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Manuscript Number: W18-1107R2

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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Manuscript Region of Origin: SPAIN

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:  $\geq 3$  tractions needed; 3rd-4th degree perineal tear; severe bleeding during episiotomy repair (decrease of  $\geq 2.5$  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 ( $3,243 \pm 425$ g versus  $3,565 \pm 330$ g;  $P = .001$ ), biparietal diameter ( $93.2 \pm 2.1$  versus  $95.2 \pm 2.3$  mm;  $p = 0.001$ ), head circumference ( $336 \pm 12$  versus  $348 \pm 6.4$  mm;  $p = 0.001$ ), sex (female 62.5% versus 29.0%;  $p = 0.010$ ), newborn weight ( $3,258 \pm 472$ g versus  $3,499 \pm 383$ g;  $p = 0.027$ ) 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.

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:  $\geq 3$  tractions needed; 3<sup>rd</sup>-4<sup>th</sup> degree perineal tear; ~~substantial~~ severe bleeding during episiotomy repair (decrease of  $\geq 2.5$  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 $\pm$ 425g versus 3,565 $\pm$ 330g;  $p=0.001$ ), biparietal diameter (93.2 $\pm$ 2.1 versus 95.2 $\pm$ 2.3 mm;  $p=0.001$ ), head circumference (336 $\pm$ 12 versus 348 $\pm$ 6.4 mm;  $p=0.001$ ), sex (female 62.5% versus 29.0%;  $p=0.010$ ), newborn weight (3,258 $\pm$ 472g versus 3,499 $\pm$ 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, Aissi 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 between 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:  $\geq 3$  tractions needed; 3<sup>rd</sup>-4<sup>th</sup> degree perineal tear; severe bleeding during episiotomy repair (decrease of  $\geq 2.5$  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 145.5° 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 < 153° 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  $\geq$  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.

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

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

21 **Any sources of financial support for the research**

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

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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.

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1 **Abstract:**

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3 **Background:**

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

13

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

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

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

7  
8 **Results:** We recruited 84 nulliparous **patients**, of ~~which~~ **whom 5 cases** were excluded due  
9 to the difficulty of adequately evaluating the biparietal diameter and head circumference. A  
10 total of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries)  
11 with 13 cases in the occiput-posterior position. We identified 31 cases of complicated  
12 operative vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No  
13 differences were identified in obstetric, neonatal or intrapartum characteristics between the  
14 two study groups (operative uncomplicated vaginal delivery versus operative complicated  
15 vaginal delivery), with the following exceptions: **estimated** fetal weight (3,243 $\pm$ 425g versus  
16 3,565 $\pm$ 330g;  $p=0.001$ ), biparietal diameter (93.2 $\pm$ 2.1 versus 95.2 $\pm$ 2.3 mm;  $p=0.001$ ), head  
17 circumference (336 $\pm$ 12 versus 348 $\pm$ 6.4 mm;  $p=0.001$ ), sex (female 62.5% versus  
18 29.0%;  $p=0.010$ ), newborn weight (3,258 $\pm$ 472g versus 3,499 $\pm$ 383g;  $p=0.027$ ) and number of  
19 tractions (median, IQR) (1 (1 to 2) versus 4 (3 to 5);  $P<0.0005$ ). To predict complicated  
20 operative deliveries, all 6 of the studied models presented an area under the ROC curve  
21 between 0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;  $p<0.0005$ ). The results of  
22 the study met the criteria of "interpretability" and "parsimony" (simplicity), allowing us to  
23 identify a binary logistic regression model based on the angle of progression and head  
24 circumference; this model ~~which~~ has an area under the ROC curve of 0.876 (95% CI 0.790-



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1 0.963;p<0.0005) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243; p<0.0005).

2

3 **Conclusion:**

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

6

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

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1 **Introduction:**

2  
3 Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral  
4 hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity  
5 (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
6 difficult operative vaginal deliveries and cesarean deliveries performed after failed  
7 operative vaginal delivery (8-13). Indeed, the reported incidence of postpartum intracranial  
8 hemorrhages after failed instrumental vaginal delivery is 1 in 334, which is 5.7 times  
9 greater than the incidence associated with spontaneous vaginal birth (8).

10 ~~According to standard clinical practice guidelines, operative vaginal deliveries must only be~~  
11 ~~performed if the fetal head is engaged and has reached at least +0 cm, with only experienced~~  
12 ~~obstetricians performing mid-foreceps deliveries (14,15).~~ Thus far, the decision to attempt  
13 operative vaginal delivery, as well as the evaluation of its potential difficulty, has relied on  
14 digital examination (14,15). However, digital exploration is a subjective and unreliable tool  
15 for this purpose (16-19). In this context, intrapartum transperineal ultrasound has been  
16 introduced in clinical practice to help predict the progression and final method of delivery  
17 [spontaneous vaginal delivery versus operative vaginal delivery ~~to complete fetal extraction~~  
18 (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict cases of  
19 complicated operative vaginal deliveries and to identify cases with a high probability of  
20 requiring cesarean delivery due to failed operative vaginal delivery (22-30). ~~To date, few~~  
21 ~~Some~~ studies have evaluated the usefulness of intrapartum transperineal ultrasound for this  
22 purpose (23-30).

23  
24 Bultez et al. (25) reported ~~that an angle of progression less than 145.5° has a sensitivity of~~

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1 ~~86.2%, specificity of 49% and positive predictive value of 24% for the prediction of~~  
2 ~~vacuum extraction failure in nulliparous women~~

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

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

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

19  
20 ~~To date,~~ However, previous studies assessing predictive models for complicated vaginal  
21 deliveries did not include fetal characteristics, such as estimated fetal weight or head  
22 circumference, which are known independent risk factors for operative vaginal and  
23 cesarean deliveries (31-33).

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

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

2

3 **Materials and Methods:**

4 This was a prospective observational study in nulliparous women with singleton pregnancy  
5 at  $\geq 37$  weeks gestation and cephalic presentation ~~who required the use of vacuum or~~  
6 ~~forceps to complete fetal extraction.~~ The study was performed between May 2016 and June  
7 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013)  
8 was approved by the local Ethics and Research Committees (May 2015).

9

10 The inclusion criteria were at term nulliparous women with uncomplicated pregnancies  
11 who required operative vaginal delivery (forceps or vacuum) ~~to complete fetal extraction.~~

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

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

2

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

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

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

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1 edge of the bony part of the fetal head. Progression distance is defined as the distance  
2 between the infrapubic line (the line through the inferior margin of the pubic symphysis  
3 perpendicular to the long axis of the symphysis) and a parallel line through the deepest  
4 bony part of the fetal head. Midline angle is defined as the angle between the  
5 anteroposterior axis of the pelvis and the fetal brain midline. Intrapartum transperineal  
6 ultrasound measurements were performed according to a previously published technique  
7 (20,36).

8  
9 The following demographic and obstetric data were recorded: maternal age; gestational age  
10 at delivery; body mass index (BMI); obstetric history; duration of the first and second  
11 stages of labor; indication for operative delivery; number of tractions performed; need for  
12 episiotomy; birth weight; and sex. Data on the following maternal and neonatal morbidity  
13 outcomes were also collected: maternal vaginal or anal sphincter tear (using Sultan’s  
14 classification of perineal tears) (37) and postpartum hemorrhage; Apgar scores after one  
15 and five minutes; arterial cord blood pH at delivery; birth trauma (cephalohematoma,  
16 intracranial hemorrhage, clavicle fracture or peripheral and cranial nerve injuries) and  
17 admission of the newborn to the neonatal unit (respiratory distress, neonatal jaundice, or  
18 risk of neonatal sepsis).

19  
20 An operative delivery was classified as “complicated” when one or more of the following  
21 situations occurred (30,38): three or more tractions were required to complete fetal  
22 extraction (39); failed operative vaginal delivery; third or higher degree perineal tear  
23 according to Sultan’s classification (37); major tear reported by the obstetrician; ~~significant~~  
24 severe bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin

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

4  
5 **Statistical analyses.**

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

14  
15 **Evaluation of logistic regression models.**

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

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

11  
12 **Results:**

13 **Study population.**

14 We recruited 84 nulliparous patients, 5 of whom were excluded due to the difficulty of  
15 adequately evaluating the biparietal diameter and fetal head circumference. In total, we  
16 evaluated 79 nulliparous patients who required operative vaginal assistance ~~to complete the~~  
17 ~~fetal extraction~~ (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).  
18 Forty-eight cases were classified as ‘uncomplicated operative vaginal deliveries’ (28  
19 vacuum-assisted deliveries and 20 forceps-assisted deliveries), and 31 were classified as  
20 ‘complicated operative vaginal deliveries’ (19 vacuum-assisted deliveries and 12 forceps-  
21 assisted deliveries). Of the 31 cases of complicated operative vaginal deliveries, a third-  
22 degree perineal tear occurred in 6 cases (19.35%). In 7 cases (22.5%), **severe** bleeding was  
23 noted while repairing the episiotomy and was confirmed by a decrease of  $\geq 2.5$  g/dL in the  
24 maternal hemoglobin level. Three or more tractions were performed in 18 cases (58.06%).



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

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

10  
11 **Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal**  
12 **deliveries.**

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

20  
21 **Predictive models of complicated deliveries.**

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

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1 binary logistic regression model that identified the variables "angle of progression with  
2 pushing" and "head circumference" as predictors of complicated operative vaginal delivery  
3 was chosen because these variables were included in the final multivariate analysis, which  
4 is shown in **Table 5**. Harrell's C-statistic, which was obtained from the AUC of the  
5 predicted probabilities by the model, was 0.876 (95% CI 0.790-0.963; p<0.0005), i.e., an  
6 initial discriminatory capacity >0.75, which is the same as the values obtained for the  
7 model adjusted by the Shrinkage uniform model, in which the C-statistic values were 0.876  
8 (95% CI 0.790-0.963; p<0.0005) (**Figures 5 and 6**). The calibration of the selected model  
9 was evaluated by calculating the calibration slope B, which was 0.984 (95% CI 0.726-  
10 1.243; p<0.0005). Pearson linear correlation coefficients were also calculated (0.906 and  
11 0.849) (**Figures 7 and 8**).

12  
13 **Comment.**

14 **Principal findings.**

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

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

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

12  
13 ~~We propose that one of the strengths of this study is based on the fact that transperineal~~  
14 ~~ultrasound requires little training and can be undertaken with the type of ultrasound~~  
15 ~~equipment that is frequently found in most delivery units worldwide. Thus, this technique is~~  
16 ~~generalizable. The Angle of Progression has proven to be easy to evaluate and is very~~  
17 ~~useful for this purpose (30). The fetal weight and head circumference are risk factors for~~  
18 ~~caesarean and operative deliveries (31-33); therefore, the evaluation of these parameters~~  
19 ~~should be included in the assessment for the prediction of the success of instrumentation.~~  
20 ~~Head circumference presents an adequate correlation with the difficulty of an instrumental~~  
21 ~~delivery, the probability of failure and the need for caesarean delivery (31,33,41). The~~  
22 ~~evaluation of head circumference in the delivery room seems to be feasible, although we~~  
23 ~~believe that the reproducibility of its measurement during the second stage of labor (when~~  
24 ~~the fetal head is already engaged in the maternal pelvis) should be assessed in future~~

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1 ~~studies.~~

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

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

6

7 **Clinical Implications.**

8 By applying the proposed predictive model, any obstetrician can easily predict the type of  
9 operative vaginal delivery that he or she will encounter in the delivery room, as a variation  
10 in head circumference can shift the situation from an uncomplicated operative vaginal  
11 delivery. In such cases, 1 or 2 tractions are needed (when an angle of progression with  
12 pushing of 146° is identified by intrapartum transperineal ultrasound) for a complicated  
13 operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal  
14 extraction (if an angle of progression with pushing of 115° is identified) (**Figure 9**) (**video**  
15 **1**).

16

17 **Research Implications.**

18 Knowing that digital examination presents a high rate of error (20-75%) in identifying ~~the~~  
19 ~~level of fetal presentation~~ (ACOG the fetal station and its degree of engagement (16-20),  
20 intrapartum transperineal ultrasound has been introduced in the delivery room to improve  
21 assessments of the progression and final method of delivery. Accordingly, Kalache et al.  
22 (45, 41) reported that an angle of progression  $\geq 120^\circ$  is associated with a high probability of  
23 vaginal delivery, whereas Ramphulm et al. (46, 42) discussed the utility of intrapartum  
24 ultrasound for evaluating fetal head position before operative vaginal delivery.

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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  $<145^\circ$  (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  $145.5^\circ$  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  $\geq 40$  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  $142^\circ$  for the angle of progression was a

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1 predictor for complicated operative vaginal deliveries. This is consistent with the results of  
2 our study (30), which identified an angle of progression with pushing <153.5° as a  
3 predictor of complicated operative deliveries (sensitivity of 86.9% and false-positive rate of  
4 5.9% (AUC of 86.9% (95% CI, 80-91).

5 Several authors have expressed interest in predicting the type of vaginal operative delivery  
6 they will encounter and the risk for cesarean delivery (49-51,45-47). ~~Their work has~~  
7 ~~mainly associated different maternal and fetal parameters with sonographic parameters not~~  
8 ~~considered until recently.~~ Their efforts have been focused on predicting the outcome of  
9 labor, that is, vaginal versus cesarean delivery, by assessing the first stage of labor. Thus,  
10 Burker et al. (50) (46) presented a predictive model of cesarean risk based on five  
11 parameters (maternal age, BMI, height, fetal abdominal circumference, and fetal head  
12 circumference) that were evaluated in the first stage of labor and found excellent calibration  
13 and discriminative ability (Kolmogorov-Smirnov, D-statistic, 0.29; 95% CI, 0.28 to  
14 0.30)and a misclassification rate of 0.21. With the same purpose of predicting the  
15 probability of vaginal delivery versus required cesarean delivery, Eggebø et al. (47) (51)  
16 introduced intrapartum transperineal ultrasound in his evaluation and presented a model  
17 based on six parameters (head-perineum distance, caput succedaneum, occiput posterior  
18 position, maternal age, gestational age, and maternal BMI), which were all evaluated during  
19 the first stage of labor, and obtained an AUC of 0.853% (95% CI, 0.678-1.000)ARC of  
20 0.853.

