level of significance was established at 95% CI ($P<0.05$).

Evaluation of logistic regression models

We designed different multivariate binary logistic regression models, using non-automated methods to predict a complicated operative delivery, including intrapartum transperineal ultrasound parameters and estimated fetal weight, fetal biparietal diameter and fetal head

circumference. These were added progressively according to how simple their evaluation was, and to their predictive capacity for the identification of a complicated operative delivery. We carried out and compared 6 binary logistic regression models (**Table 1):** We did a goodness of fit test (-2 log likelihood) and Hosmer and Lemeshow test for each model. Afterwards, C of Harrell was determined for those models with an adequate fit, in order to evaluate their discriminatory capacity (obtained as the area under the ROC curve of the predicted probabilities given by the model) and the slope and calibration graphic. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform Shrinkage factor. Once the definite multivariate binary regression model was identified, we developed a software for the prediction of complicated operative deliveries (vacuum and forceps) with the aim of making it applicable to clinical practice.

Results:

Study Population.

We recruited 84 nulliparous, out of which 5 cases have been excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. We have evaluated 79 cases of nulliparous who required instrumentation to complete the fetal extraction (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).

48 cases were classified as ‘uncomplicated operative deliveries’ (28 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 as ‘complicated operative deliveries’ (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Out of the 31 cases of

complicated deliveries, a third-degree perineal tear occurred in 6 cases (19.35 %). In 7 cases (22.5%), significant bleeding while repairing the episiotomy was noted and confirmed by a decrease of ≥ 2.5 g/dL in the maternal haemoglobin level. Three or more tractions were performed in 18 cases (58.06%).

Regarding maternal and neonatal demographic data, significant differences were noted between uncomplicated and complicated operative deliveries, in; estimated fetal weight, fetal biparietal diameter, fetal head circumference, gender and birth weight **(Table 2)**

The proportion of occiput posterior position was 13.6% (13 cases); the main indication for operative delivery was failure to progress in labor 60.75% (48 cases), and 76.2% (74 cases) required the performance of mediolateral episiotomy. Four cases (12.9%) out of the group of complicated deliveries required a caesarean section to complete fetal extraction. There was one newborn who required admission to the neonatal unit (case of mild respiratory distress).

Intrapartum transperineal ultrasound as a predictor of complicated deliveries.

Significant differences were observed between the uncomplicated and complicated cases regarding Angle of Progression at rest, Progression Distance at rest, Midline-Angle at rest, Angle of Progression with pushing and Progression Distance with pushing, with no statistically significant difference found in the Midline-Angle with pushing **(Table 3)**. The complicated delivery group required a significantly higher number of tractions (4.2±1.0) than the uncomplicated group (1.4±0.5).

Predictive models of complicated deliveries.

We have determined several binary logistic regression models to predict and explain

complicated operative deliveries. It was observed that the models presented Harrell's C statistic values that oscillating between 0.863 and 0.876, determined as an area under the ROC curve of the predicted probabilities. The model of binary logistic regression that identified the variables "Angle of progression with pushing" and " fetal head circumference " as predictors of a complicated operative delivery was chosen, as these variables were the ones included in the final multivariate analysis, shown in **Table 4**. Harrell's C statistic, obtained from the area under the ROC curve of the predicted probabilities by the model was 0.876 (95% CI 0.790 to 0.963), i.e. an intern discriminatory capacity >0.75, the same as the model adjusted by the Shrinkage uniform model, in which C results equivalent to 0.876 (95% CI 0.789 to 0.963) (**Figures 5 and 6)**. The calibration study of the selected model was performed by calculating the calibration slopes (0.984 and 1.064 in the original and Shrinkage models, respectively) Pearson linear correlation coefficients (0.906 and 0.849) (**Figures 7 and 8).**

Comment.

Principal findings.

The main finding of our study is the identification of a predictive model for complicated operative deliveries (vacuum and forceps) in nulliparous women that includes both fetal (estimated fetal weight, biparietal diameter, fetal head circumference) and intrapartum transperineal ultrasound (Angle of Progression, Progression Distance, Midline-Angle) parameters, and which is easy to use in the delivery room. This multivariate study, which follows principles of "interpretability" and "parsimony" (simplicity), has allowed us to identify a binary model based on progression angle with pushing and fetal head circumference, which has proved to predict a complicated operative delivery (87.6%). We

observed significant association between this binary model and the presence of: need of three or more tractions to complete fetal extraction, failed attempt at operative vaginal delivery, third or higher degree perineal tear, significant bleeding during the episiotomy or a significant traumatic neonatal lesion.

We believe one of the strengths of the study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that can be frequently found in most delivery units worldwide. Thus, the technique is generalizable. The Angle of Progression has proven to be easy to evaluate and to be very useful for this purpose (30). It is known that the fetal weight and the fetal head circumference are risk factors for caesarean and operative deliveries (31-33), and therefore their evaluation should be included in the assessment for the prediction of success of instrumentation. Fetal head circumference presents an adequate correlation with the difficulty of an instrumental delivery and the probability of failure and need for caesarean section (31,33,37). Its evaluation in the delivery room seems to be feasible, although we believe that the reproducibility of its measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) should be assessed in future studies.

On the other hand, estimated fetal weight is more difficult to evaluate and presents a higher error rate (38,39). We believe that new studies, including larger number of cases should evaluate the usefulness of our binary model for the prediction of complicated operative deliveries.

Clinical significance.

By applying the predictive model proposed, any obstetrician could easily predict what kind of operative delivery he or she will encounter at the delivery room, as a variation in the fetal head circumference could well shift the situation from an uncomplicated operative delivery, 1 or 2 tractions needed, (if an angle of progression with a 146º push is observed from the intrapartum transperineal ultrasound) to a complicated operative delivery, requiring 3 or 4 instrumental pulls to complete fetal extraction (if an angle of progression with push of 115º is identified) **(Figure 9) (video 1).**

Research implications

Knowing that vaginal exploration presents a high rate of error (20-75%) for the identification of the level of the fetal presentation (ACOG fetal station) and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in delivery rooms in order to improve the assessment of the progression and finalization of the delivery. In this line, Kalache et al. (41) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, while Ramphulm et al (42) describe the utility of intrapartum ultrasound for the evaluation of fetal head position before instrumentation.

Instrumental deliveries are associated with higher maternal and neonatal morbidity (1-13) especially when a caesarean section is required due to a failed attempt of instrumental delivery. An emergency C-section after a failed vacuum assisted delivery is associated with an intracranial haemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 per 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice in order to

enable the prediction of difficulty and possible complications of instrumental deliveries. Bultez et al. (25) observes that an angle of progression <145º (sensitivity 86.2%, specificity 49%) is associated with a higher rate of failed attempt of vacuum delivery. Kahrs et al (29) finds that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% risk of an emergency cesarean section.

Kasbaoui et al (43) in a prospective cohort study including 659 women, the HPD (in this study referred to as the perineum–skull distance) was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, HPD ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (44) identified that a cutoff of 142° for the angle of progression was a predictor for complicated operative deliveries, consistent with our study, which identifies an angle of progression with pushing <153.5º as a predictor for complicated operative deliveries (vacuum and forceps).

Several authors have expressed their interest in predicting the kind of vaginal delivery they will encounter and the risk for caesarean section (45-47). Their work has associated mainly different maternal and fetal parameters; with sonographic parameters only being taken into account in the recent studies. Their efforts have been focused on the prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of labor. Thus Burker et al (46) present a predictive model of caesarean risk based on five parameters (maternal age, body mass index, height, fetal abdominal circumference, and fetal head circumference) evaluated in the first stage of labor, and with a calibration and discriminative ability with a misclassification rate of 0.21. With the same purpose of predicting the probability of a vaginal delivery vs need for caesarean section, Eggebø et al (47) introduces intrapartum transperineal ultrasound in his evaluation, and presents a model

based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal body mass index), all evaluated during the first stage of labor, and with an ARC of 0.853.

We have observed a significant difference in fetal sex between study groups (62.5% of female fetuses in the uncomplicated operative deliveries vs 29% in the complicated deliveries). In 5.9% of cases we have not been able to measure the fetal head circumference during the second stage of labor with the fetal head already engaged in the maternal pelvis. Nonetheless, our predictive model, unlike previously proposed models, presents the following characteristics: 1. it can be used in the delivery room itself, 2. Provides a quick evaluation, since only 2 ultrasound parameters are involved, and 3. it appears to be easy to perform.

Strenghts and limitations

Our study has several strengths. Our study including a large series of deliveries at high-risk of ending up in complicated operative deliveries (i.e. nulliparous women and occipito-posterior position) (48,49), including both instruments (vacuum and forceps), and being evaluated by intrapartum transperineal ultrasound. Moreover, the population included in the study is representative of pregnant women who require instrumentation to complete fetal extraction, including the main indications for operative deliveries, such as non-reassuring fetal heart rate, failure to progress of labor or maternal exhaustion. Regarding the method, operative deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice. Intrapartum transperineal ultrasound was performed by

experienced sonographers with specific training in pelvic floor and intrapartum transperineal ultrasound. Lastly we identified an adequate predictive model for complicated operative deliveries that we consider easy to apply in the delivery room, since it only involves 2 elements, a fetal ultrasound parameter (fetal head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proved to be useful in the identification of difficult deliveries (24-30).

We consider as limitations of our work: the fact that we have not evaluated head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery should be designed for this purpose. We consider that the main limitation of our work is the fact that we have not evaluated the head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery. In addition, we believe that reproducibility of fetal head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proved. External validation of the predictive model should be also carried out. We consider that including other types of forceps, and not only Kiellands forceps, and using more objective parameters to classify a delivery as a 'complicated delivery' such as: need for maternal blood transfusion, traumatic fetal lesion or a cup detachment, are factors that should be taken into account in future works. Lastly, we believe that as our study was underpowered to detect neonatal and maternal morbidity, and therefore further studies should be designed for this purpose.

