RESEARCH ARTICLE

REVISED Predicting perineal trauma during childbirth using data from a general obstetric population [version 2; peer review: 2 approved]

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Abstract

Background: Perineal trauma is a common complication of childbirth and can have serious impacts on long-term health. Few studies have examined the combined effect of multiple risk factors. We developed and internally validated a risk prediction model to predict third and fourth degree perineal tears using data from a general obstetric population.

Methods: Risk prediction model using data from all singleton vaginal deliveries at Cork University Maternity Hospital (CUMH), Ireland during 2019 and 2020. Third/fourth degree tears were diagnosed by an obstetrician or midwife at time of birth and defined as tears that extended into the anal sphincter complex or involved both the anal sphincter complex and anorectal mucosa. We used univariable and multivariable logistic regression with backward stepwise selection to develop the models. Candidate predictors included infant sex, maternal age, maternal body mass index, parity, mode of delivery, birthweight, post-term delivery, induction of labour and public/private antenatal care. We used the receiver operating characteristic (ROC) curve C-statistic to assess discrimination, and bootstrapping techniques were used to assess internal validation.

Results: Of 8,403 singleton vaginal deliveries, 8,367 (99.54%) had complete data on predictors for model development. A total of 128 women (1.53%) had a third/fourth degree tear. Three variables remained in the final model: nulliparity, mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight (per 100 gram increase) (C-statistic: 0.75, 95% CI: 0.71, 0.79). We developed a nomogram to calculate individualised risk of third/fourth degree tears using these predictors. Bootstrapping indicated good internal performance.

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Any reports and responses or comments on the article can be found at the end of the article.

Conclusions: Use of our nomogram can provide an individualised risk assessment of third/fourth degree tears and potentially aid counselling of women on their potential risk.

Keywords
Perineal trauma, Prediction model, Internal validation

This article is included in the Maternal and Child Health collection.

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REVISED **Amendments from Version 1**

There are several changes to Version 2 of our article. First, we included further details on how mode of delivery was defined. Second, we included an additional table in our extended data outlining obstetric characteristics of study participants according to parity (Table A1). Third, we have acknowledged additional limitations of our study: 1) We were lacking data on length of second stage of labour, birthing position, and indication for instrumental delivery. Inclusion of these variables may have improved the accuracy of our prediction model. 2) It was necessary for us to group third and fourth degree tears together in order to minimise overfitting and maximise the number of events and total sample size in our study. 3) We were reliant on existing data for our study which can be a limitation in terms of data availability, unmeasured variables, and uncertainty around data quality. For example, we did not have access to data on why episiotomies were performed, and while episiotomy was defined according to standard practice at CUMH (i.e., right mediolateral incision), this data could not be validated due to a reliance on secondary data only for the current study. Episiotomies angled at 40–60° are associated with a reduced risk of third and fourth degree tears compared to episiotomies with a more acute angle. Therefore, a validated measure of episiotomy may be necessary to maximise model performance.

Any further responses from the reviewers can be found at the end of the article

Introduction

Perineal trauma is a very common complication of childbirth, estimated to affect up to 80% of women[1]. Severity of tears can vary considerably and can be classified into four categories from first to fourth degree. First degree tears involve injury to the perineal skin or vaginal mucosa, second degree tears extend deeper involving perineal muscles; third degree tears extend into the anal sphincter complex, while a fourth degree tears involves both the anal sphincter complex and anorectal mucosa[2,3].

The most common tear is first or second degree tear, occurring in up to ~78% of deliveries[1]. More severe injuries (third and fourth degree) occur in approximately 5–8% of primiparous women and 2–3% of multiparous women[1]. This can lead to serious impacts on women's long-term health, such as long term pelvic floor dysfunction, prolonged pain, sexual dysfunction and faecal incontinence[2,4]; the latter occurring in almost 40% of women who sustain third and fourth degree tears, despite efforts of primary repair[5].