21  
22 We observed a significant difference in fetal sex between study groups (62.5% female  
23 fetuses in the uncomplicated operative vaginal deliveries versus 29% in the complicated  
24 operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head

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

3  
4 Nonetheless, unlike previously published models (25,46,47 50,—54) for predicting  
5 complicated or difficult operative deliveries, our predictive model presents the following  
6 characteristics: 1. the model can be used in the delivery room; 2. the model provides a  
7 quick evaluation because only 2 ultrasound parameters are involved; and 3. ~~the echographic~~  
8 ~~measurements used in the model appear to be easy to perform.3.The model appears to be~~  
9 ~~easy to perform.~~

10  
11 **Strengths and limitations.**

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

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

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

14  
15 We consider the following to be limitations of our work: in our predictive model, we did  
16 not evaluate the head-perineum distance, an ultrasound parameter that appears to be very  
17 useful in predicting the difficulty of vaginal delivery, though our group has not achieved  
18 adequate reproducibility of this parameter (interobserver correlation of 0.53 (95% CI, 0.1-  
19 0.9) (36). ~~this parameter should be designed for this purpose.~~

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



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

7 **Conclusion.**

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

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1 **A SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL**  
2 **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.

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1 **Abstract:**

2

3 **Background:**

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

11

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

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

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

5 **Results:** We recruited 84 nulliparous patients, of whom 5 were excluded due to the  
6 difficulty of adequately evaluating the biparietal diameter and head circumference. A total  
7 of 79 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with  
8 13 cases in the occiput-posterior position. We identified 31 cases of complicated operative  
9 vaginal deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were  
10 identified in obstetric, neonatal or intrapartum characteristics between the two study  
11 groups (operative uncomplicated vaginal delivery versus operative complicated vaginal  
12 delivery), with the following exceptions: estimated fetal weight ( $3,243\pm 425$ g versus  
13  $3,565\pm 330$ g;  $P=0.001$ ), biparietal diameter ( $93.2\pm 2.1$  versus  $95.2\pm 2.3$  mm;  $p=0.001$ ), head  
14 circumference ( $336\pm 12$  versus  $348\pm 6.4$  mm;  $p=0.001$ ), sex (female 62.5% versus  
15 29.0%;  $p=0.010$ ), newborn weight ( $3,258\pm 472$ g versus  $3,499\pm 383$ g;  $p=0.027$ ) and number of  
16 tractions (median, IQR) (1 (1 to 2) versus 4 (3 to 5);  $P<0.0005$ ). To predict complicated  
17 operative deliveries, all 6 of the studied models presented an area under the ROC curve  
18 between 0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;  $p<0.0005$ ). The results of  
19 the study met the criteria of "interpretability" and "parsimony" (simplicity), allowing us to  
20 identify a binary logistic regression model based on the angle of progression and head  
21 circumference; this model has an area under the ROC curve of 0.876 (95% CI 0.790-  
22 0.963;  $p<0.0005$ ) and a calibration slope B of 0.984 (95% CI 0.0.726-1.243;  $p<0.0005$ ).

23  
24 **Conclusion:**

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

3

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

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1 **Introduction:**

2  
3 Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral  
4 hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity  
5 (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
6 difficult operative vaginal deliveries and cesarean deliveries performed after failed  
7 operative vaginal delivery (8-13). Indeed, the reported incidence of postpartum intracranial  
8 hemorrhages after failed instrumental vaginal delivery is 1 in 334, which is 5.7 times  
9 greater than the incidence associated with spontaneous vaginal birth (8).

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

21  
22 Bultez et al. (25) reported that when using the optimal cutoff value of 145.5° for the angle  
23 of progression to predict vacuum extraction failure in nulliparous women, the calculated  
24 area under the receiver operating characteristics (ROC) curve (AUC) was 0.67 (95% CI,

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1 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-97%), specificity of 49% (95% CI, 40-  
2 57%) and positive predictive value of 24% (95% CI, 16-34%).

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

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

12  
13 However, previous studies assessing predictive models for complicated vaginal deliveries  
14 did not include fetal characteristics, such as estimated fetal weight or head circumference,  
15 which are known independent risk factors for operative vaginal and cesarean deliveries (31-  
16 33).

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

19

20 **Materials and Methods:**

21 This was a prospective observational study in nulliparous women with singleton pregnancy  
22 at  $\geq 37$  weeks gestation and cephalic presentation. The study was performed between May  
23 2016 and June 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The  
24 study (PI-232013) was approved by the local Ethics and Research Committees (May 2015).

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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



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

2 Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo,

3 Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was

4 estimated (EFW) by intrapartum transabdominal ultrasound, while biparietal diameter

5 (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial

6 ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).

7 Intrapartum transperineal ultrasound was performed with the woman in a semirecumbent

8 position, with an empty bladder and ruptured membranes. The probe was placed between

9 the labia below the pubic symphysis. The following intrapartum parameters were assessed

10 by transperineal ultrasound (20,36) (**Table 1. Figures 2, 3 and 4**): angle of progression

11 (AoP) and progression distance (PD) evaluated on the longitudinal plane and midline angle

12 (MLA) assessed on the transverse plane. Furthermore, the angle of progression, progression

13 distance and midline angle were assessed at rest (AoP1, PD1, and MLA1, respectively) and

14 concurrently with contraction and active pushing (AoP2, PD2, and MLA2, respectively).

15 Angle of progression is defined as the angle between a line through the midline of the pubic

16 symphysis and another line from the anterior margin of the pubic symphysis to the leading

17 edge of the bony part of the fetal head. Progression distance is defined as the distance

18 between the infrapubic line (the line through the inferior margin of the pubic symphysis

19 perpendicular to the long axis of the symphysis) and a parallel line through the deepest

20 bony part of the fetal head. Midline angle is defined as the angle between the

21 anteroposterior axis of the pelvis and the fetal brain midline. Intrapartum transperineal

22 ultrasound measurements were performed according to a previously published technique

23 (20,36).

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

11  
12 An operative delivery was classified as “complicated” when one or more of the following  
13 situations occurred (30,38): three or more tractions were required to complete fetal  
14 extraction (39); failed operative vaginal delivery; third or higher degree perineal tear  
15 according to Sultan’s classification (37); major tear reported by the obstetrician; severe  
16 bleeding during the episiotomy repair confirmed by a decrease in the hemoglobin level of  
17  $\geq 2.5$  g/dL following delivery (40); or a significant traumatic neonatal lesion (subdural and  
18 intracerebral hemorrhage, epicranial subaponeurotic hemorrhage, skeletal injuries, injuries  
19 to spine and spinal cord, or peripheral and cranial nerve injuries) (30,38).

20  
21 **Statistical analyses.**

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

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

6  
7 **Evaluation of logistic regression models.**

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

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

3  
4 **Results:**

5 **Study population.**

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

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

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

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

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**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-

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1 1.243;  $p < 0.0005$ ). Pearson linear correlation coefficients were also calculated (0.906 and  
2 0.849) (**Figures 7 and 8**).

4 **Comment.**

5 **Principal findings.**

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

13 **Clinical Implications.**

14 By applying the proposed predictive model, any obstetrician can easily predict the type of  
15 operative vaginal delivery that he or she will encounter in the delivery room, as a variation  
16 in head circumference can shift the situation from an uncomplicated operative vaginal  
17 delivery. In such cases, 1 or 2 tractions are needed (when an angle of progression with  
18 pushing of  $146^\circ$  is identified by intrapartum transperineal ultrasound) for a complicated  
19 operative vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal  
20 extraction (if an angle of progression with pushing of  $115^\circ$  is identified) (**Figure 9**) (**video**  
21 **1**).

23 **Research Implications.**

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

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

7  
8 Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-  
9 13), especially when a cesarean delivery is required due to a failed operative vaginal  
10 delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is  
11 associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a  
12 convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation  
13 (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical  
14 practice to enable the prediction of the difficulty and possible complications of operative  
15 vaginal deliveries. Bultez et al. (25) reported that the optimal cutoff for angle of  
16 progression was  $145.5^\circ$  for predicting vacuum extraction failure in nulliparous women; the  
17 calculated AUC was 0.67 (95% CI, 0.57-0.77), with a sensitivity of 86.2% (95% CI, 68-  
18 97%), specificity of 49% (95% CI, 40-57%) and positive predictive value of 24% (95% CI,  
19 16-34%). Kahrs et al. (29) found that in nulliparous women with a prolonged second stage  
20 of labor, a head-perineum distance of  $>35$  mm is associated with a 22% (9/41) risk of an  
21 emergency cesarean delivery.

22  
23 In addition, Kasbaoui et al. (43) carried out a prospective cohort study including 659  
24 women, in which the head-perineum distance was measured prior to operative vaginal

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

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

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

22  
23 We observed a significant difference in fetal sex between study groups (62.5% female  
24 fetuses in the uncomplicated operative vaginal deliveries versus 29% in the complicated



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

4  
5 Nonetheless, unlike previously published models (25,46,47) for predicting complicated or  
6 difficult operative deliveries, our predictive model presents the following characteristics: 1.  
7 the model can be used in the delivery room; 2. the model provides a quick evaluation  
8 because only 2 ultrasound parameters are involved; and 3. the echographic measurements  
9 used in the model appear to be easy to perform

10  
11 **Strengths and limitations.**

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

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1 to be useful in the identification of difficult or complicated operative vaginal deliveries (24-  
2 30).

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

13  
14 We consider the following to be limitations of our work: in our predictive model, we did  
15 not evaluate the head-perineum distance, an ultrasound parameter that appears to be very  
16 useful in predicting the difficulty of vaginal delivery, though our group has not achieved  
17 adequate reproducibility of this parameter (interobserver correlation of 0.53 (95% CI, 0.1-  
18 0.9) (36). In addition, we believe that the reproducibility of head circumference  
19 measurement during the second stage of labor (when the fetal head is already engaged in  
20 the maternal pelvis) must be proven. External validation of the predictive model should also  
21 be carried out. Lastly, we consider that including other types of forceps instead of only  
22 Kielland's forceps and using additional objective parameters to classify a delivery as a  
23 "complicated operative vaginal delivery", such as the need for maternal blood transfusion,  
24 traumatic fetal lesion or cup detachment, should be considered in future studies.

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

**Table 1.** Ecographic parameters evaluated in the Intrapartum Transperineal ultrasound

<b>Model</b>	<b>Parameters included in the predictor model</b>
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 <sup>2</sup> )	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			0.585
Failure to Progress in Labor	36 (75%)	22 (70.9%)	
Maternal Exhaustion	4 (8.3%)	3 (9.6%)	
Non-reassuring fetal heart rate	8 (16.6%)	6 (19.3%)	
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

<b>Umbilical cord artery pH</b>	7.27±0.06	7.24±0.07	0.121
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**Table 3.** Maternal and neonatal characteristics in 79 nulliparous requiring operative delivery to complete fetal extraction.

<b>Intrapartum Ultrasound</b>	<b>Transperineal</b>	<b>Uncomplicated operative delivery (n= 48)</b>	<b>Complicated operative delivery (n=31)</b>	<b>P</b>
<b>AoP 1 (°)</b>		138.12±13.4	119.1±16.8	P<0.0005
<b>AoP 2(°)</b>		149.5±15.2	126.2±13.3	P<0.0005
<b>PD 1 (mm)</b>		45.0±11.5	36.4±13.7	P=0.004
<b>PD 2 (mm)</b>		52.2±14.0	41.7±13.3	P=0.002
<b>MLA 1 (°)</b>		37.8±28.9	49.0±23.1	P=0.036
<b>MLA 2 (°)</b>		37.3±31.1	40.5±19.5	P=0.537
<b>Number of instrumental tractions (median and IQR)</b>		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 5.** Final logistic regression model obtained with the angle of progression with pushing and Head Circumference.

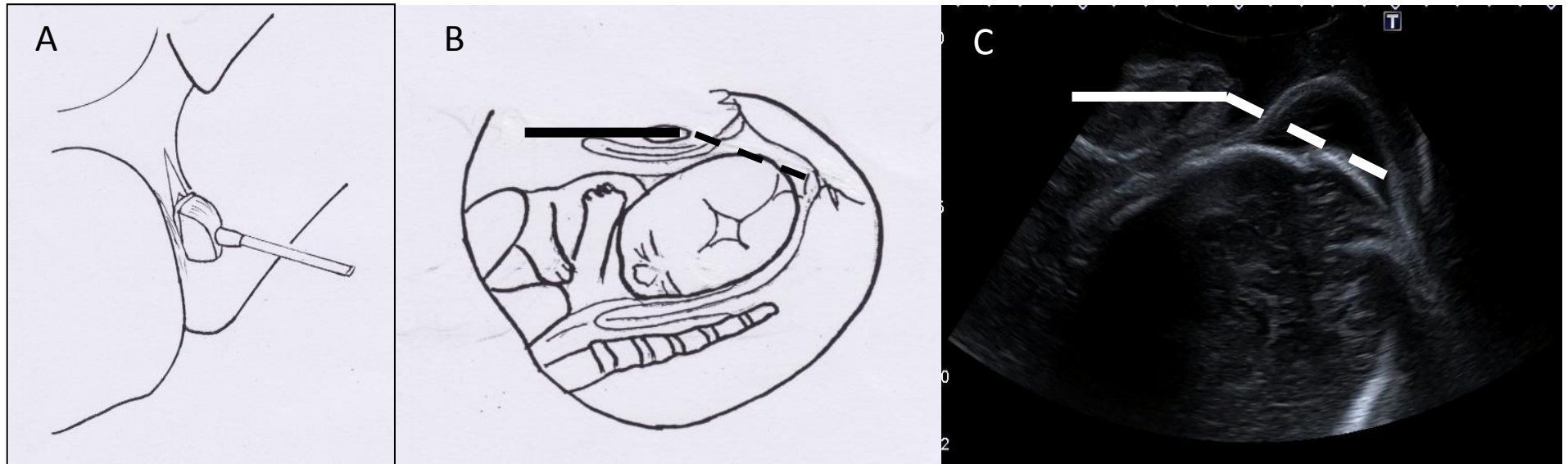
Variables in the equation		IC 95%	
	Exp (B)	lower	Upper
Angle of Progression(AoP) with pushing (per 5°)	0.698	0.568	0.855
Head Circumference (per 5 mm.)	1.665	1.111	2.484
Constant	-25.376		
Prob.COD= Probability for the identification of complicated operative deliveries  $\text{Prob.} = 1 / 1 + e^{(-25.376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