Conclusion.

The predictive model including angle of progression and fetal head circumference has

adequate predictive capacity of complicated operative deliveries (87.5%), and can be performed in the delivery room.

Acknowledgments.

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*Detailed Response to Reviewers

RESPONSE TO REVIEWER AND EDITOR COMMENTS.

Reviewer 1 Point 1.

A. Title - excellent, no changes.
B. I agree with the reviewer

Reviewer 1 Point 2.

A. Condensation - this needs to be improved. "The combination of the angle of progression and the head circumference can predict 87% of operative vaginal deliveries."
B. The change has been made
C. Page 2. Line 6-7
D. The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries.

Reviewer 1 Point 3.

A. "Implications and contributions" should be "AJOG at a Glance".
B. The change has been made
C. Page 2. Line 10
D. **AJOG AT A GLANCE**

Reviewer 1 Point 4.

A. .
   a. Why was the study performed? - the authors should write "Operative vaginal deliveries are associated with a high maternal and neonatal morbidity" (please do not use 'instrumental deliveries' throughout the manuscript - this is a poor translation from another language to English).
   b. The second sentence identifying the cases at risk for complicated operative delivery is important to improve "patient care" - "obstetric assistance in the labor ward" is obvious and unnecessary, please delete.
   c. The second paragraph is redundant - why not just say "we sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature."
   d. Please use two bullets for this section.
   e. What were the key findings - please use two bullets here as well. It is not clear what is a 'complicated' operative delivery. Also, an operative delivery can include a Cesarean delivery.
   f. What does the study add - the order should be inverted. Please use bullets.
   i. We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be

easily obtained with intrapartum sonography (head circumference and angle of progression).

ii. The predictive ability of the model is superior to other models previously reported (87% vs a range of XX-XX%).

iii. This model can be implemented in any labor and delivery unit.

B. The change has been made

C. Page 2 and 3

- A. Why was this study conducted?

  - Operative vaginal deliveries are associated with a high maternal and neonatal morbidity.
  - We sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature

  - B. What are the key findings?
    A predictive model based on the angle of progression and head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?
  - We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference).
  - The predictive ability of the model is superior to other models previously reported (87% vs a range of 56-67%).
  - This model can be implemented in any labor and delivery unit.

  - **Short version of title.**

A simple predictive model for complicated operative vaginal deliveries.

Reviewer 1 Point 4.

A. Short title - this could be "A simple predictive model for complicated operative vaginal deliveries"

B. The change has been made

C. Page 3. Line 10

D. A simple predictive model for complicated operative vaginal deliveries.

5.

Reviewer 1 Point 5.

A. The authors should not use Cesarean "section", but instead "delivery", throughout the manuscript. Similarly, the expression "operative vaginal delivery" is preferred to "instrumental delivery" as noted above. The authors should take into account that an instrumental delivery could be a Cesarean delivery - therefore, this expression is imprecise
B. The change has been made throughout the text
C. Page 4. Line 6
D. Cesarean delivery and operative vaginal delivery

Reviewer 1 Point 6.

A. The conflict of interest section can say "The authors declare no conflicts of interest."
B. The change has been made
C. Page 1. Line 20
D. The authors declare no conflicts of interest."

Reviewer 1 Point 7.

A. Please state what are the sources of support for the study, like "This study was supported by the authors as practicing physicians in the hospital and faculty members of the University of Seville, Spain"
B. The change has been made
C. Page 1. Line 23
D. This study was supported by the authors as practicing physicians in the hospital and faculty members of the University of Seville, Spain

Reviewer 1 Point 9

A. Abstract -
   a. A simple principle is that every time a comparative expression is used, there needs to be the word "than" - for example, the authors say that "complicated operative deliveries are associated with greater trauma...." Etc. However, 'greater' is a comparative expression and cannot be used without a "than" statement following, because it needs to be compared with something. This applies throughout the manuscript, and the authors need to seek advice to correct the English grammar.
B. The change has been made throughout the text
C. Page 4. Line 13-21

A.

b. The use of "complicated operative delivery" is problematic. What is a "complicated" operative delivery? The complication must be ascertained after the delivery - therefore, it is not clear to the reader what the authors mean. If what is meant is the need to use vacuum or forceps, then this is an operative vaginal delivery, and the word "complicated" is not necessary.

B. Definition is included in abstract and text
C. Page 6. Line 2-5 and
D. Complicated vaginal delivery

A. c. When reading the article and abstract, the authors have defined a complicated delivery as a vaginal delivery that has:
   i. More than 3 tractions
   ii. Is associated with 3rd or 4th degree perineal tear
   iii. Substantial bleeding during episiotomy repair, or
   iv. Substantial neonatal traumatic lesion

   The authors need to define the rationale for this choice - specifically, they need to explain why 3 or more tractions. What is the definition of substantial bleeding? What is the estimation of blood loss? What is considered a substantial neonatal traumatic lesion?
B. Clear definition has been made in the text
C. Page 6. Line 2-9 and

Complicated vaginal delivery

An operative vaginal delivery was classified as 'complicated' when one or more of the following situations occurred: ≥3 tractions needed to complete fetal extraction; 3-4th degree perineal tear; substantial bleeding during the episiotomy repair(decrease in the hemoglobin level of ≥2.5g/dL); or substantial traumatic neonatal lesion(subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries).

A. d. In the abstract, it is necessary to improve the English - for example, it is not necessary to say "fetal biparietal diameter" or "fetal head circumference" - these measurements are not being obtained from mothers, so "fetal" is not necessary.

B.The change has been made throughout the text
C.Page 4. Line 2

A. e. Similarly, the number of tractions should be presented as median and interquartile range, not as a mean and standard deviation.
B.The change has been made

C .Page 7. Line 15-16

D. number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<.0005).

A. f. The areas under the curve need to be presented with the confidence intervals and p-values. Line 16, page 4.
B.The change has been made

C .Page 7. Line 17

D. all 6 of the studied models presented an area under ROC curve between 0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;p<0.0005).

g. Multivariate study is not appropriate - this refers to the model or the study - the results of the study meet the criteria of parsimony.
B.The change has been made

C .Page 7. Line 20

D. all 6 of the studied models presented an area under ROC curve between 0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;p<0.0005).

A. h. Conclusion - the authors should refer to the angle of progression.

B. B.The change has been made
C. C .Page 8. Line 3
D. The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Reviewer 1 Point 10

a. Keywords - labor, complication, operative vaginal delivery, vacuum extraction, cesarean delivery, biomarker, birth trauma, neonatal injury, perineal laceration, postpartum hemorrhage

B.The change has been made

C .Page 8. Line 7-8

d. Labor; complication; operative vaginal delivery; vacuum extraction; cesarean delivery; biomarker; birth trauma; neonatal injury; perineal laceration; postpartum haemorrhage.

Reviewer 1 Point 10-11-12

A. Introduction - the article needs to be checked for non-idiomatic expressions (e.g. "difficult instrumentation" should not be used).
11. "Digital vaginal exploration" is non-idiomatic and should be "digital examination". This is a recurring problem with this paper, in which the authors have translated from Spanish into English.
12. There is no need to use "intrapartum transperineal ultrasound" as ITU - please delete "ITU" from the manuscript and spell out the terms.

B. The change has been made
C. Page 9. Line 23 and 10-18
D. Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult operative vaginal deliveries and caesarean deliveries performed after failed operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than the rate associated with spontaneous vaginal birth (8).
E. According to standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries (14,15). Thus far, the decision to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on digital examination (14,15). However, digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to help predict the progression and finalization of delivery [spontaneous vs. need for operative vaginal delivery to complete fetal

extraction (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative vaginal deliveries and to identify cases with a high probability of requiring caesarean delivery due to failed operative vaginal delivery (22-30). To date, few studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).

Reviewer 1 Point 13-14-15

Page 6, line 23 - the authors refer to Bultez, but the appropriate construction is "Bultez reported that in cases of vacuum-assisted delivery, XX% had a risk of failure". The same applies to the rest of the manuscript - in general, "XX/authors report that..."

14. When reporting the results of others, it is not sufficient to say "A high/low rate of failure" - precision is needed - please state the precise outcome.

15. Page 7 - "our group notes that an angle of progression of 153 is an adequate cutoff point to identify complicated operative deliveries" - I am not sure if the authors say that patients who have an angle of progression of <153 are more likely to need an operative vaginal delivery with vacuum or forceps, or more likely to have a complication - this ambiguity has to be resolved throughout the manuscript. As it is, this cannot be understood by readers.

b.The change has been made

C. Page 11. Line 15

D. Bultez et al (25) reported that an angle of progression less than 145.5° has a sensitivity of 86.2%, specificity of 49% and positive predictive value of 24% for the prediction of vacuum extraction failure in nulliparous women. Kahrs et al (29) reported that a head-perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of unsuccessful vaginal delivery and the need for caesarean delivery.
Our group (30) reported that an angle of progression with pushing < 153º presents a sensitivity of 86.9% for the identification of complicated operative vaginal deliveries (understanding as 'complicated operative delivery' those cases when ate least one of the following situations occurred: three or more tractions needed; a third-/fourth-degree perineal tear; significant bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion).

Reviewer 1 Point 16

A.. The last paragraph needs to be broken down into two parts, and needs to end with a description of the objective of the study. This last paragraph cannot be written

"We propose an evaluation of the predictive capacity..." etc. This needs to be improved, because it is not understandable.

b.The change has been made

C. Page 12. Line 13

E. To date, previous studies assessing predictive models for complicated vaginal deliveries have not included fetal characteristics, such as fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).Taking this into account, we sought to develop a model to predict complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women.