Several individual risk factors for perineal tears have been identified in the literature, including nulliparity, operative vaginal delivery, high birthweight, gestational age, and foetal head circumference[1,2,6]. However, few studies have examined the combined effect of multiple risk factors. Efforts to predict perineal tears using data available during the antepartum and intrapartum period are warranted in order to inform clinical decision-making, accurately counsel women on their individualized risk and increase patient understanding of the potential long-term consequences of specific medical interventions.

Therefore, given their long-term health impacts, the aim of this study was to develop and validate a risk prediction model to predict third and fourth degree perineal tears, using antepartum and intrapartum data from a general obstetric population.

Methods

Study population

A national project called 'The Maternal and Newborn Clinical Management System (MN-CMS)' was rolled out in the Republic of Ireland in December 2016[7]. With this system, an electronic health record was created resulting in a move from paper clinical notes, allowing for all maternal and newborn information to be stored on one record. The first maternity hospital to implement the electronic health record in the Republic of Ireland was Cork University Maternity Hospital (CUMH). As a result, we used anonymised data from all singleton vaginal deliveries at CUMH from January 2019 to December 2020 to develop and internally validate a risk prediction model for third and fourth degree perineal tears.

We obtained ethical approval from the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) (ECM4(v)09/04/2020) in June 2020. The Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD) checklist was used as a guideline for reporting our study[8] (available here).

Candidate predictors and outcome

In order to identify candidate predictors, we reviewed existing literature, used expert opinion (comprising obstetricians, epidemiologists and experts on the MN-CMS), and examined the distribution of the predictor in the data available to us, (for example, we excluded any variables with <5 exposed cases)[9] to identify routinely measured candidate predictors for third and fourth degree tears.

Candidate predictors considered for model development included infant sex, maternal age, maternal body mass index (BMI), parity, mode of delivery, birthweight, post-term delivery, induction of labour and public/private antenatal care.

A description of candidate predictors is as follows: *infant sex* was categorised as male/female. *Maternal age:* this was recorded in units of years at the initial prenatal visit. *Maternal BMI:* maternal height (cm) and weight (kg) at initial prenatal visit were used to calculate maternal BMI. This was categorised as underweight <18.5, normal weight ≥18.5 to ≤24.9, overweight ≥25 to ≤29.9 and obese ≥30 (due to small numbers, underweight and normal weight were combined). *Parity:* this was recorded as number of previous completed pregnancies and was re-categorised nulliparous or multiparous. *Mode of delivery* (with manual support technique[10]) was categorised into four different groups as follows: spontaneous vaginal delivery with episiotomy, spontaneous vaginal delivery without episiotomy, forceps delivery and ventouse delivery. We grouped ventouse delivery (with and without episiotomy) and forceps delivery (with and without episiotomy) together

due to the small number of these instrumental deliveries that occurred without episiotomy. An episiotomy was defined as a right mediolateral incision (*i.e.*, a cut made by the doctor or midwife during childbirth that begins in the middle of the vaginal opening and extends down toward the buttocks at a 45-degree angle). Caesarean deliveries were excluded as only vaginal deliveries are at risk of perineal tears. *Birthweight* was measured to the nearest gram and analysed as an increase in risk per 100 gram increase in birthweight. *Post-term delivery* was defined as delivery at ≥40 weeks' gestation (with estimated due date confirmed by first trimester ultrasound) compared to delivery at or before full-term (*i.e.*, delivery at <40 weeks' gestation). Induction of labour was recorded in the MN-CMS if any of the following methods were administered: artificial rupture of membranes, Dilapan-S®, balloon catheter, or prostaglandin gel. Public antenatal care was defined as free antenatal care through the Maternity and Infant Care Scheme in Ireland. This is available to anyone who lives in Ireland or intends to live there for at least one year. Private antenatal care was defined as choosing to pay a consultant's fee/hospital fee so that a particular obstetrician would provide the care throughout the pregnancy/birth and that recovery would take place in a private/semi-private hospital room.