**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).



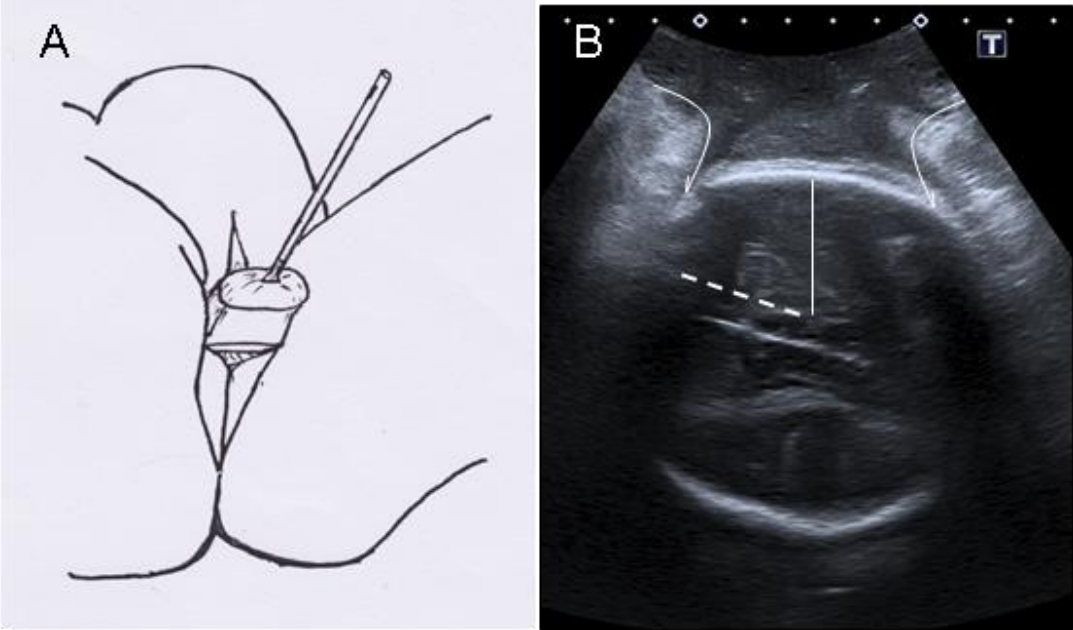
**Figure 2. Transperineal longitudinal plane at rest (A)..Angle of Progression (AoP) (B and C).**



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

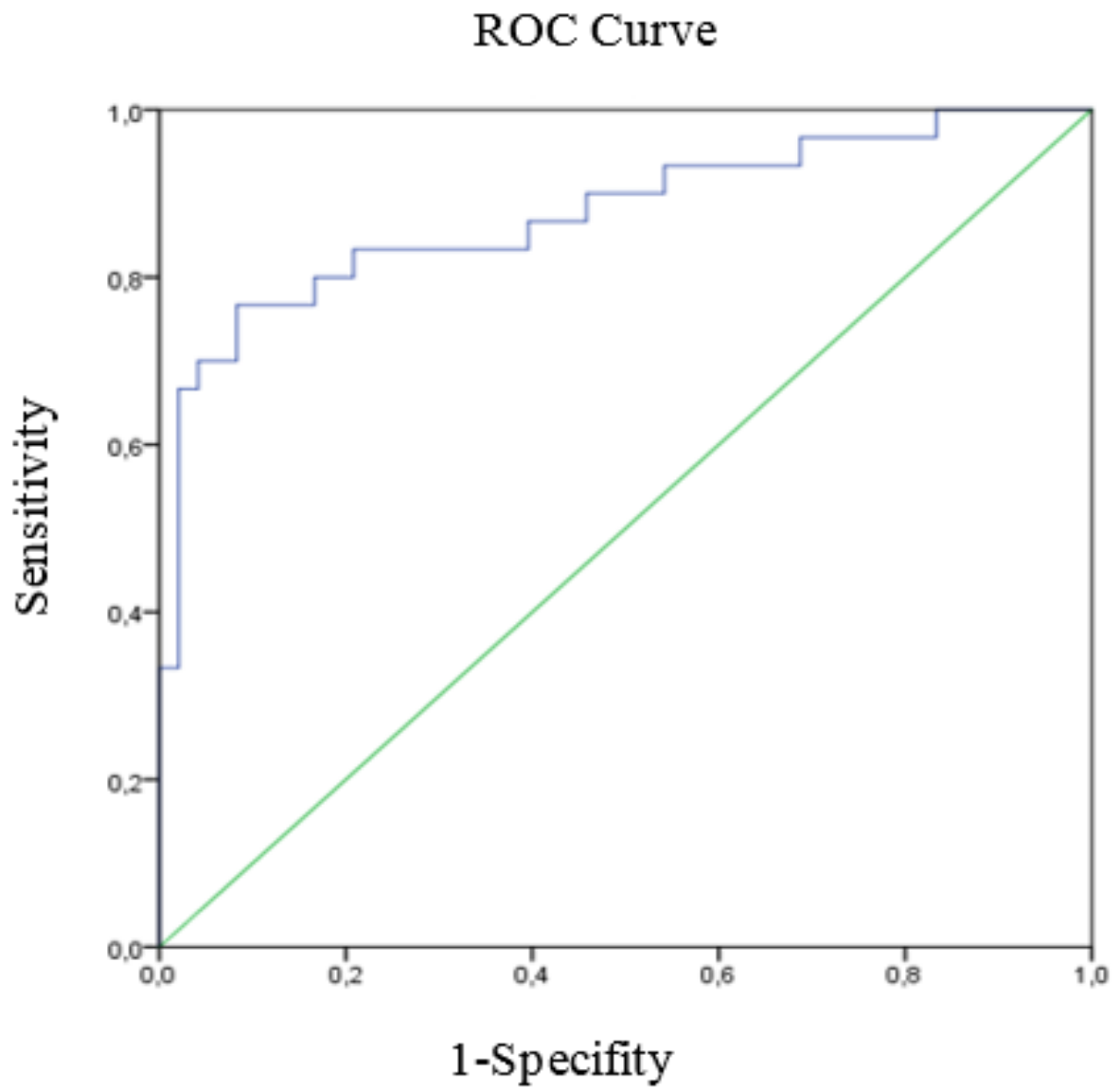


Figure 4. Transperineal axial plane at rest (A). Midline Angle (MLA) (B)



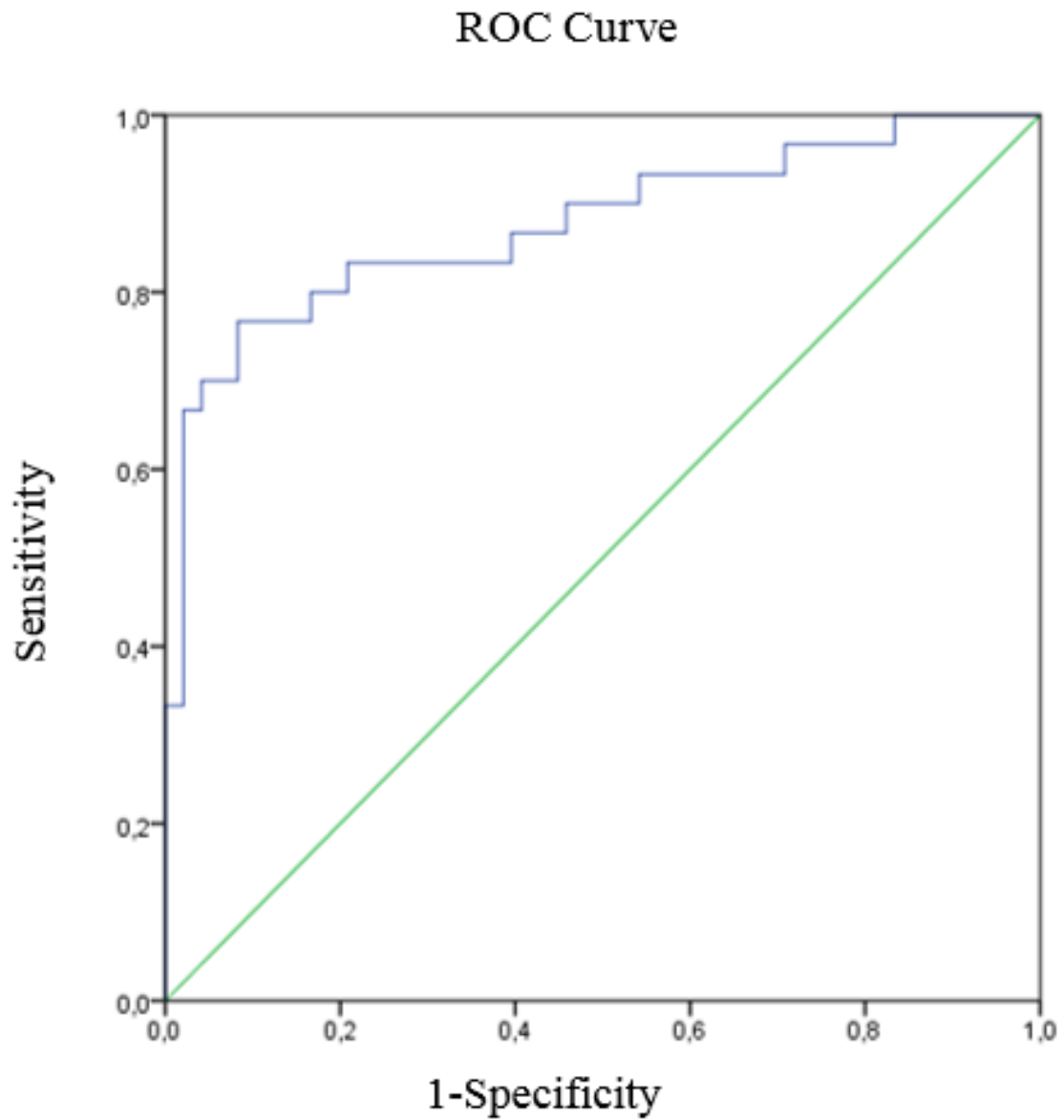
**Figure 5.** ROC curve for logistic regression model obtained from the association between Angle of Progression with pushing and Head Circumference

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

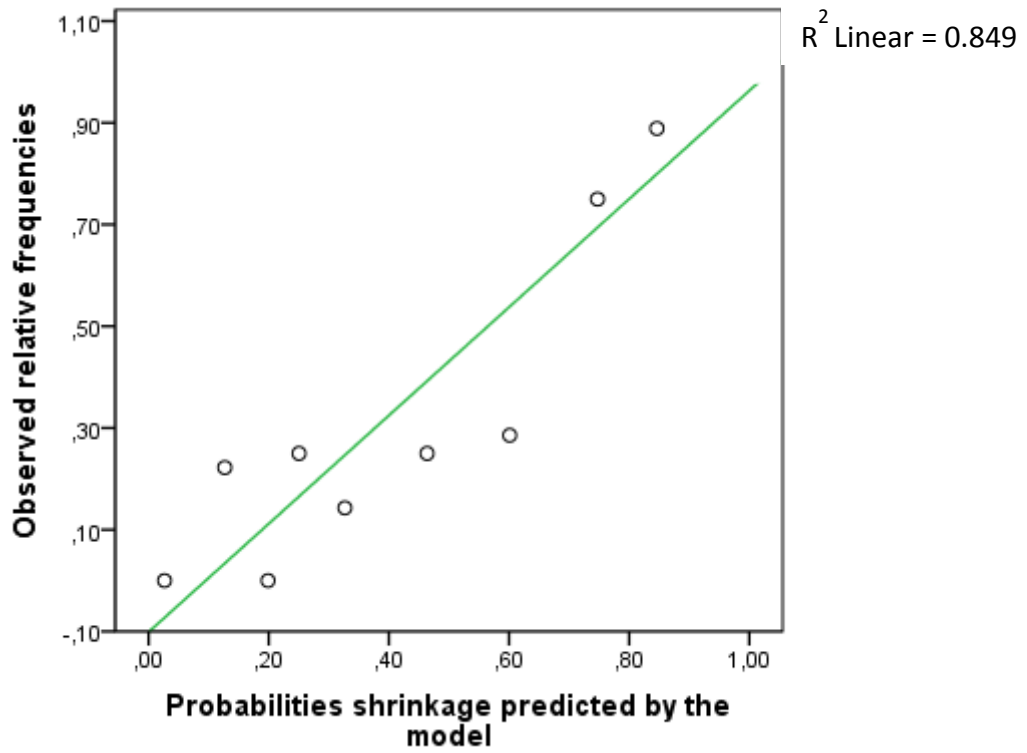


**Figure 6.** ROC curve for logistic regression model adjusted by Shrinkage method obtained from the association between Angle of Progression with pushing and Head Circumference

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



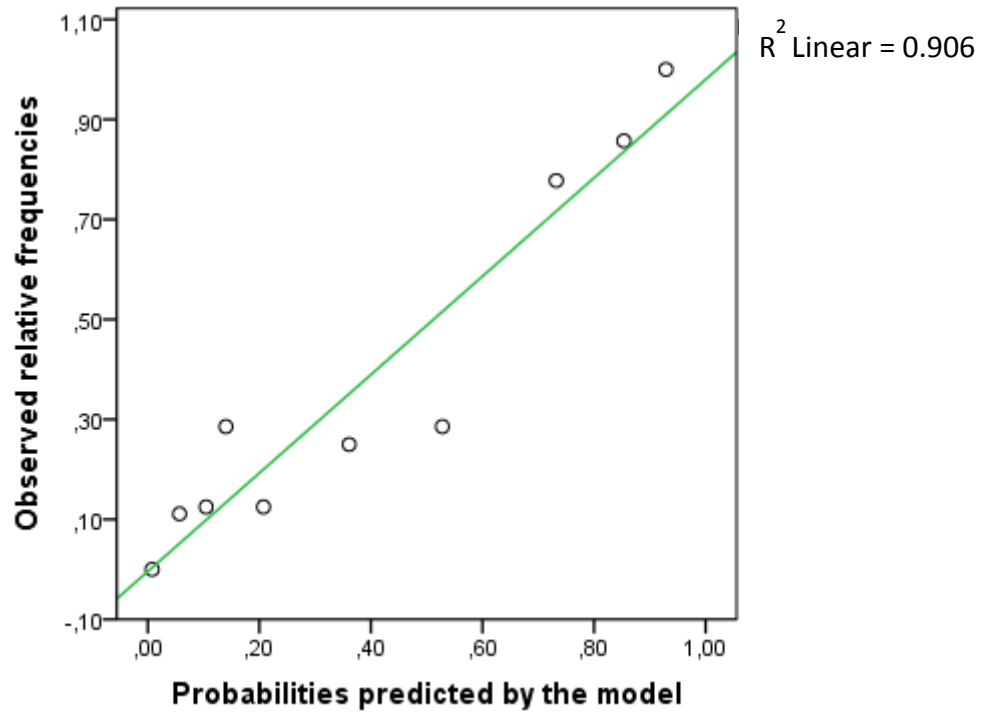
**Figure 7.** Calibration graphic of original logistic regression model adjusted by Shrinkage method obtained from the association between Angle of Progression with pushing and Head Circumference