Reviewer 1 Point 17

A. It should be "estimated fetal weight" on page 8, line 20, instead of "fetal weight"
B. The change has been made throughout the text

Reviewer 1 Point 18

A. The authors use on page 9 a number of abbreviations- lines 4, 6, 7 - it is important to have a table with all these definitions, because intrapartum sonography is not in widespread use. So if the authors want to be read and understood, greater explanation is needed.
B. New table 1

Reviewer 1 Point 19

A. The recommendation of blood loss associated with a decrease in hemoglobin >2.5 is good, but needs a reference.
B. The change has been made
C. Pag 18. 18
D. Reference 40

Reviewer 1 20-21-22.

A. Page 10, line 9 - "significant" should be replaced with another adjective

21. Page 10 - it is "Chi square" test.

22. "Evaluation of logistic regression models", line 22 - "We designed different multivariate binary logistic regression models" should be "We generated..."

a. This section needs to be reviewed - the authors can say "we performed a 'goodness-of-fit test'"

B. The change has been made

C Pag . 20

d. **Statistical analyses.**

We determined the mean and standard deviation for numeric variables and the percentage for qualitative variables. Comparisons of the numeric variables between complicated and uncomplicated operative vaginal deliveries were performed using Student´s t-test. Comparison of qualitative variables between study groups was performed using a chi-square test. Individual predictive capabilities were evaluated using the receiver operating characteristics (ROC) curve and the area under the curve (AUC). All statistical comparisons were performed using two-sided test, and $P < 0.005$ was considered statistically significant for all comparisons. Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY).

Evaluation of logistic regression models.

We generated different multivariate binary logistic regression models using non-automated methods to predict complicated operative vaginal delivery, including intrapartum transperineal ultrasound parameters and fetal weight, biparietal diameter and head circumference. These parameters were added progressively according to the simplicity of their evaluation and their predictive capacity for the identification of a complicated operative delivery. We carried out and compared 6 binary logistic

regression models (**Table 2)**. We performed a goodness-o-fit test (-2 log likelihood) and Hosmer and Lemeshow test for each model. Afterwards, C of Harrell was determined for those models with an adequate fit to evaluate their discriminatory capacity (obtained as the area under the ROC curve of the predicted probabilities given by the model) and the slope and calibration graphic. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform Shrinkage factor. Once the definite multivariate binary regression model was identified, we developed a software for the prediction of complicated operative vaginal deliveries (vacuum and forceps) with the aim of making it applicable to clinical practice.

Reviewer 1 Point 22

A.The authors need to explain what is "C of Harrell"

B. C Harrell's and the equivalent parameter Somers' D were proposed as measures of the general predictive power of a general regression model by Harrell et al. (1982) and Harrell et al. (1996).C Harrell´s is used to compare the discrimination ability of the three models.

Reviewer 1 Point 23

23. Discussion - should be "Clinical Implications" and "Research Implications" - not 'Significance'.

B. The change has been made
C Pag . 31.23

Reviewer 1 Point 24

24. Conclusion of the article should be "A predictive model with two parameters (head circumference and angle of progression) could predict 87% of operative vaginal deliveries."

B. The change has been made

C. Pag 37

D.The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Reviewer 1 Point 25

25. It is unclear if the authors have compared their results with those of others.

B. The change has been made

C. Pag 33-35

D.

Research Implications

Knowing that digital examination presents a high rate of error (20-75%) for the identification of the level of fetal presentation (ACOG fetal station) and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the delivery room to improve the assessment of the progression and finalization of delivery. Based on this, Kalache et al. (45) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility of intrapartum ultrasound for the evaluation of fetal head position before operative vaginal delivery.

Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13), especially when a caesarean delivery is required due to a failed operative vaginal delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a

convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to enable the prediction of difficulty and possible complications of operative vaginal deliveries. Bultez et al. (25) observed that an angle of progression <145° (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated with a higher rate of failed vacuum delivery. Kahrs et al (29) found that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% risk of an emergency cesarean delivery.

Kasbaoui et al (47) carried out a prospective cohort study including 659 women, in which the head-perineum distance (in this study referred to as the perineum–skull distance) was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (48) identified that a cutoff of 142° for the angle of progression was a predictor for complicated operative vaginal deliveries, which is consistent with the results of our study (30), which identified an angle of progression with pushing <153.5° as a predictor for complicated operative deliveries (sensitivity 86.9%).

Several authors have expressed their interest in predicting the kind of vaginal operative delivery they will encounter and the risk for caesarean delivery (49-51). Their work has mainly associated different maternal and fetal parameters with sonographic parameters that have only been taken into account in recent studies. Their efforts have been focused on the prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of labor. Thus, Burker et al (50) present a predictive model of caesarean risk based on five parameters (maternal age, body mass index, height, fetal abdominal circumference, and fetal head circumference) evaluated in the first stage of

labor, with calibration and discriminative ability and a misclassification rate of 0.21. With the same purpose of predicting the probability of vaginal delivery vs the need for caesarean delivery, Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation and presents a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal body mass index), which are all evaluated during the first stage of labor, with an ARC of 0.853.

Review 1 26

26. Figures 5-6 are ROC curves. The vertical axis needs to list Sensitivity, and it is not appropriately written for either figure. Moreover, the area under the curve, confidence intervals, and p-values need to be listed on the figures.

B. The change has been made

C. Figure 5-6 N

Review 1 27-28-29

27. Figure 7 requires review by the authors. The word "lineal" is not English. The same applies to Figure 8.
28. When reviewing the legends - please pay attention to the use of the article "the".
29. The PowerPoint presentation is too crowded and needs to be broken down into smaller slides without so much text. Otherwise, it would not be downloaded or used. In addition, the names of the authors need to be listed on the horizontal axis - at present, these are not visible.

B. The change has been made

C. New Figure 7,8 and powetpoint

LESIONES TRAUMATICAS DE RN

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Mechanical birth-related trauma to the neonate: An imaging perspective

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A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS.

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Any sources of financial support for the research

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CONDENSATION, ~~IMPLICATIONS AND CONTRIBUTION~~, AJOG AT A GLANCE, SHORT VERSION OF TITLE

- **CONDENSATION.**

~~We propose a simple model to predict the implications of an operative vaginal delivery.~~ The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries.

- **~~IMPLICATIONS AND CONTRIBUTIONS~~. AJOG AT A GLANCE**

- A. Why was this study conducted?

~~Instrumental deliveries are associated with higher maternal and neonatal morbidity. Identifying the cases at high risk for complicated operative deliveries is important to improve obstetric assistance in the labor ward.~~

- Operative vaginal deliveries are associated with a high maternal and neonatal morbidity.
- We sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature

~~Intrapartum ultrasound can become a useful tool in the delivery room. Therefore, we believe the development of a predictive model for complicated operative deliveries based on intrapartum parameters (angle of progression and fetal head circumference), could be of great utility for obstetricians assisting instrumental deliveries.~~

- B. What are the key findings?
    - A predictive model that includes angle of progression and fetal head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?
- We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be easily obtained with intrapartum sonography (head circumference and angle of progression).
- The predictive ability of the model is superior to other models previously reported (87% vs a range of 56-67%).
- This model can be implemented in any labor and delivery unit.

~~Previous predictive models for difficult vaginal deliveries or need for cesarean section required the combination of multiple parameters (up to 6 parameters), which were evaluated during the first stage of labor.~~
~~We present a simple and quick predictive model for complicated operative deliveries (requiring only 2 ultrasound parameters) which can be performed during second stage of labor.~~

- **Short version of title.**

~~Predictive model for complicated operative vaginal deliveries.~~

A simple predictive model for complicated operative vaginal deliveries

Abstract:

~~**BACKGROUND:**~~

~~Complicated operative vaginal deliveries are associated a greater neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a caesarean section is needed to complete fetal extraction. The decision to perform an instrumental delivery has traditionally been based on a subjective assessment by digital vaginal examination, combined with the clinical expertise of the obstetrician carrying out the delivery. To date, there is no method of objectively quantifying the likelihood of a successful delivery. Intrapartum ultrasound has a potential to improve the precision in assessing and managing instrumental deliveries.~~

BACKGROUND:

Complicated operative vaginal deliveries are associated with a high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a caesarean delivery is needed to complete fetal extraction. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination, combined with the clinical expertise of the obstetrician carrying out the delivery. To date, there is no method of objectively quantifying the likelihood of a successful delivery. Intrapartum ultrasound has the potential to improve precision in the assessment and management of operative deliveries.

~~**OBJECTIVE:** The aim of the study is to compare predictive models for the identification~~

~~of complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.~~

OBJECTIVE: The aim of this study was to compare predictive models for the identification of complicated operative vaginal deliveries (vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.

~~**Study design:** We performed a prospective cohort study in nulliparous women at term, with singleton pregnancies, at full dilatation that underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (Angle of Progression, Progression-Distance, Midline-Angle) was performed immediately before instrument application, both at rest and concurrently with pushing. Intrapartum evaluation of fetal biometric parameters was also carried out (estimated fetal weight, fetal head circumference and biparietal diameter). An operative vaginal delivery was classified as 'complicated' when one or more of the following situations occurred: ≥3 tractions needed to complete fetal extraction; 3-4th degree perineal tear; substantial bleeding during the episiotomy repair; or substantial traumatic neonatal lesion. Six predictive models were evaluated (information available in table 2).~~

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intrapartum evaluation of fetal biometric parameters was also carried out (fetal weight, head circumference and biparietal diameter). An operative vaginal delivery was classified as 'complicated' when one or more of the following situations occurred: ≥3 tractions needed to complete fetal extraction; 3-4th degree perineal tear; substantial bleeding during the episiotomy repair(decrease in the hemoglobin level of ≥2.5g/dL); or substantial traumatic neonatal lesion(subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).