Outcome: Degree of tear was diagnosed by an obstetrician or midwife at time of birth and recorded in the MN-CMS. Third/fourth degree tears were tears that extended into the anal sphincter complex or involved both the anal sphincter complex and anorectal mucosa.

Statistical analysis

All statistical analyses were performed using Stata MP 14.2 (RRID:SCR_012763) (free alternative, RStudio). We used univariable analysis to examine associations between candidate predictors and third/fourth degree tears. To develop the prediction model, any variables that were statistically significant in the univariable analysis (*i.e.*, p-value < 0.1) were included in multivariable logistic regression with backward stepwise selection (with a p-value of 0.1 for exclusion). Therefore, all candidate predictors considered statistically significant in the univariable analysis were included at first and the least useful predictors (*i.e.*, the variable that is the least statistically significant) were subsequently removed one-by-one.

Sample size calculations: We used the *pmsampsize* command to calculate the minimum sample size and number of events required for model development to minimise overfitting. Assuming an outcome event proportion (prevalence) of 0.015, a c-statistic of 0.75, a target shrinkage factor of 0.9, and 12 predictors/categories, then a minimum sample size of 7,995 (with 120 events) would be required to minimise overfitting[11].

Model performance: Spline functions with 3, 4 and 5 knots were used to assess non-linear functions for any continuous predictors included in model development. These were plotted against the original variable to compare the linear function with the spline function, while Akaike information criterion (AIC) and Bayesian information criterion (BIC) statistics were calculated to examine model fit.

We examined model performance by assessing overall fit, discrimination and calibration. Brier Score and Cragg & Uhler's (Nagelkerke) R^2 assessed overall fit. The area under the receiver operating characteristic curve (ROC) C-statistic assessed discrimination (*i.e.*, how well the model differentiates between those patients who experience third/fourth degree tears and those who do not[9]). Calibration-in-the-large (CITL), calibration slope (C-slope) and calibration plot (*pmcalplot*) of observed against expected probabilities across 10 risk groups of individuals assessed calibration (*i.e.*, how closely the predictions of the models match the observed outcomes in the data[9,12]).

Internal validation: To examine internal validation of our model, assess overfitting and calculate the optimism adjusted C-statistic, CITL and C-slope, we used bootstrapping techniques (with 1,000 repetitions). Finally, a graphical representation of our prediction model (*i.e.*, nomogram) was developed to provide individualised risk assessment for third/fourth degree tears.

Results

There was a total of 8,403 singleton vaginal deliveries at CUMH during 2019 and 2020, of which 8,367 (99.54%) had complete data on predictors for model development. A total of 128 women (1.53%) were recorded as sustaining third/fourth degree tears (n=123 and 5 respectively). Mother and child characteristics of study participants who did and did not sustain a third/fourth degree tear are outlined in Table 1. Obstetric characteristics of study participants by parity and results of univariable analysis are shown in Tables A1 and A2 as *Extended data*[8], with nulliparity, mode of delivery, increasing birthweight and post-term delivery significantly associated with an increased risk of third/fourth degree tears. These variables were used in the multivariable logistic regression with backward stepwise selection to develop the prediction model for third/fourth degree tears.

Risk prediction model

Third/fourth degree tears: Three variables were considered the best combined predictors of third/fourth degree tears using multivariable logistic regression with backward stepwise selection (C-statistic: 0.75, 95% CI: 0.71, 0.79). These included parity (specifically nulliparous), mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight (per 100 gram increase) (Table 2).

We developed a nomogram to provide an individualised risk assessment of third/fourth degree perineal tear using these predictors (Figure 1). For example, a forceps delivery (score 1.5), birthweight of ~4,600 grams (score 7), and nulliparous woman (score 3.5), the total score is 12, corresponding to an ~10% risk of third/fourth degree perineal tear.