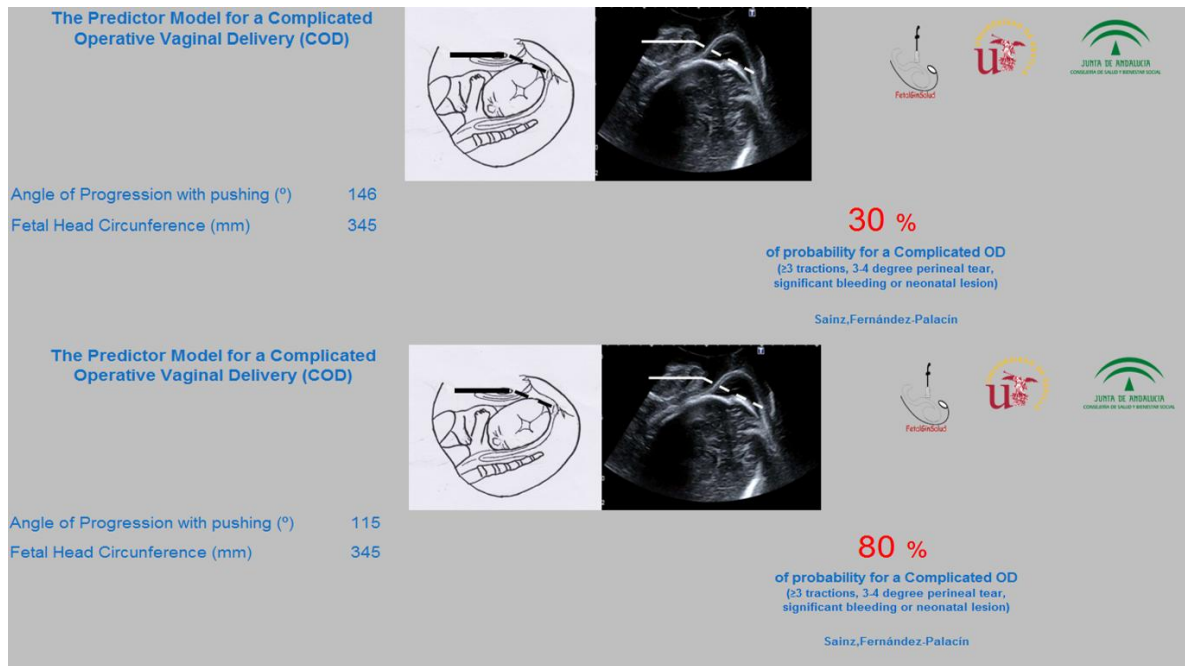




**Figure 8.** Calibration graphic of original logistic regression model obtained from the association between Angle of Progression with pushing and Head Circumference



**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.



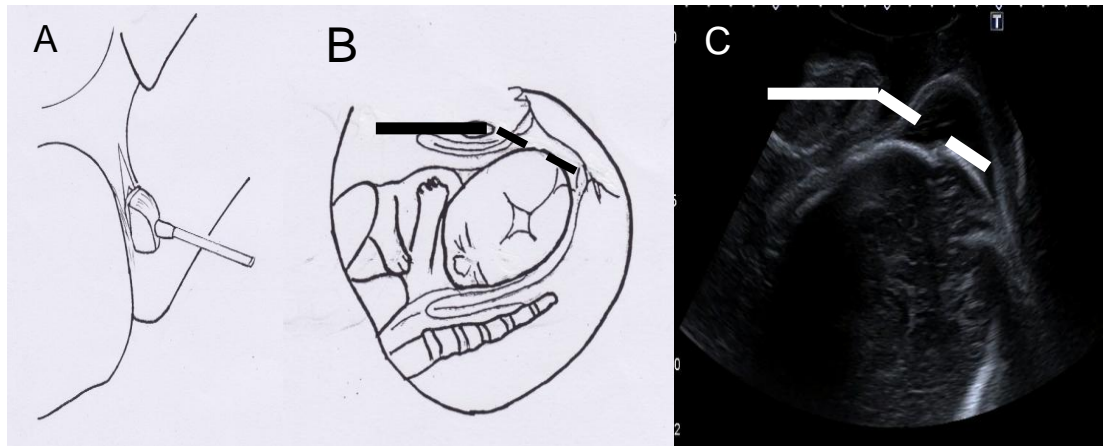
# SIMPLE MODEL TO PREDICT THE COMPLICATED OPERATIVE VAGINAL DELIVERIES USING VACUUM OR FORCEPS

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

*American Journal of Obstetrics & Gynecology*

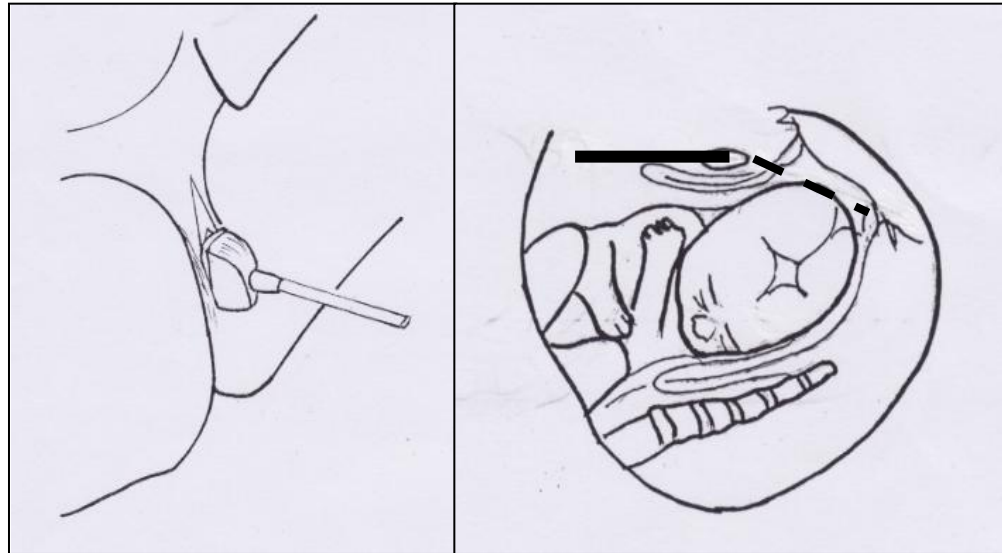
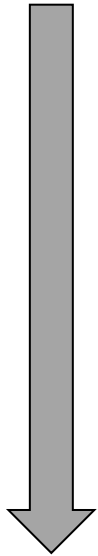
- The digital examination presents a high rate of error (20-75%) for the identification of the level of the fetal presentation (ACOG fetal station) and its degree of engagement (Dupuis O, Am J Obstet Gynecol 2005)

**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).



- 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)

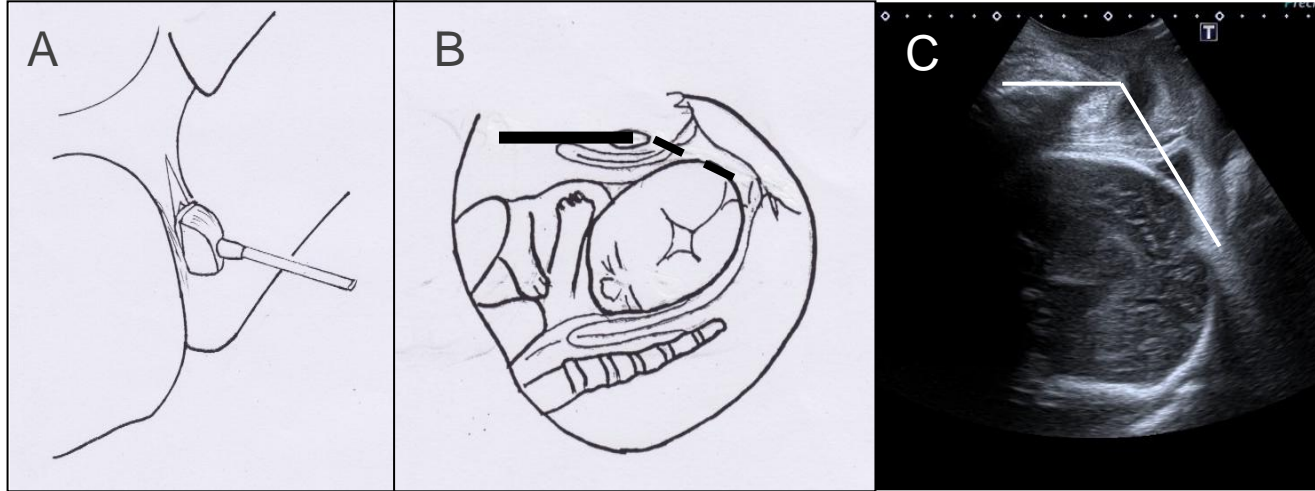
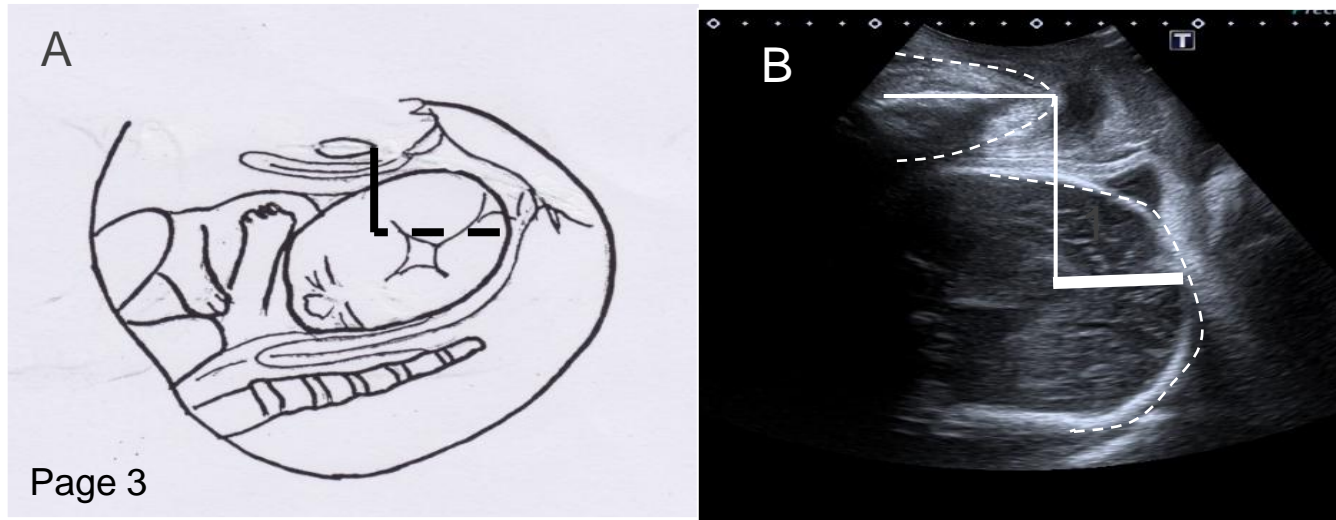


Figure 2. Transperineal longitudinal plane (A). Progression Distance (B)



# Intrapartum Transperineal Ultrasound

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

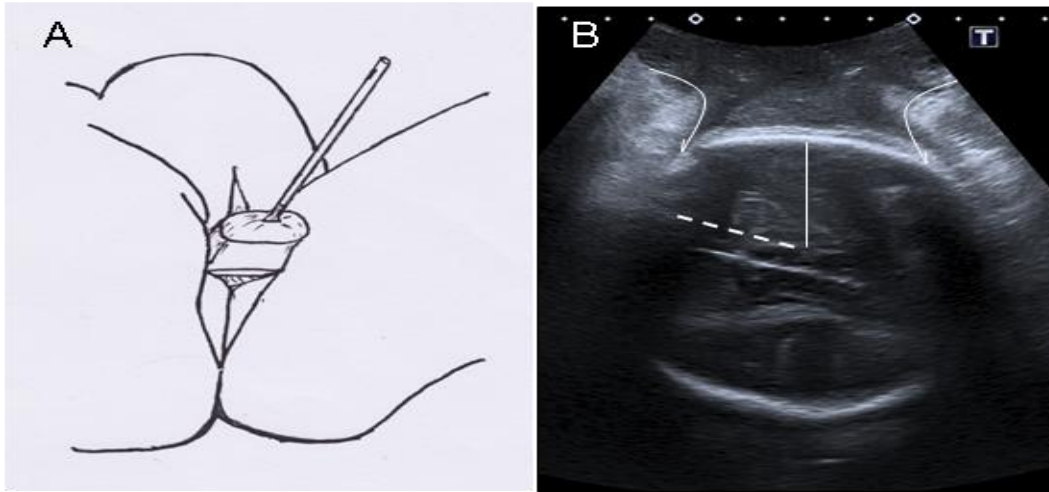
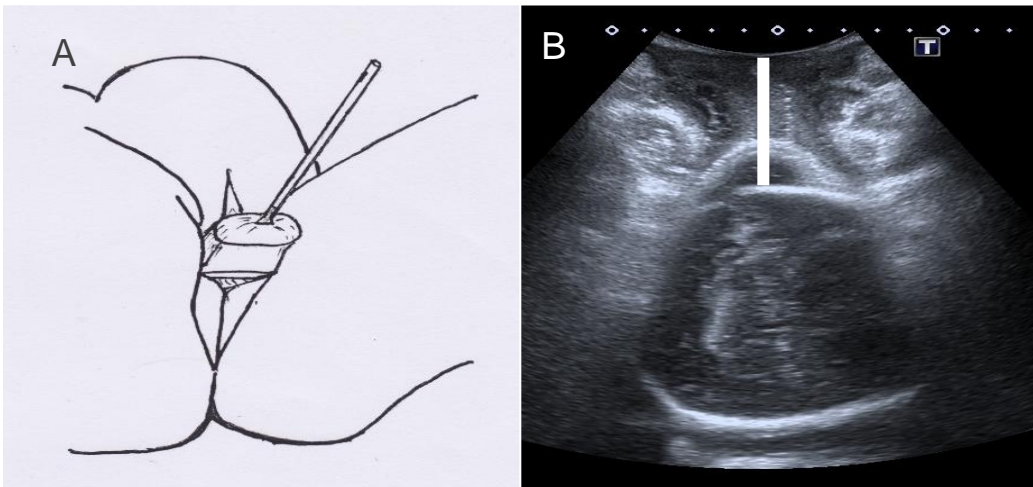
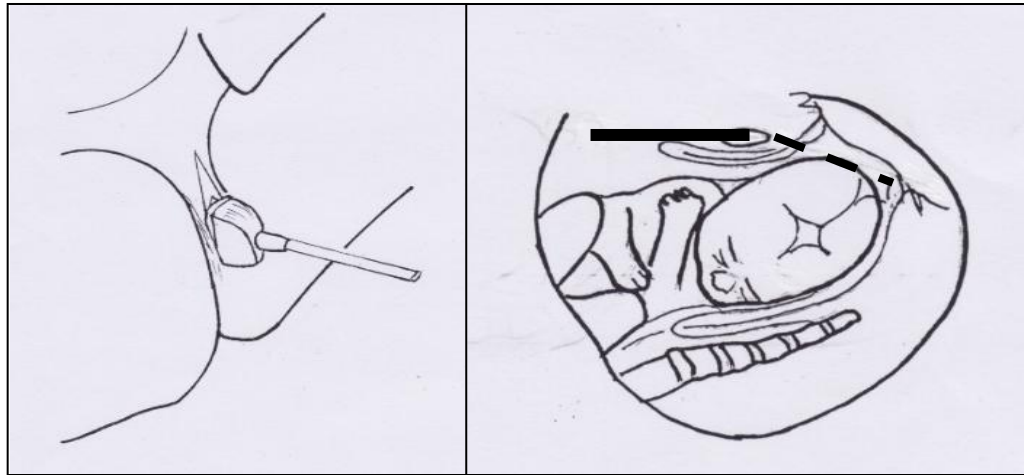