Results: We recruited 84 nulliparous, out of which 5 cases have been excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. 79 nulliparous were studied (47 vacuum deliveries, 32 forceps deliveries) with 13 cases in occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries or 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*P*=.001), fetal biparietal diameter(93.2±2.1 versus 95.2±2.3mm;*P*=.001), fetal head circumference(336±12 versus 348±6.4mm;*P*=.001), gender(female 62.5% versus 29.0%;*P*=.010), newborn weight(3,258±472g versus 3,499±383g;*P*=.027) and number of tractions(median,IQR)(1(1 to 2) versus 4(3 to 5);*P*<.0005). In order to predict complicated operative deliveries, all 6 models studied presented an area under ROC curve between 0.863 and 0.876 (95%CI 0.775-0.950 and 0.790-0.963; p<0.0005). This multivariate study,

~~The results of the study meet the criteria of "interpretability" and "parsimony"(simplicity), has allowed us to identify a binary logistic regression model based on angle of progression and fetal head circumference, which presents an area under ROC curve of 0.876 (95%CI 0.790-0.963; p<0.0005) and a calibration slope B-0.984 (95%CI 0.0.726-1.243; p<0.0005).~~

Results: We recruited 84 nulliparous, of which 5 cases were excluded due to the difficulty of adequately evaluating the biparietal diameter and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*P*=.001), biparietal diameter(93.2±2.1 versus 95.2±2.3 mm;*P*=.001), head circumference(336±12 versus 348±6.4 mm;*P*=.001), gender(female 62.5% versus 29.0%;*P*=.010), newborn weight(3,258±472g versus 3,499±383g;*P*=.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under ROC curve between 0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on angle of progression and head circumference, which has an area under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope of B-0.984 (95% CI 0.0.726-1.243; p<0.0005).

Conclusion: ~~The predictive model including angle of progression and fetal head~~

~~circumference has adequate predictive capacity of complicated operative deliveries (87.5%).~~

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Keywords: ~~angle of progression; forceps; intrapartum ultrasound; labor; operative delivery; progression distance; translabial ultrasound; transperineal ultrasound; vacuum~~ Labor; complication; operative vaginal delivery; vacuum extraction; cesarean delivery; biomarker; birth trauma; neonatal injury; perineal laceration; postpartum haemorrhage.

Introduction

~~Operative vaginal deliveries are associated with an increased neonatal (subdural or cerebral haemorrhage, convulsions, mechanical ventilation) (1-3) and maternal morbidity (haemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult of operative vaginal deliveries and caesarean section performed after a failed attempt of operative vaginal delivery (8-13) ?. Indeed, the incidence rate reported for postpartum intracranial haemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than the rate associated with spontaneous vaginal birth (8).~~

~~According to the standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries (14,15). Thus far, the decision to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on digital examination digital vaginal exploration (14,15). However, it is well known that digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound (ITU) has been introduced in clinical practice to help predict the progression and finalization of the delivery [spontaneous vs. need for operative vaginal delivery to complete fetal extraction (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative vaginal deliveries and to identify cases with high probability of requiring caesarean section due to failure of instrumentation (22-30). To date, few studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).~~

Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity

(hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult operative vaginal deliveries and caesarean deliveries performed after failed operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than the rate associated with spontaneous vaginal birth (8).

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~~Bultez et al (25) reported that in cases of vacuum-assisted deliveries with que an angle of progression less than 145.5º presented for predicting vacuum extraction failure in nulliparous women had a sensitivity of 86.2%, specificity of 49% and positive predictive value of 24%. Kahrs et al (29) identifies, reported that a head-perineum distance > 35 mm presenta una sensibilidad del 56%, as predictor of unsuccessful vaginal delivery and need for cesarean section.~~

~~Our group (30)) reported that notes that an angle of progression with pushing < 153º is an presenta una sensibilidad del 86.9% to identify complicated operative vaginal deliveries (when one or more of the following situations occurred: three or more tractions; a third-/fourth-degree perineal tear; significant bleeding during the episiotomy repair; major tear or significant traumatic neonatal lesion).~~

Bultez et al (25) reported that an angle of progression less than 145.5° has a sensitivity of 86.2%, specificity of 49% and positive predictive value of 24% for the prediction of vacuum extraction failure in nulliparous women. Kahrs et al (29) reported that a head-perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of unsuccessful vaginal delivery and the need for caesarean delivery.

Our group (30) reported that an angle of progression with pushing < 153º presents a sensitivity of 86.9% for the identification of complicated operative vaginal deliveries (understanding as ‘complicated operative delivery’ those cases when ate least one of the following situations occurred: three or more tractions needed; a third-/fourth-degree perineal tear; significant bleeding during the episiotomy repair; a major tear; or significant

traumatic neonatal lesion).

~~To the date, previous studies assessing predictive models for complicated vaginal deliveries have not included fetal characteristics, such as estimated fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).~~

~~Taking this into account, we propose an evaluation of the predictive capacity of intrapartum transperineal ultrasound parameters associated with fetal characteristics for the identification of We sought to develop a model to predict complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women.~~

To date, previous studies assessing predictive models for complicated vaginal deliveries have not included fetal characteristics, such as fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

Taking this into account, we sought to develop a model to predict complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women.

~~**Material and Methods:**~~

~~This was a prospective observational study of nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation, who required the use of vacuum or forceps to complete the fetal extraction. The study was performed between May 2016 and June 2017 in Valme's University Hospital Maternity Unit in Seville, Spain. The study (PI-~~

~~232013) was approved by the local Ethics and Research Committees (May 2015).~~

~~Inclusion criteria were: at term nulliparous women with uncomplicated pregnancies who required operative vaginal delivery (forceps or vacuum) to complete fetal extraction. Indications for operative delivery were: non-reassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in cases of prolonged fetal bradycardia or late heart-rate decelerations with absent fetal heart-rate variability. Operative deliveries were performed by obstetricians with more than 4 years of experience in instrumental operative vaginal deliveries. All forceps deliveries were performed using Kielland's forceps, while for all vacuum assisted deliveries the same model of rigid metal vacuum was used (Bird´s cup n° 5). The fetal head station was assessed by digital examination transvaginal digital examination for low or outlet instrumental operative vaginal deliveries, as defined by the American College of Obstetricians and Gynecologists (14). Subsequently, a transabdominal ultrasound was performed to monitor the fetal head position. Managing obstetricians were different from those performing the intrapartum transperineal ultrasound and were blinded to the sonographic data registered. The intrapartum transperineal ultrasound was performed exclusively by a group of five obstetricians (J.S, C.B, P.F, A.A, J.G-M) who had demonstrated competency for this type of ultrasound examination (30).~~

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~~Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide an informed consent before being enrolled in the study. Once the patient had signed the informed consent, the intrapartum transperineal ultrasound was performed as described below. When one of the listed indications for the operative vaginal delivery occurred, the~~

managing obstetrician chose the instrument that considered most appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokio, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while fetal biparietal diameter (BPD) and fetal head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in semirecumbent position, with an empty bladder and ruptured membranes. The probe was placed between the labia, below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (Table 1. **Figures 2, 3 and 4)**: Angle of Progression (AoP) and Progression-Distance (PD), evaluated on the longitudinal plane, and Midline-Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression, Progression-Distance and Midline-Angle were assessed at rest (AoP1, PD1, MLA1) and concurrently with contraction and active pushing (AoP2, PD2, MLA2). Angle of Progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading edge of the bony part of the fetal head. Progression-Distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline-Angle is defined as the angle between the anteroposterior axis of the pelvis and foetal brain midline. Intrapartum transperineal ultrasound measurements were obtained according to previously published technique.

~~The following demographic and obstetric data were recorded: maternal age, gestational age at delivery; body mass index (BMI); obstetric history; duration of first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight and gender. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (37) and postpartum haemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial haemorrhage, clavicle fracture) and admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, risk of neonatal sepsis).~~

~~An operative delivery was classified as complicated when one or more of the following situations occurred (30,38): three or more tractions were required to complete fetal extraction (39), failed attempt at operative vaginal delivery, third or higher degree perineal tear according to Sultan's classification (37), major tear reported by the obstetrician, significant bleeding during the episiotomy repair confirmed by a decrease in the haemoglobin level of ≥2.5 g/dL following the delivery (40), or a significant traumatic neonatal lesion.~~

Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide informed consent before being enrolled in the study. Once the patient had provided signed informed consent, the intrapartum transperineal ultrasound was performed as described below. When one of the listed indications for operative vaginal delivery occurred, the

managing obstetrician chose the instrument that was considered most appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while ~~fetal~~ biparietal diameter (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in semirecumbent position, with an empty bladder and ruptured membranes. The probe was placed between the labia below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (Table 1. **Figures 2, 3 and 4)**: Angle of Progression (AoP) and Progression-Distance (PD) evaluated on the longitudinal plane and Midline-Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression, Progression-Distance and Midline-Angle were assessed at rest (AoP1, PD1, and MLA1, respectively) and concurrently with contraction and active pushing (AoP2, PD2, and MLA2, respectively). Angle of Progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading edge of the bony part of the fetal head. Progression-Distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline-Angle is defined as the angle between the anteroposterior axis of the pelvis and fetal brain midline. Intrapartum transperineal ultrasound measurements were obtained according to previously published technique.

The following demographic and obstetric data were recorded: maternal age; gestational age at delivery; body mass index (BMI); obstetric history; duration of first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight; and gender. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (37) and postpartum hemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial hemorrhage, clavicle fracture or peripheral and cranial nerve injuries) and admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, or risk of neonatal sepsis).

An operative delivery was classified as complicated when one or more of the following situations occurred (30,38): three or more tractions were required to complete fetal extraction (39); failed operative vaginal delivery; third or higher degree perineal tear according to Sultan's classification (37); major tear reported by the obstetrician; significant bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin level of ≥2.5 g/dL following delivery (40); or a significant traumatic neonatal lesion (subdural and intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries)(30,38).