Figure 4. Transperineal axial plane at rest (A). Head-Perineum Distance (B)



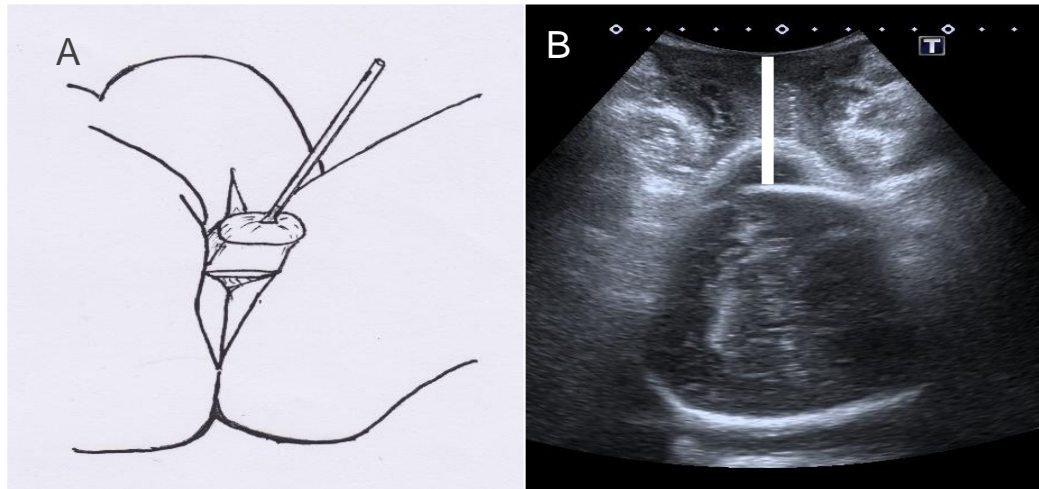
- Intrapartum transperineal ultrasound is useful to predict cases of complicated operative vaginal deliveries.
  - Angle of progression  $< 145^\circ$  presents a higher risk of failure in cases of vacuum assisted deliveries (Bultez, Ultrasound Obstet Gynecol 2016)
  - Head Perineum distance  $> 45$  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)**

- Objective: 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:

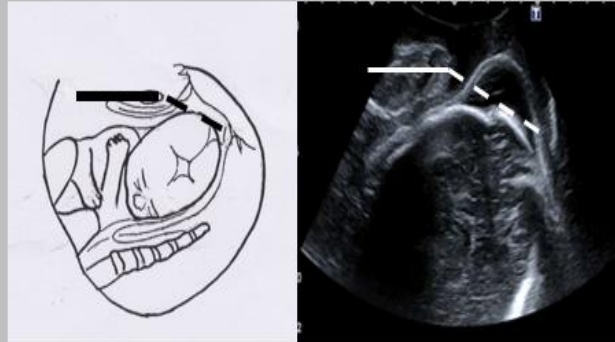
- An operative vaginal delivery was classified as 'complicated' when one or more of the following situations occurred:
  - ≥3 tractions needed to complete fetal extraction
  - 3-4<sup>th</sup> degree perineal tear
  - Severe bleeding during the episiotomy repair
  - Significant traumatic neonatal lesion.

- 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 (°)	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 ° and a Head Circunference of 348 mm. This situation associates a 28% of probability for Complicated operative vaginal delivery

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



Angle of Progression with pushing (°) 110  
Fetal Head Circumference (mm) 348

**89 %**

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

Sainz, Fernández-Palacín



**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  $110^{\circ}$  and a Head Circumference of 348 mm. This situation associates a 89% of probability for Complicated operative vaginal delivery

## Video

[Click here to download Video: video 1.mp4](#)

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Each author is required to submit a signed Statement of Authorship upon submission. This applies to all submission types including Editorials, Letters to the Editor, etc.

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**Manuscript title:** A SIMPLE MODEL TO PREDICT COMPLICATED OPERATIVE VAGINAL DELIVERIES USING A VACUUM OR FORCEPS.

**Corresponding author:** José Antonio Sainz

**Authors may either sign the same form or submit individually**

I am an author on this submission, have adhered to all editorial policies for submission as described in the Information for Authors, attest to having met all authorship criteria, and all potential conflicts of interest / financial disclosures appears on the title page of the submission.

**Signatures are required - typed signatures are unacceptable.**

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**Signature:** Department of Obstetrics and Gynecology,  
Hospital de Valme of Seville, Spain.



Typed or CLEARLY Printed Name: José Antonio García-Mejido

**Signature:** Department of Obstetrics and Gynecology,  
Hospital de Valme of Seville, Spain.



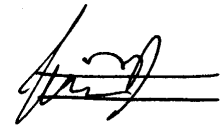
Typed or CLEARLY Printed Name: Adriana Aquise

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Typed or CLEARLY Printed Name: Carlota Borrero

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Hospital de Valme of Seville, Spain.



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Hospital de Valme of Seville, Spain.



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**Authorship.**

Each author must qualify by having participated actively and sufficiently in the study that is being performed and reported.

**Conflict of interest.**

It doesn't exist any trade association of any author of the text neither any economic benefit with the realization of this work and their publication

**Previous publication**

The declarations and opinions expressed in the articles and communications belong to the authors and not of the editor or publisher.

**IRB approval.**

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

Ecografía Transperial intraparto para la instrumentación con vacuum

Cuyo investigador principal en este Centro es:

José Antonio Sainz Bueno

Valorando positivamente la capacidad del investigador, objetivos y memoria del estudio, que se enmarca dentro de las líneas de investigación consolidadas en este Centro. Y que dicho proyecto, es adecuado para su presentación a la actual convocatoria de financiación de proyectos de investigación y planes de formación investigadora de Ciencias de la Salud, en la Comunidad Autónoma Andaluza, según Orden de 19 de julio de 2007, publicado en BOJA 149 de 30 de julio de 2007.

Lo que firmo en Sevilla a 6 de septiembre de 2007.

Fdo. María Teresa Estacio Gil, con NIF: 31.628.2337, Secretaria de la Comisión de Investigación del Hospital Universitario de Valme de Sevilla

VºBº Dr. Rafael Vazquez Garcia, con NIF: 05.123.9555, Presidente de la Comisión de Investigación del Hospital Universitario de Valme de Sevilla

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2. Prof. GC Di Renzo.Obstetric and Gynecology University of Perugia. Italy  
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### **Introduction:**

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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.**

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**Previous publication**

The declarations and opinions expressed in the articles and communications belong to the authors and not of the editor or publisher.

**IRB approval.**

Yes

**Permissions**

Charts don't exist neither you figure of other authors

**Patient consent**

I have obtained written patient consent



**Fdo Dr Sainz Bueno**



La Comisión de Ética e Investigación del Hospital Universitario Virgen de Valme de Sevilla,

**CERTIFICA:**

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Ecografía Transperial intraparto para la instrumentación con vacuum

Cuyo investigador principal en este Centro es:

José Antonio Sainz Bueno

Valorando positivamente la capacidad del investigador, objetivos y memoria del estudio, que se enmarca dentro de las líneas de investigación consolidadas en este Centro. Y que dicho proyecto, es adecuado para su presentación a la actual convocatoria de financiación de proyectos de investigación y planes de formación investigadora de Ciencias de la Salud, en la Comunidad Autónoma Andaluza, según Orden de 19 de julio de 2007, publicado en BOJA 149 de 30 de julio de 2007.

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Fdo. María Teresa Estacio Gil, con NIF: 31.628.2337, Secretaria de la Comisión de Investigación del Hospital Universitario de Valme de Sevilla

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

5     **Authors: José Antonio Sainz (1,2), José Antonio García-Mejido (1), Adriana Aquise**  
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18    Phone: 0034 630132948     E-mail: joseantoniosainz@hotmail.es

20    **Conflict of interest:**

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

25    **Any sources of financial support for the research**

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4 1 **CONDENSATION, IMPLICATIONS AND CONTRIBUTION, SHORT VERSION**  
5 2 **OF TITLE**  
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8 4 • **CONDENSATION.**  
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10 6 We propose a simple model to predict the implications of an operative vaginal delivery.  
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12 8 • **IMPLICATIONS AND CONTRIBUTIONS.**  
13 9

14 10 • A. Why was this study conducted?

15 11 Instrumental deliveries are associated with higher maternal and neonatal morbidity.  
16 12 Identifying the cases at high risk for complicated operative deliveries is important to  
17 13 improve obstetric assistance in the labor ward.  
18 14

19 15 Intrapartum ultrasound can become a useful tool in the delivery room. Therefore, we  
20 16 believe the development of a predictive model for complicated operative deliveries based  
21 17 on intrapartum parameters (angle of progression and fetal head circumference), could be of  
22 18 great utility for obstetricians assisting instrumental deliveries.  
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24 20  
25 21 • B. What are the key findings?

26 22 A predictive model that includes angle of progression and fetal head circumference has an  
27 23 identifying capacity of 87.5% for complicated operative deliveries  
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29 24 • C. What does this study add to what is already known?

30 25  
31 26 Previous predictive models for difficult vaginal deliveries or need for cesarean section  
32 27 required the combination of multiple parameters (up to 6 parameters), which were  
33 28 evaluated during the first stage of labor.  
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35 30 We present a simple and quick predictive model for complicated operative deliveries  
36 31 (requiring only 2 ultrasound parameters) which can be performed during second stage of  
37 32 labor.  
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39 33 • **Short version of title.**

40 34 Predictive model for complicated operative vaginal deliveries.  
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**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:  $\geq 3$  tractions needed to complete fetal extraction; 3-4<sup>th</sup> degree perineal tear; substantial bleeding during the episiotomy repair; or substantial

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

3  
4 **Results:** We recruited 84 nulliparous, out of which 5 cases have been excluded due to the  
5 difficulty of adequately evaluating the biparietal diameter and fetal head circumference. 79  
6 nulliparous were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13 cases in  
7 occiput-posterior position. We identified 31 cases of complicated operative deliveries (19  
8 vacuum-deliveries or 12 forceps-deliveries). No differences were identified in obstetric,  
9 neonatal or intrapartum characteristics between the two study groups (operative  
10 uncomplicated delivery versus operative complicated delivery), with the following  
11 exceptions: estimated fetal weight(3,243±425g versus 3,565±330g;*P*=.001), fetal biparietal  
12 diameter(93.2±2.1 versus 95.2±2.3mm;*P*=.001), fetal head circumference(336±12 versus  
13 348±6.4mm;*P*=.001), gender(female 62.5% versus 29.0%;*P*=.010), newborn  
14 weight(3,258±472g versus 3,499±383g;*P*=.027) and number of tractions(1.4±0.5 vs  
15 4.2±1.0;*P*<.0005). In order to predict complicated operative deliveries, all 6 models studied  
16 presented an area-under-ROC-curve between 0.863 and 0.876. This multivariate study,  
17 which follows principles of "interpretability" and "parsimony"(simplicity), has allowed us  
18 to identify a binary logistic regression model based on angle of progression and fetal head  
19 circumference, which presents an area-under-ROC-curve of 0.876 (95% CI0.790-0.963)  
20 and a calibration slope B-0.906.

21 **Conclusion:** The predictive model including angle of progression and fetal head  
22 circumference has adequate predictive capacity of complicated operative deliveries  
23 (87.5%), and can be performed in the delivery room.

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

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

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1 **Introduction**

2  
3 Operative deliveries are associated with an increased neonatal (subdural or cerebral  
4 haemorrhage, convulsions, mechanical ventilation) (1-3) and maternal morbidity  
5 (haemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
6 difficult instrumentation and caesarean section performed after a failed attempt of operative  
7 vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum intracranial  
8 haemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times greater than  
9 the rate associated with spontaneous vaginal birth (8).

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

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

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

11

12 **Material and Methods:**

13 This was a prospective observational study of nulliparous women with singleton pregnancy  
14 at  $\geq 37$  weeks gestation and cephalic presentation, who required the use of vacuum or  
15 forceps to complete the fetal extraction. The study was performed between May 2016 and  
16 June 2017 in Valme's University Hospital Maternity Unit in Seville, Spain. The study (PI-  
17 232013) was approved by the local Ethics and Research Committees (May 2015).

18

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

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

11  
12 Whenever a potentially eligible woman was identified at our maternity unit during the  
13 beginning of labor, she was invited to participate in the trial and was asked to provide an  
14 informed consent before being enrolled in the study. Once the patient had signed the  
15 informed consent, the intrapartum transperineal ultrasound was performed as described  
16 below. When one of the listed indications for the operative delivery occurred, the managing  
17 obstetrician chose the instrument that considered most appropriate for the clinical  
18 circumstance and his/her skill level (14).

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

24 Intrapartum transperineal ultrasound was performed with the woman in semirecumbent



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

16  
17 The following demographic and obstetric data were recorded: maternal age, gestational age  
18 at delivery; body mass index (BMI); obstetric history; duration of first and second stages of  
19 labor; indication for operative delivery; number of tractions performed; need for  
20 episiotomy; birth weight and gender. Data on the following maternal and neonatal  
21 morbidity outcomes were also collected: maternal vaginal or anal sphincter tear (using  
22 Sultan's classification of perineal tears) (30) and postpartum haemorrhage; Apgar scores  
23 after one and five minutes; arterial cord blood pH at delivery; birth trauma  
24 (cephalohematoma, intracranial haemorrhage, clavicle fracture) and admission of the

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

3  
4 An operative delivery was classified as complicated when one or more of the following  
5 situations occurred (30): three or more tractions were required to complete fetal extraction,  
6 failed attempt at operative vaginal delivery, third or higher degree perineal tear according to  
7 Sultan’s classification, major tear reported by the obstetrician, significant bleeding during  
8 the episiotomy repair confirmed by a decrease in the haemoglobin level of  $\geq 2.5$  g/dL  
9 following the delivery, or a significant traumatic neonatal lesion.

10

11 **Statistical analyses.**

12 Statistical analyses were performed using IBM SPSS statistics software version 22 (IBM,  
13 Armonk, NY). We determined the mean and standard deviations for numeric variables, and  
14 the percentage for qualitative variables. Comparisons of numeric variables between  
15 complicated and uncomplicated operative delivery were performed using Student’s t-test.  
16 Comparison of qualitative variables between study groups was performed using a chi-  
17 squared test. Individual predictive capabilities were evaluated using the receiver–operating  
18 characteristics (ROC) curve and the area under the curve (AUC). The level of significance  
19 was established at 95% CI ( $P < 0.05$ ).