~~Statistical analyses.~~

We determined the mean and standard deviations for numeric variables, and the percentage for qualitative variables. Comparisons of numeric variables between complicated and uncomplicated operative vaginal delivery were performed using Student´s t-test. Comparison of qualitative variables between study groups was performed using a chi-square test. Individual predictive capabilities were evaluated using the receiver operating characteristics (ROC) curve and the area under the curve (AUC). The level of significance was established at 95% CI ($P<0.05$). All statistical comparisons were conducted using two-sided test, and P < 0.005 was considered to be statistically significant for all comparisons. Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY).

Evaluation of logistic regression models.

We designed generated different multivariate binary logistic regression models, using non-automated methods to predict a complicated operative vaginal delivery, including intrapartum transperineal ultrasound parameters and estimated fetal weight, fetal biparietal diameter and fetal head circumference. These were added progressively according to how simple their evaluation was, and to their predictive capacity for the identification of a complicated operative delivery. We carried out and compared 6 binary logistic regression models (**Table 2):** We performed a goodness-o-fit test did a goodness of fit test (-2 log likelihood) and Hosmer and Lemeshow test for each model. Afterwards, C of Harrell was determined for those models with an adequate fit, in order to evaluate their discriminatory capacity (obtained as the area under the ROC curve of the predicted probabilities given by the model) and the slope and calibration graphic. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and

~~interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform Shrinkage factor. Once the definite multivariate binary regression model was identified, we developed a software for the prediction of complicated operative vaginal deliveries (vacuum and forceps) with the aim of making it applicable to clinical practice.~~

Statistical analyses.

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~~**Results:**~~

~~**Study Population.**~~

~~We recruited 84 nulliparous, out of which 5 cases have been excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. We have evaluated 79 cases of nulliparous who required instrumentation operative vaginal assisted to complete the fetal extraction (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).~~

~~48 cases were classified as 'uncomplicated operative vaginal deliveries' (28 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 as 'complicated operative~~

vaginal deliveries' (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Out of the 31 cases of complicated operative vaginal deliveries, a third-degree perineal tear occurred in 6 cases (19.35 %). In 7 cases (22.5%), significant bleeding while repairing the episiotomy was noted and confirmed by a decrease of ≥ 2.5 g/dL in the maternal haemoglobin level. Three or more tractions were performed in 18 cases (58.06%).

Regarding maternal and neonatal demographic data, significant differences were noted between uncomplicated and complicated operative vaginal deliveries, in; fetal weight, biparietal diameter, head circumference, gender and birth weight **(Table 3)**

The proportion of occiput posterior position was 13.6% (13 cases); the main indication for operative vaginal delivery was failure to progress in labor 60.75% (48 cases), and 76.2% (74 cases) required the performance of mediolateral episiotomy. Four cases (12.9%) out of the group of complicated operative vaginal deliveries required a caesarean section to complete fetal extraction. There was one newborn who required admission to the neonatal unit (case of mild respiratory distress).

Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal deliveries.

Significant differences were observed between the uncomplicated and complicated operative vaginal deliveries cases regarding Angle of Progression at rest, Progression Distance at rest, Midline-Angle at rest, Angle of Progression with pushing and Progression Distance with pushing, with no statistically significant difference found in the Midline-Angle with pushing **(Table 4)**. The complicated operative vaginal delivery group required a significantly higher number of tractions (4.2±1.0) than the uncomplicated operative vaginal delivery group (1.4±0.5).

~~Predictive models of complicated deliveries.~~

~~We have determined several binary logistic regression models to predict and explain complicated operative vaginal deliveries. It was observed that the models presented Harrell's C statistic values that oscillating between 0.863 and 0.876, determined as an area under the ROC curve of the predicted probabilities. The model of binary logistic regression that identified the variables "Angle of progression with pushing" and "head circumference " as predictors of a complicated operative vaginal delivery was chosen, as these variables were the ones included in the final multivariate analysis, shown in **Table 5**. Harrell's C statistic, obtained from the area under the ROC curve of the predicted probabilities by the model was 0.876 (95% CI 0.790 to 0.963), 0.876 (95%CI 0.790-0.963; p<0.0005), i.e. an intern discriminatory capacity >0.75, the same as the model adjusted by the Shrinkage uniform model, in which C results equivalent to 0.876 (95% CI 0.789 to 0.963)), 0.876 (95%CI 0.790-0.963; p<0.0005), **(Figures 5 and 6)**. The calibration study of the selected model was performed by calculating the calibration slopes (0.984 and 1.064 in the original and Shrinkage models, respectively) slope B 0.984 (95%CI 0.0.726-1.243; p<0.0005). Pearson linear correlation coefficients (0.906 and 0.849) (**Figures 7 and 8).**~~

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significantly higher number of tractions (4 tractions) than the uncomplicated operative vaginal delivery group (1 traction).

Predictive models of complicated deliveries.

We determined several binary logistic regression models to predict and explain complicated operative vaginal deliveries. We observed that the models presented Harrell's C statistic values oscillating between 0.863 and 0.876, determined as the area under the ROC curve of the predicted probabilities. The model of binary logistic regression that identified the variables "Angle of progression with pushing" and "head circumference" as predictors of complicated operative vaginal delivery was chosen, as these variables were included in the final multivariate analysis, which is shown in **Table 5**. Harrell's C statistic, which was obtained from the area under the ROC curve of the predicted probabilities by the model, was 0.876 (95% CI 0.790-0.963; p<0.0005), i.e., an intern discriminatory capacity >0.75, which is the same as the values obtained for the model adjusted by the Shrinkage uniform model, in which the C results were equivalent to 0.876 (95% CI 0.790-0.963; p<0.0005), (**Figures 5 and 6)**. The calibration study of the selected model was performed by calculating the calibration slope B-0.984 (95% CI 0.0.726-1.243; p<0.0005). Pearson linear correlation coefficients were also calculated (0.906 and 0.849) (**Figures 7 and 8).**

Comment.

Principal findings.

The main finding of our study is the identification of a predictive model for complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women that includes both fetal (fetal weight, biparietal diameter, head circumference) and intrapartum transperineal ultrasound (Angle of Progression, Progression Distance, Midline-Angle) parameters, and which is easy to use in the delivery room. This multivariate study, which follows principles of "interpretability" and "parsimony" (simplicity), has allowed us to identify a binary model based on progression angle with pushing and head circumference, which has proved to predict a complicated operative vaginal delivery (87.6%). We observed significant association between this binary model and the presence of: need of three or more tractions to complete fetal extraction, failed attempt at operative vaginal delivery, third or higher degree perineal tear, significant bleeding during the episiotomy or a significant traumatic neonatal lesion.

We believe one of the strengths of the study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that can be frequently found in most delivery units worldwide. Thus, the technique is generalizable. The Angle of Progression has proven to be easy to evaluate and to be very useful for this purpose (30). It is known that the fetal weight and the fetal head circumference are risk factors for caesarean and operative deliveries (31-33), and therefore their evaluation should be included in the assessment for the prediction of success of instrumentation. Fetal Head circumference presents an adequate correlation with the difficulty of an instrumental delivery and the probability of failure and need for caesarean

section (31,33,41). Its evaluation in the delivery room seems to be feasible, although we believe that the reproducibility of its measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) should be assessed in future studies.

On the other hand, estimated fetal weight is more difficult to evaluate and presents a higher error rate (42-44). We believe that new studies, including larger number of cases should evaluate the usefulness of our binary model for the prediction of complicated operative vaginal deliveries.

Clinical significance. Implications

By applying the predictive model proposed, any obstetrician could easily predict what kind of operative vaginal delivery he or she will encounter at the delivery room, as a variation in the fetal head circumference could well shift the situation from an uncomplicated operative vaginal delivery, 1 or 2 tractions needed, (if an angle of progression with a 146º push is observed from the intrapartum transperineal ultrasound) to a complicated operative vaginal delivery, requiring 3 or 4 instrumental pulls to complete fetal extraction (if an angle of progression with push of 115º is identified) **(Figure 9) (video 1).**

Research Implications

Knowing that digital examination vaginal exploration presents a high rate of error (20-75%) for the identification of the level of the fetal presentation (ACOG fetal station) and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in delivery rooms in order to improve the assessment of the progression and finalization of the delivery. In this line, Kalache et al. (45) reported that an angle of progression ≥120° is

associated with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility of intrapartum ultrasound for the evaluation of fetal head position before instrumentation. of operative vaginal delivery

Instrumental Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13) especially when a caesarean section is required due to a failed attempt of instrumental operative vaginal delivery. An emergency C-section cesarean delivery after a failed vacuum assisted delivery is associated with an intracranial haemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 per 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice in order to enable the prediction of difficulty and possible complications of instrumental operative vaginal deliveries. Bultez et al. (25) observes that an angle of progression <145º (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) is associated with a higher rate of failed attempt of vacuum delivery. Kahrs et al (29) finds that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% risk of an emergency cesarean section delivery.

Kasbaoui et al (47) in a prospective cohort study including 659 women, the HPD head-perineum distance (in this study referred to as the perineum-skull distance) was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (48) identified that a cutoff of 142° for the angle of progression was a predictor for complicated operative vaginal deliveries, consistent with our study (30),

~~which identifies an angle of progression with pushing <153.5º as a predictor for complicated operative deliveries (sensitivity 86.9%).~~

~~Several authors have expressed their interest in predicting the kind of vaginal operative delivery they will encounter and the risk for caesarean section delivery (49-51). Their work has associated mainly different maternal and fetal parameters; with sonographic parameters only being taken into account in the recent studies. Their efforts have been focused on the prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of labor. Thus Burker et al (50) present a predictive model of caesarean risk based on five parameters (maternal age, body mass index, height, fetal abdominal circumference, and fetal head circumference) evaluated in the first stage of labor, and with a calibration and discriminative ability with a misclassification rate of 0.21. With the same purpose of predicting the probability of a vaginal delivery vs need for caesarean section, Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation, and presents a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal body mass index), all evaluated during the first stage of labor, and with an ARC of 0.853.~~

~~We have observed a significant difference in fetal sex between study groups (62.5% of female fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated operative vaginal deliveries). In 5.9% of cases we have not been able to measure the fetal head circumference during the second stage of labor with the fetal head already engaged in the maternal pelvis.~~

~~Nonetheless, our predictive model, unlike previously proposed models predictors previamente publicados (25,60,61) para la predicción de la complicated or dificultad of~~

~~operative vaginal delivery~~, ~~presents the following characteristics: 1. it can be used in the delivery room itself, 2. Provides a quick evaluation, since only 2 ultrasound parameters are involved, and 3. it appears to be easy to perform.~~

Comment.

Principal findings.

The main finding of our study is the identification of a predictive model for complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women that includes both fetal (fetal weight, biparietal diameter, head circumference) and intrapartum transperineal ultrasound (Angle of Progression, Progression Distance, Midline-Angle) parameters and that is easy to use in the delivery room. This multivariate study, which follows principles of "interpretability" and "parsimony" (simplicity), has allowed us to identify a binary model based on progression angle with pushing and head circumference, which has been proven to predict complicated operative vaginal delivery (87.6%). We observed a significant association between this binary model and the need for three or more tractions to complete fetal extractions, failed attempts at operative vaginal delivery, third or higher degrees of perineal tears, significant bleeding during episiotomy or a significant traumatic neonatal lesion.

We propose that one of the strengths of this study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that is frequently found in most delivery units worldwide. Thus, this technique is generalizable. The Angle of Progression has proven to be easy to evaluate and is very useful for this purpose (30). The fetal weight and head circumference are risk factors for

caesarean and operative deliveries (31-33); therefore, the evaluation of these parameters should be included in the assessment for the prediction of the success of instrumentation. Head circumference presents an adequate correlation with the difficulty of an instrumental delivery, the probability of failure and the need for caesarean delivery (31,33,41). The evaluation of head circumference in the delivery room seems to be feasible, although we believe that the reproducibility of its measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) should be assessed in future studies.

However, fetal weight is more difficult to evaluate and presents a higher error rate (42-44). We propose that new studies, which will include a larger number of cases, should be conducted to evaluate the usefulness of our binary model for the prediction of complicated operative vaginal deliveries.

Clinical Implications

By applying the predictive model proposed, any obstetrician could easily predict the kind of operative vaginal delivery that he or she will encounter in the delivery room, as a variation in the head circumference could shift the situation from an uncomplicated operative vaginal delivery, where 1 or 2 tractions are needed (when an angle of progression with a push of 146° is identified by intrapartum transperineal ultrasound) to a complicated operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an angle of progression with push of 115° is identified) **(Figure 9) (video 1).**

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Knowing that digital examination presents a high rate of error (20-75%) for the

identification of the level of fetal presentation (ACOG fetal station) and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the delivery room to improve the assessment of the progression and finalization of delivery. Based on this, Kalache et al. (45) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility of intrapartum ultrasound for the evaluation of fetal head position before operative vaginal delivery.

Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13), especially when a caesarean delivery is required due to a failed operative vaginal delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to enable the prediction of difficulty and possible complications of operative vaginal deliveries. Bultez et al. (25) observed that an angle of progression <145° (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated with a higher rate of failed vacuum delivery. Kahrs et al (29) found that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% risk of an emergency cesarean delivery.

Kasbaoui et al (47) carried out a prospective cohort study including 659 women, in which the head-perineum distance (in this study referred to as the perineum–skull distance) was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with

the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (48) identified that a cutoff of 142° for the angle of progression was a predictor for complicated operative vaginal deliveries, which is consistent with the results of our study (30), which identified an angle of progression with pushing <153.5° as a predictor for complicated operative deliveries (sensitivity 86.9%).

Several authors have expressed their interest in predicting the kind of vaginal operative delivery they will encounter and the risk for caesarean delivery (49-51). Their work has mainly associated different maternal and fetal parameters with sonographic parameters that have only been taken into account in recent studies. Their efforts have been focused on the prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of labor. Thus, Burker et al (50) present a predictive model of caesarean risk based on five parameters (maternal age, body mass index, height, fetal abdominal circumference, and fetal head circumference) evaluated in the first stage of labor, with calibration and discriminative ability and a misclassification rate of 0.21. With the same purpose of predicting the probability of vaginal delivery vs the need for caesarean delivery, Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation and presents a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal body mass index), which are all evaluated during the first stage of labor, with an ARC of 0.853.

We observed a significant difference in fetal sex between study groups (62.5% of female fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head circumference during the second stage of labor with the fetal head already engaged in the

maternal pelvis.

Nonetheless, our predictive model, unlike previously published models (25, 60, 61) for the prediction of complicated or difficult operative deliveries, presents the following characteristics: 1. the model can be used in the delivery room itself; 2. the model provides a quick evaluation since only 2 ultrasound parameters are involved; and 3. the model appears to be easy to perform.

~~**Strenghts and limitations**~~

~~Our study has several strengths. Our study including a large series of deliveries at high-risk of ending up in complicated operative vaginal deliveries (i.e. nulliparous women and occipito-posterior position) (52,53), including both instruments (vacuum and forceps), and being evaluated by intrapartum transperineal ultrasound. Moreover, the population included in the study is representative of pregnant women who require instrumentation operative vaginal assisted to complete fetal extraction, including the main indications for operative vaginal deliveries, such as non-reassuring fetal heart rate, failure to progress of labor or maternal exhaustion. Regarding the method, operative vaginal deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice. Intrapartum transperineal ultrasound was performed by experienced sonographers with specific training in pelvic floor and intrapartum transperineal ultrasound. Lastly we identified an adequate predictive model for complicated operative vaginal deliveries that we consider easy to apply in the delivery room, since it only involves 2 elements, a fetal~~

~~ultrasound parameter (head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proved to be useful in the identification of difficult in operative vaginal deliveries (24-30).~~

~~We consider as limitations of our work: the fact that we have not evaluated head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery should be designed for this purpose.~~

~~We consider that the main limitation of our work is the fact that we have not evaluated the head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery. In addition, we believe that reproducibility of head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proved. External validation of the predictive model should be also carried out. We consider that including other types of forceps, and not only Kiellands forceps, and using more objective parameters to classify a delivery as a 'complicated operative vaginal delivery' such as: need for maternal blood transfusion, traumatic fetal lesion or a cup detachment, are factors that should be taken into account in future works. Lastly, we believe that as our study was underpowered to detect neonatal and maternal morbidity, and therefore further studies should be designed for this purpose.~~

Strengths and limitations

This study has several strengths. First, our study includes a large series of deliveries at high risk of ending up in complicated operative vaginal deliveries (i.e., nulliparous women and occipito-posterior position) (52,53); the use of two types of instruments (vacuum and forceps); and an evaluation by intrapartum transperineal ultrasound. Moreover, the

population included in this study is representative of pregnant women who require operative vaginal delivery to complete fetal extraction, including the main indications for operative vaginal deliveries, such as nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Regarding the method, operative vaginal deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice. Intrapartum transperineal ultrasound was performed by experienced sonographers with specific training in pelvic floor and intrapartum transperineal ultrasound. Lastly, we identified an adequate predictive model for complicated operative vaginal deliveries that we consider easy to apply in the delivery room since it only involves 2 elements, a fetal ultrasound parameter (head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proven to be useful in the identification of difficult operative vaginal deliveries (24-30).

We consider the following as limitations of our work: the fact that we did not evaluate head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery; this parameter should be designed for this purpose.

We consider that the main limitation of our work is that we did not evaluate the head-perineum distance, which currently seems to be a very useful ultrasound parameter to predict the difficulty of vaginal delivery, in our predictive model. In addition, we believe that the reproducibility of head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proven. The external validation of the predictive model should also be carried out. We consider that including other types of forceps, not only Kielland's forceps, and using more objective parameters to classify a delivery as a 'complicated operative vaginal delivery', such as the

need for maternal blood transfusion, traumatic fetal lesion or cup detachment, are factors that should be taken into account in future studies. Lastly, we believe that, as our study was underpowered to detect neonatal and maternal morbidity, further studies for the assessment of these parameters should be carried out.

Conclusion.

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Conclusion.

~~The predictive model including angle of progression and fetal head circumference has adequate predictive capacity of complicated operative deliveries (87.5%), and can be performed in the delivery room.~~

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Acknowledgments.

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A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS.

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- **CONDENSATION, AJOG AT A GLANCE, SHORT VERSION OF TITLE**

- **CONDENSATION.**

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries.

- **AJOG AT A GLANCE**

- A. Why was this study conducted?

- Operative vaginal deliveries are associated with a high maternal and neonatal morbidity.
- We sought to develop a model to predict complicated operative deliveries and compare the performance of our model with others previously reported in the literature

- B. What are the key findings?

A predictive model based on the angle of progression and head circumference has an identifying capacity of 87.5% for complicated operative deliveries

- C. What does this study add to what is already known?

- We report a simple and rapid predictive model for complicated operative deliveries. The model requires only two parameters that can be easily obtained with intrapartum sonography (angle of progression and head circumference).
- The predictive ability of the model is superior to other models previously reported (87% vs a range of 56-67%).
- This model can be implemented in any labor and delivery unit.

- **Short version of title.**

A simple predictive model for complicated operative vaginal deliveries.

Abstract:

BACKGROUND:

Complicated operative vaginal deliveries are associated with a high neonatal morbidity and maternal trauma, especially if the procedure is unsuccessful and a caesarean delivery is needed to complete fetal extraction. The decision to perform an operative vaginal delivery has traditionally been based on a subjective assessment by digital vaginal examination, combined with the clinical expertise of the obstetrician carrying out the delivery. To date, there is no method of objectively quantifying the likelihood of a successful delivery. Intrapartum ultrasound has the potential to improve precision in the assessment and management of operative deliveries.