20

21 **Evaluation of logistic regression models**

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

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

15  
16 **Results:**

17 **Study Population.**

18 We recruited 84 nulliparous, out of which 5 cases have been excluded due to the difficulty  
19 of adequately evaluating the biparietal diameter and fetal head circumference. We have  
20 evaluated 79 cases of nulliparous who required instrumentation to complete the fetal  
21 extraction (47 vacuum-assisted deliveries and 32 forceps-assisted deliveries).  
22 48 cases were classified as ‘uncomplicated operative deliveries’ (28 vacuum-assisted  
23 deliveries and 20 forceps-assisted deliveries), and 31 as ‘complicated operative deliveries’  
24 (19 vacuum-assisted deliveries and 12 forceps-assisted deliveries). Out of the 31 cases of

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

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

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

14  
15 **Intrapartum transperineal ultrasound as a predictor of complicated deliveries.**

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

22  
23 **Predictive models of complicated deliveries.**

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

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1 complicated operative deliveries. It was observed that the models presented Harrell's C  
2 statistic values that oscillating between 0.863 and 0.876, determined as an area under the  
3 ROC curve of the predicted probabilities. The model of binary logistic regression that  
4 identified the variables "Angle of progression with pushing" and " fetal head circumference  
5 " as predictors of a complicated operative delivery was chosen, as these variables were the  
6 ones included in the final multivariate analysis, shown in **Table 4**. Harrell's C statistic,  
7 obtained from the area under the ROC curve of the predicted probabilities by the model  
8 was 0.876 (95% CI 0.790 to 0.963), i.e. an intern discriminatory capacity >0.75, the same  
9 as the model adjusted by the Shrinkage uniform model, in which C results equivalent to  
10 0.876 (95% CI 0.789 to 0.963) (**Figures 5 and 6**). The calibration study of the selected  
11 model was performed by calculating the calibration slopes (0.984 and 1.064 in the original  
12 and Shrinkage models, respectively) Pearson linear correlation coefficients (0.906 and  
13 0.849) (**Figures 7 and 8**).

14  
15 **Comment.**

16 **Principal findings.**

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

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

5  
6 We believe one of the strengths of the study is based on the fact that transperineal  
7 ultrasound requires little training and can be undertaken with the type of ultrasound  
8 equipment that can be frequently found in most delivery units worldwide. Thus, the  
9 technique is generalizable. The Angle of Progression has proven to be easy to evaluate and  
10 to be very useful for this purpose (30). It is known that the fetal weight and the fetal head  
11 circumference are risk factors for caesarean and operative deliveries (31-33), and therefore  
12 their evaluation should be included in the assessment for the prediction of success of  
13 instrumentation. Fetal head circumference presents an adequate correlation with the  
14 difficulty of an instrumental delivery and the probability of failure and need for caesarean  
15 section (31,33,37). Its evaluation in the delivery room seems to be feasible, although we  
16 believe that the reproducibility of its measurement during the second stage of labor (when  
17 the fetal head is already engaged in the maternal pelvis) should be assessed in future  
18 studies.

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

23

24 **Clinical significance.**

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

### 9 **Research implications**

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

18  
19 Instrumental deliveries are associated with higher maternal and neonatal morbidity (1-13)  
20 especially when a caesarean section is required due to a failed attempt of instrumental  
21 delivery. An emergency C-section after a failed vacuum assisted delivery is associated with  
22 an intracranial haemorrhage rate of 1 in every 334 newborns and a convulsion rate of 1 per  
23 145, with 1 in every 64 newborns needing mechanical ventilation (1). In this context,  
24 intrapartum transperineal ultrasound has been introduced in clinical practice in order to

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1 enable the prediction of difficulty and possible complications of instrumental deliveries.  
2 Bultez et al. (25) observes that an angle of progression  $<145^\circ$  (sensitivity 86.2%, specificity  
3 49%) is associated with a higher rate of failed attempt of vacuum delivery. Kahrs et al (29)  
4 finds that in nulliparous women with a prolonged second stage of labor, a head-perineum  
5 distance of  $>35$  mm is associated with a 22% risk of an emergency cesarean section.  
6 Kasbaoui et al (43) in a prospective cohort study including 659 women, the HPD (in this  
7 study referred to as the perineum–skull distance) was measured prior to operative vaginal  
8 delivery. After adjustment for parity, presentation type and fetal macrosomia,  $HPD \geq 40$  mm  
9 was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).  
10 Martins et al. (44) identified that a cutoff of  $142^\circ$  for the angle of progression was a  
11 predictor for complicated operative deliveries, consistent with our study, which identifies  
12 an angle of progression with pushing  $<153.5^\circ$  as a predictor for complicated operative  
13 deliveries (vacuum and forceps).  
14 Several authors have expressed their interest in predicting the kind of vaginal delivery they  
15 will encounter and the risk for caesarean section (45-47). Their work has associated mainly  
16 different maternal and fetal parameters; with sonographic parameters only being taken into  
17 account in the recent studies. Their efforts have been focused on the prediction of the  
18 outcome of labor, vaginal versus caesarean delivery, by the assessment of the first stage of  
19 labor. Thus Burker et al (46) present a predictive model of caesarean risk based on five  
20 parameters (maternal age, body mass index, height, fetal abdominal circumference, and  
21 fetal head circumference) evaluated in the first stage of labor, and with a calibration and  
22 discriminative ability with a misclassification rate of 0.21. With the same purpose of  
23 predicting the probability of a vaginal delivery vs need for caesarean section, Eggebø et al  
24 (47) introduces intrapartum transperineal ultrasound in his evaluation, and presents a model



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

4  
5 We have observed a significant difference in fetal sex between study groups (62.5% of  
6 female fetuses in the uncomplicated operative deliveries vs 29% in the complicated  
7 deliveries). In 5.9% of cases we have not been able to measure the fetal head circumference  
8 during the second stage of labor with the fetal head already engaged in the maternal pelvis.  
9 Nonetheless, our predictive model, unlike previously proposed models, presents the  
10 following characteristics: 1. it can be used in the delivery room itself, 2. Provides a quick  
11 evaluation, since only 2 ultrasound parameters are involved, and 3. it appears to be easy to  
12 perform.

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14  
15 **Strengths and limitations**

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

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

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

10 We consider that the main limitation of our work is the fact that we have not evaluated the  
11 head-perineum distance in our predictive model, which currently seems to be a very useful  
12 ultrasound parameter to predict the difficulty of a vaginal delivery. In addition, we believe  
13 that reproducibility of fetal head circumference measurement during the second stage of  
14 labor (when the fetal head is already engaged in the maternal pelvis) must be proved.

15 External validation of the predictive model should be also carried out. We consider that  
16 including other types of forceps, and not only Kiellands forceps, and using more objective  
17 parameters to classify a delivery as a ‘complicated delivery’ such as: need for maternal  
18 blood transfusion, traumatic fetal lesion or a cup detachment, are factors that should be  
19 taken into account in future works. Lastly, we believe that as our study was underpowered  
20 to detect neonatal and maternal morbidity, and therefore further studies should be designed  
21 for this purpose.

22  
23 **Conclusion.**

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

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

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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:  $\geq 3$  tractions needed to complete fetal extraction; 3-4<sup>th</sup> degree perineal tear; substantial bleeding during the episiotomy repair (decrease in the hemoglobin level of  $\geq 2.5$ g/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);  $P < 0.0005$ ).

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. The change has been made

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.



- 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 < 153° presents a sensitivity of 86.9% for the identification of complicated operative vaginal deliveries (understanding as 'complicated operative delivery' those cases when at 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-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 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  $\geq 120^\circ$  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  $<145^\circ$  (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  $\geq 40$  mm was significantly associated with the occurrence of a difficult extraction (odds ratio 2.38).

Martins et al. (48) identified that a cutoff of  $142^\circ$  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  $<153.5^\circ$  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

[Insights Imaging](#). 2018 Feb; 9(1): 103–118.

Published online 2018 Jan 22. doi: [10.1007/s13244-017-0586-x](https://doi.org/10.1007/s13244-017-0586-x)

PMCID: PMC5825313

PMID: [29356945](https://pubmed.ncbi.nlm.nih.gov/29356945/)

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

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

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19  
20 **Conflict of interest. The authors declare no conflicts of interest.**

21 **Any sources of financial support for the research**

22  
23 **Sources of support for the study. This study was supported by the authors as**  
24 **practicing physicians in the hospital and faculty members of the University of Seville,**  
25 **Spain.**

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4 1 ~~CONDENSATION, IMPLICATIONS AND CONTRIBUTION, AJOG AT A GLANCE,~~  
5 2 ~~SHORT VERSION OF TITLE~~

6 3  
7 4  
8 4 • **CONDENSATION.**

9 5  
10 6 ~~We propose a simple model to predict the implications of an operative vaginal delivery.~~  
11 7 ~~The combination of the angle of progression and the head circumference can predict 87%~~  
12 8 ~~of complicated operative vaginal deliveries.~~

13 9  
14 10 • ~~IMPLICATIONS AND CONTRIBUTIONS. AJOG AT A GLANCE~~

15 11  
16 12 • A. Why was this study conducted?

17 13 ~~Instrumental deliveries are associated with higher maternal and neonatal morbidity.~~  
18 14 ~~Identifying the cases at high risk for complicated operative deliveries is important to~~  
19 15 ~~improve obstetric assistance in the labor ward.~~

- 20 16  
21 17 • **Operative vaginal deliveries are associated with a high maternal and neonatal**  
22 18 **morbidity.**  
23 19 • **We sought to develop a model to predict complicated operative deliveries and**  
24 20 **compare the performance of our model with others previously reported in the**  
25 21 **literature**

26 22  
27 23 ~~Intrapartum ultrasound can become a useful tool in the delivery room. Therefore, we~~  
28 24 ~~believe the development of a predictive model for complicated operative deliveries based~~  
29 25 ~~on intrapartum parameters (angle of progression and fetal head circumference), could be of~~  
30 26 ~~great utility for obstetricians assisting instrumental deliveries.~~

31 27  
32 28  
33 29 • B. What are the key findings?

- 34 30 ○ A predictive model that includes angle of progression and fetal head  
35 31 circumference has an identifying capacity of 87.5% for **complicated**  
36 32 **operative deliveries**

37 33 • C. What does this study add to what is already known?

- 38 34 • **We report a simple and rapid predictive model for complicated operative deliveries.**  
39 35 **The model requires only two parameters that can be easily obtained with**  
40 36 **intrapartum sonography (head circumference and angle of progression).**  
41 37 • **The predictive ability of the model is superior to other models previously reported**  
42 38 **(87% vs a range of 56-67%).**  
43 39 • **This model can be implemented in any labor and delivery unit.**

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1 ~~Previous predictive models for difficult vaginal deliveries or need for cesarean section~~  
2 ~~required the combination of multiple parameters (up to 6 parameters), which were~~  
3 ~~evaluated during the first stage of labor.~~

4 ~~We present a simple and quick predictive model for complicated operative deliveries~~  
5 ~~(requiring only 2 ultrasound parameters) which can be performed during second stage of~~  
6 ~~labor.~~

7  
8       • **Short version of title.**

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

10  
11 **A simple predictive model for complicated operative vaginal deliveries**

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**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~~

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~~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:  $\geq 3$  tractions needed to complete fetal extraction; 3-4<sup>th</sup> degree perineal tear; substantial bleeding during the episiotomy repair; or substantial traumatic neonatal lesion. Six predictive models were evaluated (information available in table 2).~~

**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



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

10 **Results:** We recruited 84 nulliparous, out of which 5 cases have been excluded due to the  
11 difficulty of adequately evaluating the biparietal diameter and fetal head circumference. 79  
12 nulliparous were studied (47 vacuum deliveries, 32 forceps deliveries) with 13 cases in  
13 occiput posterior position. We identified 31 cases of **complicated operative vaginal**  
14 **deliveries** (19 vacuum deliveries or 12 forceps deliveries). No differences were identified  
15 in obstetric, neonatal or intrapartum characteristics between the two study groups(operative  
16 uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the  
17 following exceptions: estimated fetal weight( $3,243 \pm 425$ g versus  $3,565 \pm 330$ g;  $P = .001$ ), fetal  
18 biparietal diameter( $93.2 \pm 2.1$  versus  $95.2 \pm 2.3$ mm;  $P = .001$ ), fetal head  
19 circumference( $336 \pm 12$  versus  $348 \pm 6.4$ mm;  $P = .001$ ), gender(female 62.5% versus  
20 29.0%;  $P = .010$ ), newborn weight( $3,258 \pm 472$ g versus  $3,499 \pm 383$ g;  $P = .027$ ) and number of  
21 tractions(median,IQR)(**1(1 to 2) versus 4(3 to 5);  $P < .0005$** ). In order to predict complicated  
22 operative deliveries, all 6 models studied presented an **area under ROC curve between**  
23 **0.863 and 0.876 (95% CI 0.775-0.950 and 0.790-0.963;  $p < 0.0005$ ).** This multivariate study,

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~~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~~

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1 ~~circumference has adequate predictive capacity of complicated operative deliveries~~  
2 ~~(87.5%),~~

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

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

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# 1 Introduction

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3 Operative vaginal deliveries are associated with an increased neonatal (subdural or cerebral  
4 haemorrhage, convulsions, mechanical ventilation) (1-3) and maternal morbidity  
5 (haemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
6 ~~difficult of operative vaginal deliveries and caesarean section performed after a failed~~  
7 ~~attempt of operative vaginal delivery (8-13) ?~~. Indeed, the incidence rate reported for  
8 postpartum intracranial haemorrhages after failed instrumental vaginal delivery is 1 in 334,  
9 5.7 times greater than the rate associated with spontaneous vaginal birth (8).

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

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

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1 (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
2 difficult operative vaginal deliveries and caesarean deliveries performed after failed  
3 operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum  
4 intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times  
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6 According to standard clinical practice guidelines, operative vaginal deliveries must only be  
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9 to attempt operative vaginal delivery, as well as the evaluation of its potential difficulty, has  
10 relied on digital examination (14,15). However, digital exploration is a subjective and  
11 unreliable tool for this purpose (16-19). In this context, intrapartum transperineal  
12 ultrasound has been introduced in clinical practice to help predict the progression and  
13 finalization of delivery [spontaneous vs. need for operative vaginal delivery to complete  
14 fetal extraction (16,17)]. Moreover, intrapartum transperineal ultrasound is used to predict  
15 cases of complicated operative vaginal deliveries and to identify cases with a high  
16 probability of requiring caesarean delivery due to failed operative vaginal delivery (22-30).  
17 To date, few studies have evaluated the usefulness of intrapartum transperineal ultrasound  
18 for this purpose (23-30).

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~~Bultez et al (25) reported that in cases of vacuum-assisted deliveries with que an angle of progression less than 145.5° 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 < 153° 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 < 153° 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

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1 traumatic neonatal lesion).

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

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

12

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

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

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19

20 **Material and Methods:**

21 This was a prospective observational study of nulliparous women with singleton pregnancy  
22 at  $\geq 37$  weeks gestation and cephalic presentation, who required the use of vacuum or  
23 forceps to complete the fetal extraction. The study was performed between May 2016 and  
24 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).

## **Materials and Methods:**

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5 who required operative vaginal delivery (forceps or vacuum) to complete fetal extraction.  
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7 progress in labor or maternal exhaustion. Intrapartum ultrasound was not performed in  
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17 to the sonographic data registered. The intrapartum transperineal ultrasound was performed  
18 exclusively by a group of five obstetricians (J.S, C.B, P.F, A.A, and J.G-M) who had  
19 demonstrated competency for this type of ultrasound examination (30).

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

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1 managing obstetrician chose the instrument that considered most appropriate for the clinical  
2 circumstance and his/her skill level (14).  
3 ~~Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokio,~~  
4 ~~Japan) with a 3.75 MHz convex probe (2D ultrasound method). Fetal weight (34) was~~  
5 ~~estimated (EFW) by intrapartum transabdominal ultrasound, while fetal biparietal diameter~~  
6 ~~(BPD) and fetal head circumference (HC) were evaluated by either transabdominal or~~  
7 ~~translabial ultrasound (using the transthalamic plane of the fetal head) (Figure 1) (35).~~  
8 ~~Intrapartum transperineal ultrasound was performed with the woman in semirecumbent~~  
9 ~~position, with an empty bladder and ruptured membranes. The probe was placed between~~  
10 ~~the labia, below the pubic symphysis. The following intrapartum parameters were assessed~~  
11 ~~by transperineal ultrasound (20,36) (Table 1. Figures 2, 3 and 4): Angle of Progression~~  
12 ~~(AoP) and Progression Distance (PD), evaluated on the longitudinal plane, and Midline-~~  
13 ~~Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression,~~  
14 ~~Progression Distance and Midline Angle were assessed at rest (AoP1, PD1, MLA1) and~~  
15 ~~concurrently with contraction and active pushing (AoP2, PD2, MLA2). Angle of~~  
16 ~~Progression is defined as the angle between a line through the midline of the pubic~~  
17 ~~symphysis and another line from the anterior margin of the pubic symphysis to the leading~~  
18 ~~edge of the bony part of the fetal head. Progression Distance is defined as the distance~~  
19 ~~between the infrapubic line (the line through the inferior margin of the pubic symphysis~~  
20 ~~perpendicular to the long axis of the symphysis) and a parallel line through the deepest~~  
21 ~~bony part of the fetal head. Midline Angle is defined as the angle between the~~  
22 ~~anteroposterior axis of the pelvis and foetal brain midline. Intrapartum transperineal~~  
23 ~~ultrasound measurements were obtained according to previously published technique.~~

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

11  
12 An operative delivery was classified as complicated when one or more of the following  
13 situations occurred (30,38): three or more tractions were required to complete fetal  
14 extraction (39), failed attempt at operative vaginal delivery, third or higher degree perineal  
15 tear according to Sultan's classification (37), major tear reported by the obstetrician,  
16 significant bleeding during the episiotomy repair confirmed by a decrease in the  
17 haemoglobin level of  $\geq 2.5$  g/dL following the delivery (40), or a significant traumatic  
18 neonatal lesion.

19  
20 Whenever a potentially eligible woman was identified at our maternity unit during the  
21 beginning of labor, she was invited to participate in the trial and was asked to provide  
22 informed consent before being enrolled in the study. Once the patient had provided signed  
23 informed consent, the intrapartum transperineal ultrasound was performed as described  
24 below. When one of the listed indications for operative vaginal delivery occurred, the

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1 managing obstetrician chose the instrument that was considered most appropriate for the  
2 clinical circumstance and his/her skill level (14).  
3 Ultrasound examination was performed using a Toshiba Famio 8 ultrasound system (Tokyo,  
4 Japan) with a 3.75-MHz convex probe (2D ultrasound method). Fetal weight (34) was  
5 estimated (EFW) by intrapartum transabdominal ultrasound, while fetal-biparietal diameter  
6 (BPD) and head circumference (HC) were evaluated by either transabdominal or translabial  
7 ultrasound (using the transthalamic plane of the fetal head) (**Figure 1**) (35).  
8 Intrapartum transperineal ultrasound was performed with the woman in semirecumbent  
9 position, with an empty bladder and ruptured membranes. The probe was placed between  
10 the labia below the pubic symphysis. The following intrapartum parameters were assessed  
11 by transperineal ultrasound (20,36) (Table 1. **Figures 2, 3 and 4**): Angle of Progression  
12 (AoP) and Progression-Distance (PD) evaluated on the longitudinal plane and Midline-  
13 Angle (MLA) assessed on the transverse plane. Furthermore, Angle of Progression,  
14 Progression-Distance and Midline-Angle were assessed at rest (AoP1, PD1, and MLA1,  
15 respectively) and concurrently with contraction and active pushing (AoP2, PD2, and  
16 MLA2, respectively). Angle of Progression is defined as the angle between a line through  
17 the midline of the pubic symphysis and another line from the anterior margin of the pubic  
18 symphysis to the leading edge of the bony part of the fetal head. Progression-Distance is  
19 defined as the distance between the infrapubic line (the line through the inferior margin of  
20 the pubic symphysis perpendicular to the long axis of the symphysis) and a parallel line  
21 through the deepest bony part of the fetal head. Midline-Angle is defined as the angle  
22 between the anteroposterior axis of the pelvis and fetal brain midline. Intrapartum  
23 transperineal ultrasound measurements were obtained according to previously published  
24 technique.

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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  $\geq 2.5$  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.**

1 We determined the mean and standard deviations for numeric variables, and the percentage  
2 for qualitative variables. Comparisons of numeric variables between complicated and  
3 uncomplicated operative vaginal delivery were performed using Student's t test.  
4 Comparison of qualitative variables between study groups was performed using a chi-  
5 square test. Individual predictive capabilities were evaluated using the receiver operating  
6 characteristics (ROC) curve and the area under the curve (AUC). ~~The level of significance~~  
7 ~~was established at 95% CI (P<0.05). All statistical comparisons were conducted using~~  
8 ~~two sided test, and P < 0.005 was considered to be statistically significant for all~~  
9 ~~comparisons. Statistical analyses were performed using IBM SPSS statistics software~~  
10 ~~version 22 (IBM, Armonk, NY).~~

#### 12 **Evaluation of logistic regression models.**

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

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

### 8 **Statistical analyses.**

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10 for qualitative variables. Comparisons of the numeric variables between complicated and  
11 uncomplicated operative vaginal deliveries were performed using Student's t-test.  
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14 characteristics (ROC) curve and the area under the curve (AUC). All statistical comparisons  
15 were performed using two-sided test, and  $P < 0.005$  was considered statistically significant  
16 for all comparisons. Statistical analyses were performed using IBM SPSS statistics software  
17 version 22 (IBM, Armonk, NY).

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21 methods to predict complicated operative vaginal delivery, including intrapartum  
22 transperineal ultrasound parameters and fetal weight, biparietal diameter and head  
23 circumference. These parameters were added progressively according to the simplicity of  
24 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-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 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 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~~



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

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

9 The proportion of occiput posterior position was 13.6% (13 cases); the main indication for  
10 operative vaginal delivery was failure to progress in labor 60.75% (48 cases), and 76.2%  
11 (74 cases) required the performance of mediolateral episiotomy. Four cases (12.9%) out of  
12 the group of complicated operative vaginal deliveries required a caesarean section to  
13 complete fetal extraction. There was one newborn who required admission to the neonatal  
14 unit (case of mild respiratory distress).

15  
16 **Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal**  
17 **deliveries.**

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

## **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**).

## **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).

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1 48 cases were classified as ‘uncomplicated operative vaginal deliveries’ (28 vacuum-  
2 assisted deliveries and 20 forceps-assisted deliveries), and 31 were classified as  
3 ‘complicated operative vaginal deliveries’ (19 vacuum-assisted deliveries and 12 forceps-  
4 assisted deliveries). Out of the 31 cases of complicated operative vaginal deliveries, a third-  
5 degree perineal tear occurred in 6 cases (19.35 %). In 7 cases (22.5%), significant bleeding  
6 while repairing the episiotomy was noted and confirmed by a decrease of  $\geq 2.5$  g/dL in the  
7 maternal hemoglobin level. Three or more tractions were performed in 18 cases (58.06%).  
8 Regarding maternal and neonatal demographic data, significant differences were noted  
9 between uncomplicated and complicated operative vaginal deliveries, in fetal weight,  
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15 complete fetal extraction. There was one newborn who required admission to the neonatal  
16 unit (case of mild respiratory distress).

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18 **Intrapartum transperineal ultrasound as a predictor of complicated operative vaginal**  
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20 Significant differences were observed between the uncomplicated and complicated  
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1 significantly higher number of tractions (4 tractions) than the uncomplicated operative  
2 vaginal delivery group (1 traction).

3  
4 **Predictive models of complicated deliveries.**

5 We determined several binary logistic regression models to predict and explain complicated  
6 operative vaginal deliveries. We observed that the models presented Harrell's C statistic  
7 values oscillating between 0.863 and 0.876, determined as the area under the ROC curve of  
8 the predicted probabilities. The model of binary logistic regression that identified the  
9 variables "Angle of progression with pushing" and "head circumference" as predictors of  
10 complicated operative vaginal delivery was chosen, as these variables were included in the  
11 final multivariate analysis, which is shown in **Table 5**. Harrell's C statistic, which was  
12 obtained from the area under the ROC curve of the predicted probabilities by the model,  
13 was 0.876 (95% CI 0.790-0.963;  $p < 0.0005$ ), i.e., an intern discriminatory capacity  $> 0.75$ ,  
14 which is the same as the values obtained for the model adjusted by the Shrinkage uniform  
15 model, in which the C results were equivalent to 0.876 (95% CI 0.790-0.963;  $p < 0.0005$ ),  
16 (**Figures 5 and 6**). The calibration study of the selected model was performed by  
17 calculating the calibration slope  $B = 0.984$  (95% CI 0.0726-1.243;  $p < 0.0005$ ). Pearson linear  
18 correlation coefficients were also calculated (0.906 and 0.849) (**Figures 7 and 8**).

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1 **Comment.**

2 **Principal findings.**

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

15  
16 ~~We believe one of the strengths of the study is based on the fact that transperineal~~  
17 ~~ultrasound requires little training and can be undertaken with the type of ultrasound~~  
18 ~~equipment that can be frequently found in most delivery units worldwide. Thus, the~~  
19 ~~technique is generalizable. The Angle of Progression has proven to be easy to evaluate and~~  
20 ~~to be very useful for this purpose (30). It is known that the fetal weight and the fetal head~~  
21 ~~circumference are risk factors for caesarean and operative deliveries (31-33), and therefore~~  
22 ~~their evaluation should be included in the assessment for the prediction of success of~~  
23 ~~instrumentation. Fetal Head circumference presents an adequate correlation with the~~  
24 ~~difficulty of an instrumental delivery and the probability of failure and need for caesarean~~

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

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

#### 9 10 **Clinical significance. Implications**

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

#### 18 19 **Research Implications**

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

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

4  
5 Instrumental ~~Operative vaginal deliveries~~ are associated with higher maternal and neonatal  
6 morbidity (1-13) especially when a caesarean section is required due to a failed attempt of  
7 instrumental operative vaginal delivery. An emergency C-section ~~cesarean delivery~~ after a  
8 failed vacuum assisted delivery is associated with an intracranial haemorrhage rate of 1 in  
9 every 334 newborns and a convulsion rate of 1 per 145, with 1 in every 64 newborns  
10 needing mechanical ventilation (1). In this context, intrapartum transperineal ultrasound has  
11 been introduced in clinical practice in order to enable the prediction of difficulty and  
12 possible complications of instrumental ~~operative vaginal~~ deliveries. Bultez et al. (25)  
13 observes that an angle of progression  $<145^\circ$  (sensitivity 86.2%, specificity 49% ~~and~~  
14 ~~positive predictive value of 24%~~) is associated with a higher rate of failed attempt of  
15 vacuum delivery. Kahrs et al (29) finds that in nulliparous women with a prolonged second  
16 stage of labor, a head perineum distance of  $>35$  mm is associated with a 22% risk of an  
17 emergency cesarean section ~~delivery~~.

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

23 Martins et al. (48) identified that a cutoff of  $142^\circ$  for the angle of progression was a  
24 predictor for complicated operative vaginal deliveries, consistent with our study (30);

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~~1 which identifies an angle of progression with pushing  $<153.5^\circ$  as a predictor for  
2 complicated operative deliveries (sensitivity 86.9%).~~

~~3 Several authors have expressed their interest in predicting the kind of vaginal operative  
4 delivery they will encounter and the risk for caesarean section delivery (49-51). Their work  
5 has associated mainly different maternal and fetal parameters; with sonographic parameters  
6 only being taken into account in the recent studies. Their efforts have been focused on the  
7 prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of  
8 the first stage of labor. Thus Burkner et al (50) present a predictive model of caesarean risk  
9 based on five parameters (maternal age, body mass index, height, fetal abdominal  
10 circumference, and fetal head circumference) evaluated in the first stage of labor, and with  
11 a calibration and discriminative ability with a misclassification rate of 0.21. With the same  
12 purpose of predicting the probability of a vaginal delivery vs need for caesarean section,  
13 Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation, and  
14 presents a model based on six parameters (head-perineum distance, caput succedaneum,  
15 occiput posterior position, maternal age, gestational age, and maternal body mass index), all  
16 evaluated during the first stage of labor, and with an ARC of 0.853.~~

~~17  
18 We have observed a significant difference in fetal sex between study groups (62.5% of  
19 female fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated  
20 operative vaginal deliveries). In 5.9% of cases we have not been able to measure the fetal  
21 head circumference during the second stage of labor with the fetal head already engaged in  
22 the maternal pelvis.~~

~~23 Nonetheless, our predictive model, unlike previously proposed models **predictors**  
24 **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

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

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

13

14 **Clinical Implications**

15 By applying the predictive model proposed, any obstetrician could easily predict the kind of  
16 operative vaginal delivery that he or she will encounter in the delivery room, as a variation  
17 in the head circumference could shift the situation from an uncomplicated operative vaginal  
18 delivery, where 1 or 2 tractions are needed (when an angle of progression with a push of  
19 146° is identified by intrapartum transperineal ultrasound) to a complicated operative  
20 vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an  
21 angle of progression with push of 115° is identified) **(Figure 9) (video 1)**.