OBJECTIVE: The aim of this study was to compare predictive models for the identification of complicated operative vaginal deliveries(vacuum or forceps) based on intrapartum transperineal ultrasound in nulliparous women.

Study design: We performed a prospective cohort study in nulliparous women at term, with singleton pregnancies and, at full dilatation who underwent intrapartum transperineal ultrasound evaluation prior to operative vaginal delivery. Managing obstetricians were blinded to the ultrasound data. Intrapartum transperineal ultrasound (Angle of Progression, Progression-Distance, and Midline-Angle) was performed immediately before instrument application, both at rest and concurrently with pushing. The intrapartum evaluation of fetal biometric parameters was also carried out (fetal weight, head circumference and biparietal diameter). An operative vaginal delivery was classified as 'complicated' when one or more of the following situations occurred: ≥3 tractions

needed to complete fetal extraction; 3-4th degree perineal tear; substantial bleeding during the episiotomy repair(decrease in the hemoglobin level of ≥2.5g/dL); or substantial traumatic neonatal lesion(subdural-intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries). Six predictive models were evaluated (information available in Table 2).

Results: We recruited 84 nulliparous, of which 5 cases were excluded due to the difficulty of adequately evaluating the biparietal diameter and head circumference. A total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in occiput-posterior position. We identified 31 cases of complicated operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified in obstetric, neonatal or intrapartum characteristics between the two study groups(operative uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the following exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*P*=.001), biparietal diameter(93.2±2.1 versus 95.2±2.3 mm;*P*=.001), head circumference(336±12 versus 348±6.4 mm;*P*=.001), gender(female 62.5% versus 29.0%;*P*=.010), newborn weight(3,258±472g versus 3,499±383g;*P*=.027) and number of tractions (median, IQR) (1 (1 to 2)versus 4 (3 to 5);*P*<.0005). To predict complicated operative deliveries, all 6 of the studied models presented an area under ROC curve between 0.863 and 0.876(95% CI 0.775-0.950 and 0.790-0.963;p<0.0005). The results of the study met the criteria of "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic regression model based on angle of progression and head circumference, which has an area

under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope of B-0.984 (95% CI 0.0.726-1.243; p<0.0005).

Conclusion:

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

Keywords: Labor; complication; operative vaginal delivery; vacuum extraction; cesarean delivery; biomarker; birth trauma; neonatal injury; perineal laceration; postpartum hemorrhage.

Introduction

Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of difficult operative vaginal deliveries and caesarean deliveries performed after failed operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than the rate associated with spontaneous vaginal birth (8).

According to standard clinical practice guidelines, operative vaginal deliveries must only be performed if the fetal head is engaged and has reached at least +0 cm, with only experienced obstetricians performing mid-forceps deliveries (14,15). Thus far, the decision to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on digital examination (14,15). However, digital exploration is a subjective and unreliable tool for this purpose (16-19). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to help predict the progression and finalization of delivery [spontaneous vs. need for operative vaginal delivery to complete fetal extraction (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of complicated operative vaginal deliveries and to identify cases with a high probability of requiring caesarean delivery due to failed operative vaginal delivery (22-30). To date, few studies have evaluated the usefulness of intrapartum transperineal ultrasound for this purpose (23-30).

Bultez et al (25) reported that an angle of progression less than 145.5° has a sensitivity of

86.2%, specificity of 49% and positive predictive value of 24% for the prediction of vacuum extraction failure in nulliparous women. Kahrs et al (29) reported that a head-perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of unsuccessful vaginal delivery and the need for caesarean delivery.

Our group (30) reported that an angle of progression with pushing < 153º presents a sensitivity of 86.9% for the identification of complicated operative vaginal deliveries (understanding as 'complicated operative delivery' those cases when ate least one of the following situations occurred: three or more tractions needed; a third-/fourth-degree perineal tear; significant bleeding during the episiotomy repair; a major tear; or significant traumatic neonatal lesion).

To date, previous studies assessing predictive models for complicated vaginal deliveries have not included fetal characteristics, such as fetal weight or head circumference, which are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

Taking this into account, we sought to develop a model to predict complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women.

Materials and Methods:

This was a prospective observational study in nulliparous women with singleton pregnancy at ≥ 37 weeks gestation and cephalic presentation, who required the use of vacuum or forceps to complete fetal extraction. The study was performed between May 2016 and June 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

The inclusion criteria were at term nulliparous women with uncomplicated pregnancies who required operative vaginal delivery (forceps or vacuum) to complete fetal extraction. The indications for operative delivery were nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in cases of prolonged fetal bradycardia or late heart-rate decelerations with absent fetal heart-rate variability. Operative deliveries were performed by obstetricians with more than 4 years of experience in operative vaginal deliveries. All forceps deliveries were performed using Kielland's forceps, while, for all vacuum-assisted deliveries, the same model of rigid metal vacuum was used (Bird´s cup n° 5). The fetal head station was assessed by digital examination for low or outlet operative vaginal deliveries, as defined by the American College of Obstetricians and Gynecologists (14). Subsequently, a transabdominal ultrasound was performed to monitor the fetal head position. Managing obstetricians were different from those performing the intrapartum transperineal ultrasound and were blinded to the sonographic data registered. The intrapartum transperineal ultrasound was performed exclusively by a group of five obstetricians (J.S, C.B, P.F, A.A, and J.G-M) who had demonstrated competency for this type of ultrasound examination (30).

Whenever a potentially eligible woman was identified at our maternity unit during the beginning of labor, she was invited to participate in the trial and was asked to provide informed consent before being enrolled in the study. Once the patient had provided signed informed consent, the intrapartum transperineal ultrasound was performed as described below. When one of the listed indications for operative vaginal delivery occurred, the managing obstetrician chose the instrument that was considered most appropriate for the clinical circumstance and his/her skill level (14).

Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo, Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was estimated (EFW) by intrapartum transabdominal ultrasound, while ~~fetal~~ biparietal diameter (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

Intrapartum transperineal ultrasound was performed with the woman in semirecumbent position, with an empty bladder and ruptured membranes. The probe was placed between the labia below the pubic symphysis. The following intrapartum parameters were assessed by transperineal ultrasound (20,36) (**Table 1. Figures 2, 3 and 4)**: Angle of Progression (AoP) and Progression-Distance (PD) evaluated on the longitudinal plane and Midline-Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression, Progression-Distance and Midline-Angle were assessed at rest (AoP1, PD1, and MLA1, respectively) and concurrently with contraction and active pushing (AoP2, PD2, and MLA2, respectively). Angle of Progression is defined as the angle between a line through the midline of the pubic symphysis and another line from the anterior margin of the pubic symphysis to the leading edge of the bony part of the fetal head. Progression-Distance is defined as the distance between the infrapubic line (the line through the inferior margin of the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line through the deepest bony part of the fetal head. Midline-Angle is defined as the angle between the anteroposterior axis of the pelvis and fetal brain midline. Intrapartum transperineal ultrasound measurements were obtained according to previously published technique.

The following demographic and obstetric data were recorded: maternal age; gestational age

at delivery; body mass index (BMI); obstetric history; duration of first and second stages of labor; indication for operative delivery; number of tractions performed; need for episiotomy; birth weight; and gender. Data on the following maternal and neonatal morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan's classification of perineal tears) (37) and postpartum hemorrhage; Apgar scores after one and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma, intracranial hemorrhage, clavicle fracture or peripheral and cranial nerve injuries) and admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, or risk of neonatal sepsis).

An operative delivery was classified as complicated when one or more of the following situations occurred (30,38): three or more tractions were required to complete fetal extraction (39); failed operative vaginal delivery; third or higher degree perineal tear according to Sultan's classification (37); major tear reported by the obstetrician; significant bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin level of ≥2.5 g/dL following delivery (40); or a significant traumatic neonatal lesion (subdural and intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries to spine and spinal cord, or peripheral and cranial nerve injuries)(30,38).

Statistical analyses.

We determined the mean and standard deviation for numeric variables and the percentage for qualitative variables. Comparisons of the numeric variables between complicated and uncomplicated operative vaginal deliveries were performed using Student´s t-test. Comparison of qualitative variables between study groups was performed using a chi-

square test. Individual predictive capabilities were evaluated using the receiver operating characteristics (ROC) curve and the area under the curve (AUC). All statistical comparisons were performed using two-sided test, and $P < 0.005$ was considered statistically significant for all comparisons. Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM, Armonk, NY).

Evaluation of logistic regression models.

We generated different multivariate binary logistic regression models using non-automated methods to predict complicated operative vaginal delivery, including intrapartum transperineal ultrasound parameters and fetal weight, biparietal diameter and head circumference. These parameters were added progressively according to the simplicity of their evaluation and their predictive capacity for the identification of a complicated operative delivery. We carried out and compared 6 binary logistic regression models (**Table 2)**. We performed a goodness-o-fit test (-2 log likelihood) and Hosmer and Lemeshow test for each model. Afterwards, C of Harrell was determined for those models with an adequate fit to evaluate their discriminatory capacity (obtained as the area under the ROC curve of the predicted probabilities given by the model) and the slope and calibration graphic. The final model was chosen according to its discriminatory capacity and calibration graphic, in line with parsimony and interpretability principles. The models were calibrated by calculating calibration slopes and graphs. The last two analyses were performed based on the original model and the model adjusted for a uniform Shrinkage factor. Once the definite multivariate binary regression model was identified, we developed a software for the prediction of complicated operative vaginal deliveries (vacuum and forceps) with the aim of making it applicable to clinical practice.

Results:

Study Population.

We recruited 84 nulliparous, out of which 5 cases were excluded due to the difficulty of adequately evaluating the biparietal diameter and fetal head circumference. We evaluated 79 cases of nulliparous who required operative vaginal assistance to complete the fetal extraction (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).