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23 **Research Implications**

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

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1 identification of the level of fetal presentation (ACOG fetal station) and its degree of  
2 engagement (16-20), intrapartum transperineal ultrasound has been introduced in the  
3 delivery room to improve the assessment of the progression and finalization of delivery.  
4 Based on this, Kalache et al. (45) reported that an angle of progression  $\geq 120^\circ$  is associated  
5 with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility  
6 of intrapartum ultrasound for the evaluation of fetal head position before operative vaginal  
7 delivery.  
8  
9 Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-  
10 13), especially when a caesarean delivery is required due to a failed operative vaginal  
11 delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is  
12 associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a  
13 convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation  
14 (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical  
15 practice to enable the prediction of difficulty and possible complications of operative  
16 vaginal deliveries. Bultez et al. (25) observed that an angle of progression  $< 145^\circ$   
17 (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated  
18 with a higher rate of failed vacuum delivery. Kahrs et al (29) found that in nulliparous  
19 women with a prolonged second stage of labor, a head-perineum distance of  $> 35$  mm is  
20 associated with a 22% risk of an emergency cesarean delivery.  
21 Kasbaoui et al (47) carried out a prospective cohort study including 659 women, in which  
22 the head-perineum distance (in this study referred to as the perineum–skull distance) was  
23 measured prior to operative vaginal delivery. After adjustment for parity, presentation type  
24 and fetal macrosomia, head-perineum distance  $\geq 40$  mm was significantly associated with

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1 the occurrence of a difficult extraction (odds ratio 2.38).  
2 Martins et al. (48) identified that a cutoff of 142° for the angle of progression was a  
3 predictor for complicated operative vaginal deliveries, which is consistent with the results  
4 of our study (30), which identified an angle of progression with pushing <153.5° as a  
5 predictor for complicated operative deliveries (sensitivity 86.9%).  
6 Several authors have expressed their interest in predicting the kind of vaginal operative  
7 delivery they will encounter and the risk for caesarean delivery (49-51). Their work has  
8 mainly associated different maternal and fetal parameters with sonographic parameters that  
9 have only been taken into account in recent studies. Their efforts have been focused on the  
10 prediction of the outcome of labor, vaginal versus caesarean delivery, by the assessment of  
11 the first stage of labor. Thus, Burker et al (50) present a predictive model of caesarean risk  
12 based on five parameters (maternal age, body mass index, height, fetal abdominal  
13 circumference, and fetal head circumference) evaluated in the first stage of labor, with  
14 calibration and discriminative ability and a misclassification rate of 0.21. With the same  
15 purpose of predicting the probability of vaginal delivery vs the need for caesarean delivery,  
16 Eggebø et al (51) introduces intrapartum transperineal ultrasound in his evaluation and  
17 presents a model based on six parameters (head-perineum distance, caput succedaneum,  
18 occiput posterior position, maternal age, gestational age, and maternal body mass index),  
19 which are all evaluated during the first stage of labor, with an ARC of 0.853.  
20  
21 We observed a significant difference in fetal sex between study groups (62.5% of female  
22 fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated  
23 operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head  
24 circumference during the second stage of labor with the fetal head already engaged in the

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1 maternal pelvis.

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

9

10

11 **Strengths and limitations**

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

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

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

7 ~~We consider that the main limitation of our work is the fact that we have not evaluated the~~  
8 ~~head-perineum distance in our predictive model, which currently seems to be a very useful~~  
9 ~~ultrasound parameter to predict the difficulty of a vaginal delivery. In addition, we believe~~

10 ~~that reproducibility of head circumference measurement during the second stage of labor~~  
11 ~~(when the fetal head is already engaged in the maternal pelvis) must be proved. External~~  
12 ~~validation of the predictive model should be also carried out. We consider that including~~

13 ~~other types of forceps, and not only Kiellands forceps, and using more objective parameters~~  
14 ~~to classify a delivery as a '**complicated operative vaginal delivery**' such as: need for~~  
15 ~~maternal blood transfusion, traumatic fetal lesion or a cup detachment, are factors that~~

16 ~~should be taken into account in future works. Lastly, we believe that as our study was~~  
17 ~~underpowered to detect neonatal and maternal morbidity, and therefore further studies~~  
18 ~~should be designed for this purpose.~~

19

## 20 **Strengths and limitations**

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

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

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

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

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

6 **Conclusion.**

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

12 **Conclusion.**

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

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



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

**3  
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25 Spain.**

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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.

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1 **Abstract:**

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3 **BACKGROUND:**

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

12

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

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

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

7  
8 **Results:** We recruited 84 nulliparous, of which 5 cases were excluded due to the difficulty  
9 of adequately evaluating the biparietal diameter and head circumference. A total of 79  
10 nulliparous patients were studied (47 vacuum-deliveries, 32 forceps-deliveries) with 13  
11 cases in occiput-posterior position. We identified 31 cases of complicated operative vaginal  
12 deliveries (19 vacuum-deliveries and 12 forceps-deliveries). No differences were identified  
13 in obstetric, neonatal or intrapartum characteristics between the two study groups(operative  
14 uncomplicated vaginal delivery versus operative complicated vaginal delivery), with the  
15 following exceptions: estimated fetal weight( $3,243\pm 425\text{g}$  versus  $3,565\pm 330\text{g}$ ;  $P=.001$ ),  
16 biparietal diameter( $93.2\pm 2.1$  versus  $95.2\pm 2.3$  mm;  $P=.001$ ), head circumference( $336\pm 12$   
17 versus  $348\pm 6.4$  mm;  $P=.001$ ), gender(female 62.5% versus 29.0%;  $P=.010$ ), newborn  
18 weight( $3,258\pm 472\text{g}$  versus  $3,499\pm 383\text{g}$ ;  $P=.027$ ) and number of tractions (median, IQR) (1  
19 (1 to 2) versus 4 (3 to 5);  $P<.0005$ ). To predict complicated operative deliveries, all 6 of the  
20 studied models presented an area under ROC curve between 0.863 and 0.876(95% CI  
21 0.775-0.950 and 0.790-0.963;  $p<0.0005$ ). The results of the study met the criteria of  
22 "interpretability" and "parsimony"(simplicity), allowing us to identify a binary logistic  
23 regression model based on angle of progression and head circumference, which has an area

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1 under the ROC curve of 0.876(95% CI 0.790-0.963;p<0.0005) and a calibration slope of B-  
2 0.984 (95% CI 0.0.726-1.243; p<0.0005).

4 **Conclusion:**

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

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

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1 **Introduction**

2  
3 Operative vaginal deliveries are associated with increased neonatal (subdural or cerebral  
4 hemorrhage, convulsions and mechanical ventilation) (1-3) and maternal morbidity  
5 (hemorrhage, perineal injuries) (3-7). This higher morbidity is even greater in cases of  
6 difficult operative vaginal deliveries and caesarean deliveries performed after failed  
7 operative vaginal delivery (8-13). Indeed, the incidence rate reported for postpartum  
8 intracranial hemorrhages after failed instrumental vaginal delivery is 1 in 334, 5.7 times  
9 greater than the rate associated with spontaneous vaginal birth (8).

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

23  
24 Bultez et al (25) reported that an angle of progression less than 145.5° has a sensitivity of

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1 86.2%, specificity of 49% and positive predictive value of 24% for the prediction of  
2 vacuum extraction failure in nulliparous women. Kahrs et al (29) reported that a head-  
3 perineum distance of more than 35 mm presents a sensitivity of 56% for the prediction of  
4 unsuccessful vaginal delivery and the need for caesarean delivery.  
5 Our group (30) reported that an angle of progression with pushing < 153° presents a  
6 sensitivity of 86.9% for the identification of complicated operative vaginal deliveries  
7 (understanding as ‘complicated operative delivery’ those cases when at least one of the  
8 following situations occurred: three or more tractions needed; a third-/fourth-degree  
9 perineal tear; significant bleeding during the episiotomy repair; a major tear; or significant  
10 traumatic neonatal lesion).

11  
12 To date, previous studies assessing predictive models for complicated vaginal deliveries  
13 have not included fetal characteristics, such as fetal weight or head circumference, which  
14 are known independent risk factors for operative vaginal and cesarean deliveries (31-33).

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

17  
18 **Materials and Methods:**

19 This was a prospective observational study in nulliparous women with singleton pregnancy  
20 at  $\geq 37$  weeks gestation and cephalic presentation, who required the use of vacuum or  
21 forceps to complete fetal extraction. The study was performed between May 2016 and June  
22 2017 at Valme University Hospital Maternity Unit in Seville, Spain. The study (PI-232013)  
23 was approved by the local Ethics and Research Committees (May 2015).

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

17  
18 Whenever a potentially eligible woman was identified at our maternity unit during the  
19 beginning of labor, she was invited to participate in the trial and was asked to provide  
20 informed consent before being enrolled in the study. Once the patient had provided signed  
21 informed consent, the intrapartum transperineal ultrasound was performed as described  
22 below. When one of the listed indications for operative vaginal delivery occurred, the  
23 managing obstetrician chose the instrument that was considered most appropriate for the  
24 clinical circumstance and his/her skill level (14).



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

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

23  
24   The following demographic and obstetric data were recorded: maternal age; gestational age

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

10

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

19

20 **Statistical analyses.**

21 We determined the mean and standard deviation for numeric variables and the percentage  
22 for qualitative variables. Comparisons of the numeric variables between complicated and  
23 uncomplicated operative vaginal deliveries were performed using Student’s t-test.  
24 Comparison of qualitative variables between study groups was performed using a chi-

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

6  
7 **Evaluation of logistic regression models.**

8 We generated different multivariate binary logistic regression models using non-automated  
9 methods to predict complicated operative vaginal delivery, including intrapartum  
10 transperineal ultrasound parameters and fetal weight, biparietal diameter and head  
11 circumference. These parameters were added progressively according to the simplicity of  
12 their evaluation and their predictive capacity for the identification of a complicated  
13 operative delivery. We carried out and compared 6 binary logistic regression models (**Table**  
14 **2**). We performed a goodness-of-fit test (-2 log likelihood) and Hosmer and Lemeshow test  
15 for each model. Afterwards, C of Harrell was determined for those models with an adequate  
16 fit to evaluate their discriminatory capacity (obtained as the area under the ROC curve of  
17 the predicted probabilities given by the model) and the slope and calibration graphic. The  
18 final model was chosen according to its discriminatory capacity and calibration graphic, in  
19 line with parsimony and interpretability principles. The models were calibrated by  
20 calculating calibration slopes and graphs. The last two analyses were performed based on  
21 the original model and the model adjusted for a uniform Shrinkage factor. Once the definite  
22 multivariate binary regression model was identified, we developed a software for the  
23 prediction of complicated operative vaginal deliveries (vacuum and forceps) with the aim  
24 of making it applicable to clinical practice.

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**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  $\geq 2.5$  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).

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

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

10

11 **Predictive models of complicated deliveries.**

12 We determined several binary logistic regression models to predict and explain complicated  
13 operative vaginal deliveries. We observed that the models presented Harrell's C statistic  
14 values oscillating between 0.863 and 0.876, determined as the area under the ROC curve of  
15 the predicted probabilities. The model of binary logistic regression that identified the  
16 variables "Angle of progression with pushing" and "head circumference" as predictors of  
17 complicated operative vaginal delivery was chosen, as these variables were included in the  
18 final multivariate analysis, which is shown in **Table 5**. Harrell's C statistic, which was  
19 obtained from the area under the ROC curve of the predicted probabilities by the model,  
20 was 0.876 (95% CI 0.790-0.963;  $p < 0.0005$ ), i.e., an intern discriminatory capacity  $> 0.75$ ,  
21 which is the same as the values obtained for the model adjusted by the Shrinkage uniform  
22 model, in which the C results were equivalent to 0.876 (95% CI 0.790-0.963;  $p < 0.0005$ ),  
23 (**Figures 5 and 6**). The calibration study of the selected model was performed by  
24 calculating the calibration slope  $B = 0.984$  (95% CI 0.0726-1.243;  $p < 0.0005$ ). Pearson linear

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

2

3 **Comment.**

4 **Principal findings.**

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

17

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

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

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

### 12 **Clinical Implications**

13 By applying the predictive model proposed, any obstetrician could easily predict the kind of  
14 operative vaginal delivery that he or she will encounter in the delivery room, as a variation  
15 in the head circumference could shift the situation from an uncomplicated operative vaginal  
16 delivery, where 1 or 2 tractions are needed (when an angle of progression with a push of  
17 146° is identified by intrapartum transperineal ultrasound) to a complicated operative  
18 vaginal delivery, requiring 3 or 4 instrumental tractions to complete fetal extraction (if an  
19 angle of progression with push of 115° is identified) **(Figure 9) (video 1)**.

### 21 **Research Implications**

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

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1 delivery room to improve the assessment of the progression and finalization of delivery.  
2 Based on this, Kalache et al. (45) reported that an angle of progression  $\geq 120^\circ$  is associated  
3 with a high probability of vaginal delivery, while Ramphulm et al (46) reported the utility  
4 of intrapartum ultrasound for the evaluation of fetal head position before operative vaginal  
5 delivery.  
6  
7 Operative vaginal deliveries are associated with higher maternal and neonatal morbidity (1-  
8 13), especially when a caesarean delivery is required due to a failed operative vaginal  
9 delivery. An emergency cesarean delivery after a failed vacuum-assisted delivery is  
10 associated with an intracranial hemorrhage rate of 1 in every 334 newborns and a  
11 convulsion rate of 1 in 145, with 1 in every 64 newborns needing mechanical ventilation  
12 (1). In this context, intrapartum transperineal ultrasound has been introduced in clinical  
13 practice to enable the prediction of difficulty and possible complications of operative  
14 vaginal deliveries. Bultez et al. (25) observed that an angle of progression  $< 145^\circ$   
15 (sensitivity 86.2%, specificity 49% and positive predictive value of 24%) was associated  
16 with a higher rate of failed vacuum delivery. Kahrs et al (29) found that in nulliparous  
17 women with a prolonged second stage of labor, a head-perineum distance of  $> 35$  mm is  
18 associated with a 22% risk of an emergency cesarean delivery.  
19 Kasbaoui et al (47) carried out a prospective cohort study including 659 women, in which  
20 the head-perineum distance (in this study referred to as the perineum–skull distance) was  
21 measured prior to operative vaginal delivery. After adjustment for parity, presentation type  
22 and fetal macrosomia, head-perineum distance  $\geq 40$  mm was significantly associated with  
23 the occurrence of a difficult extraction (odds ratio 2.38).  
24 Martins et al. (48) identified that a cutoff of  $142^\circ$  for the angle of progression was a



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

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

18  
19 We observed a significant difference in fetal sex between study groups (62.5% of female  
20 fetuses in the uncomplicated operative vaginal deliveries vs 29% in the complicated  
21 operative vaginal deliveries). In 5.9% of cases, we were not able to measure the head  
22 circumference during the second stage of labor with the fetal head already engaged in the  
23 maternal pelvis.

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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).

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

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

17  
18 **Conclusion.**

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

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