48 cases were classified as 'uncomplicated operative vaginal deliveries' (28 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 were classified as 'complicated operative vaginal deliveries' (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Out of the 31 cases of complicated operative vaginal deliveries, a third-degree perineal tear occurred in 6 cases (19.35 %). In 7 cases (22.5%), significant bleeding while repairing the episiotomy was noted and confirmed by a decrease of ≥ 2.5 g/dL in the maternal hemoglobin level. Three or more tractions were performed in 18 cases (58.06%).

Regarding maternal and neonatal demographic data, significant differences were noted between uncomplicated and complicated operative vaginal deliveries, in fetal weight, biparietal diameter, head circumference, gender and birth weight **(Table 3).**

The proportion of occiput posterior position was 13.6% (13 cases); the main indication for operative vaginal delivery was failure to progress in labor 60.75% (48 cases), and 76.2% (74 cases) required the performance of mediolateral episiotomy. Four cases (12.9%) out of the group of complicated operative vaginal deliveries required a caesarean section to complete fetal extraction. There was one newborn who required admission to the neonatal unit (case of mild respiratory distress).

Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal deliveries.

Significant differences were observed between the uncomplicated and complicated operative vaginal delivery cases regarding Angle of Progression at rest, Progression Distance at rest, Midline-Angle at rest, Angle of Progression with pushing and Progression Distance with pushing, with no statistically significant difference found in the Midline-Angle with pushing **(Table 4)**. The complicated operative vaginal delivery group required a significantly higher number of tractions (4 tractions) than the uncomplicated operative vaginal delivery group (1 traction).

Predictive models of complicated deliveries.

We determined several binary logistic regression models to predict and explain complicated operative vaginal deliveries. We observed that the models presented Harrell's C statistic values oscillating between 0.863 and 0.876, determined as the area under the ROC curve of the predicted probabilities. The model of binary logistic regression that identified the variables "Angle of progression with pushing" and "head circumference" as predictors of complicated operative vaginal delivery was chosen, as these variables were included in the final multivariate analysis, which is shown in **Table 5**. Harrell's C statistic, which was obtained from the area under the ROC curve of the predicted probabilities by the model, was 0.876 (95% CI 0.790-0.963; $p<0.0005$), i.e., an intern discriminatory capacity >0.75, which is the same as the values obtained for the model adjusted by the Shrinkage uniform model, in which the C results were equivalent to 0.876 (95% CI 0.790-0.963; $p<0.0005$), (**Figures 5 and 6)**. The calibration study of the selected model was performed by calculating the calibration slope B-0.984 (95% CI 0.0.726-1.243; $p<0.0005$). Pearson linear

correlation coefficients were also calculated (0.906 and 0.849) (**Figures 7 and 8).**

Comment.

Principal findings.

The main finding of our study is the identification of a predictive model for complicated operative vaginal deliveries (vacuum and forceps) in nulliparous women that includes both fetal (fetal weight, biparietal diameter, head circumference) and intrapartum transperineal ultrasound (Angle of Progression, Progression Distance, Midline-Angle) parameters and that is easy to use in the delivery room. This multivariate study, which follows principles of "interpretability" and "parsimony" (simplicity), has allowed us to identify a binary model based on progression angle with pushing and head circumference, which has been proven to predict complicated operative vaginal delivery (87.6%). We observed a significant association between this binary model and the need for three or more tractions to complete fetal extractions, failed attempts at operative vaginal delivery, third or higher degrees of perineal tears, significant bleeding during episiotomy or a significant traumatic neonatal lesion.

We propose that one of the strengths of this study is based on the fact that transperineal ultrasound requires little training and can be undertaken with the type of ultrasound equipment that is frequently found in most delivery units worldwide. Thus, this technique is generalizable. The Angle of Progression has proven to be easy to evaluate and is very useful for this purpose (30). The fetal weight and head circumference are risk factors for caesarean and operative deliveries (31-33); therefore, the evaluation of these parameters should be included in the assessment for the prediction of the success of instrumentation.

Head circumference presents an adequate correlation with the difficulty of an instrumental delivery, the probability of failure and the need for caesarean delivery (31,33,41). The evaluation of head circumference in the delivery room seems to be feasible, although we believe that the reproducibility of its measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) should be assessed in future studies.

However, fetal weight is more difficult to evaluate and presents a higher error rate (42-44). We propose that new studies, which will include a larger number of cases, should be conducted to evaluate the usefulness of our binary model for the prediction of complicated operative vaginal deliveries.

Clinical Implications

By applying the predictive model proposed, any obstetrician could easily predict the kind of operative vaginal delivery that he or she will encounter in the delivery room, as a variation in the head circumference could shift the situation from an uncomplicated operative vaginal delivery, where 1 or 2 tractions are needed (when an angle of progression with a push of 146° is identified by intrapartum transperineal ultrasound) to a complicated operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an angle of progression with push of 115° is identified) **(Figure 9) (video 1).**

Research Implications

Knowing that digital examination presents a high rate of error (20-75%) for the identification of the level of fetal presentation (ACOG fetal station) and its degree of engagement (16-20), intrapartum transperineal ultrasound has been introduced in the

delivery room to improve the assessment of the progression and finalization of delivery. Based on this, Kalache et al. (45) reported that an angle of progression ≥120° is associated with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility of intrapartum ultrasound for the evaluation of fetal head position before operative vaginal delivery.

Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-13), especially when a caesarean delivery is required due to a failed operative vaginal delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical practice to enable the prediction of difficulty and possible complications of operative vaginal deliveries. Bultez et al. (25) observed that an angle of progression <145° (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated with a higher rate of failed vacuum delivery. Kahrs et al (29) found that in nulliparous women with a prolonged second stage of labor, a head-perineum distance of >35 mm is associated with a 22% risk of an emergency cesarean delivery.

Kasbaoui et al (47) carried out a prospective cohort study including 659 women, in which the head-perineum distance (in this study referred to as the perineum–skull distance) was measured prior to operative vaginal delivery. After adjustment for parity, presentation type and fetal macrosomia, head-perineum distance ≥40 mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (48) identified that a cutoff of 142° for the angle of progression was a

predictor for complicated operative vaginal deliveries, which is consistent with the results of our study (30), which identified an angle of progression with pushing <153.5° as a predictor for complicated operative deliveries (sensitivity 86.9%).

Several authors have expressed their interest in predicting the kind of vaginal operative delivery they will encounter and the risk for caesarean delivery (49-51). Their work has mainly associated different maternal and fetal parameters with sonographic parameters that have only been taken into account in recent studies. Their efforts have been focused on the prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of labor. Thus, Burker et al (50) present a predictive model of caesarean risk based on five parameters (maternal age, body mass index, height, fetal abdominal circumference, and fetal head circumference) evaluated in the first stage of labor, with calibration and discriminative ability and a misclassification rate of 0.21. With the same purpose of predicting the probability of vaginal delivery vs the need for caesarean delivery, Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation and presents a model based on six parameters (head-perineum distance, caput succedaneum, occiput posterior position, maternal age, gestational age, and maternal body mass index), which are all evaluated during the first stage of labor, with an ARC of 0.853.

We observed a significant difference in fetal sex between study groups (62.5% of female fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head circumference during the second stage of labor with the fetal head already engaged in the maternal pelvis.

Nonetheless, our predictive model, unlike previously published models (25, 50, 51) for the prediction of complicated or difficult operative deliveries, presents the following characteristics: 1. the model can be used in the delivery room itself; 2. the model provides a quick evaluation since only 2 ultrasound parameters are involved; and 3. the model appears to be easy to perform.

Strengths and limitations

This study has several strengths. First, our study includes a large series of deliveries at high risk of ending up in complicated operative vaginal deliveries (i.e., nulliparous women and occipito-posterior position) (52,53); the use of two types of instruments (vacuum and forceps); and an evaluation by intrapartum transperineal ultrasound. Moreover, the population included in this study is representative of pregnant women who require operative vaginal delivery to complete fetal extraction, including the main indications for operative vaginal deliveries, such as nonreassuring fetal heart rate, failure to progress in labor or maternal exhaustion. Regarding the method, operative vaginal deliveries were performed exclusively by senior obstetricians who had extensive experience in obstetric practice. Intrapartum transperineal ultrasound was performed by experienced sonographers with specific training in pelvic floor and intrapartum transperineal ultrasound. Lastly, we identified an adequate predictive model for complicated operative vaginal deliveries that we consider easy to apply in the delivery room since it only involves 2 elements, a fetal ultrasound parameter (head circumference) (31-33) and an intrapartum transperineal ultrasound parameter (angle of progression), which have proven to be useful in the identification of difficult operative vaginal deliveries (24-30).

We consider the following as limitations of our work: the fact that we did not evaluate head-perineum distance in our predictive model, which currently seems to be a very useful ultrasound parameter to predict the difficulty of a vaginal delivery; this parameter should be designed for this purpose.

We consider that the main limitation of our work is that we did not evaluate the head-perineum distance, which currently seems to be a very useful ultrasound parameter to predict the difficulty of vaginal delivery, in our predictive model. In addition, we believe that the reproducibility of head circumference measurement during the second stage of labor (when the fetal head is already engaged in the maternal pelvis) must be proven. The external validation of the predictive model should also be carried out. We consider that including other types of forceps, not only Kielland's forceps, and using more objective parameters to classify a delivery as a 'complicated operative vaginal delivery', such as the need for maternal blood transfusion, traumatic fetal lesion or cup detachment, are factors that should be taken into account in future studies. Lastly, we believe that, as our study was underpowered to detect neonatal and maternal morbidity, further studies for the assessment of these parameters should be carried out.

Conclusion.

The combination of the angle of progression and the head circumference can predict 87% of complicated operative vaginal deliveries and can be performed in the delivery room.

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