Table 1. Characteristics of study participants who did and did not sustain a third/fourth degree tear.

Characteristic	Did not sustain third/fourth degree tear N=8239	Sustained third/fourth degree tear N=128
Infant sex		
Female	4,099 (49.7)	65 (50.8)
Male	4,140 (50.3)	63 (49.2)
Maternal age (years)	33.7 (5.1)	33.2 (4.3)
Maternal BMI		
Underweight/normal weight	4,158 (50.5)	67 (52.3)
Overweight	2,455 (29.80)	45 (35.2)
Obese	1,408 (17.1)	14 (10.9)
Unknown	218 (2.6)	2 (1.6)
Parity		
≥1	5,098 (61.9)	30 (23.4)
0	3,141 (38.1)	98 (76.6)
Mode of delivery with/without episiotomy		
SVD without episiotomy	5,728 (69.5)	53 (41.4)
SVD with episiotomy	577 (7.0)	12 (9.4)
Forceps delivery	409 (5.0)	19 (14.8)
Ventouse delivery	1,525 (18.5)	44 (34.4)
Birthweight (grams)	3,452.0 (523.8)	3591.4 (484.0)
Post-term delivery		
<40 weeks' gestation	4,366 (53.0)	56 (43.8)
≥40 weeks' gestation	3,873 (47.0)	72 (56.2)
Induction of labour		
No	6,453 (78.3)	101 (78.9)
Yes	1,786 (21.7)	27 (21.1)
Public/private antenatal care		
Private	1,415 (17.2)	16 (12.5)
Public	6,834 (82.8)	112 (87.5)

N (%) for categorical variables, mean (SD) for continuous variables.

Abbreviations: BMI, body mass index; SVD, spontaneous vaginal delivery.

Model performance and internal validation

There was little difference between the shape of the linear function for birthweight compared to the spline function using 3 and 4 knots, while 5 knots overfit the data (Figure A1, found as *Extended data*[8]). The AIC and BIC statistics were lowest for the linear function; therefore, birthweight was analysed as a linear function.

The result for the Brier Score and Cragg & Uhler's (Nagelkerke) R^2 were 0.014 and 0.083, respectively. Average model predictions matched average observed outcomes for the 10 risk groups of individuals (*i.e.*, the deciles of risk that were used as cut-off points to compare observed and expected probabilities in groups of individuals), as indicated by the calibration plot, suggesting good calibration. The majority of

Table 2. Best combined predictors for third/fourth degree tear and assessment of model performance.

Characteristic	Coefficient (95% CI)	N (%) or Mean (SD)	OR (95% CI)
Parity			
≥1	-	5,128 (61.3)	ref
0	1.56 (1.11, 2.01)	3,239 (38.7)	4.75 (3.03, 7.44)
Mode of delivery			
SVD without episiotomy	-	5,781 (69.1)	ref
Forceps delivery	0.71 (0.16, 1.26)	428 (5.1)	2.03 (1.17, 3.51)
Ventouse delivery	0.40 (-0.02, 0.81)	1,569 (18.8)	1.48 (0.98, 2.24)
Birthweight[a]	0.07 (0.03, 0.10)	3,454.1 (523.4)	1.07 (1.03, 1.11)
Intercept	-7.62 (-6.31, -8.92)	-	-
Discrimination	**Original apparent**	**Optimism**	**Optimism adjusted**
C-statistic	0.75 (95% CI: 0.71, 0.79)	0.01	0.74
Calibration			
CITL	0 (95% CI: -0.17, 0.17)	0.001	-0.001
C-slope	1 (95% CI: 0.79, 1.20)	0.06	0.94

[a]Per 100 gram increase in birthweight

Abbreviations: SD, standard deviation; OR, odds ratio; 95% CI, 95% confidence interval; ref, reference category; SVD, spontaneous vaginal delivery; CITL, calibration-in-the-large; C-slope, calibration slope.

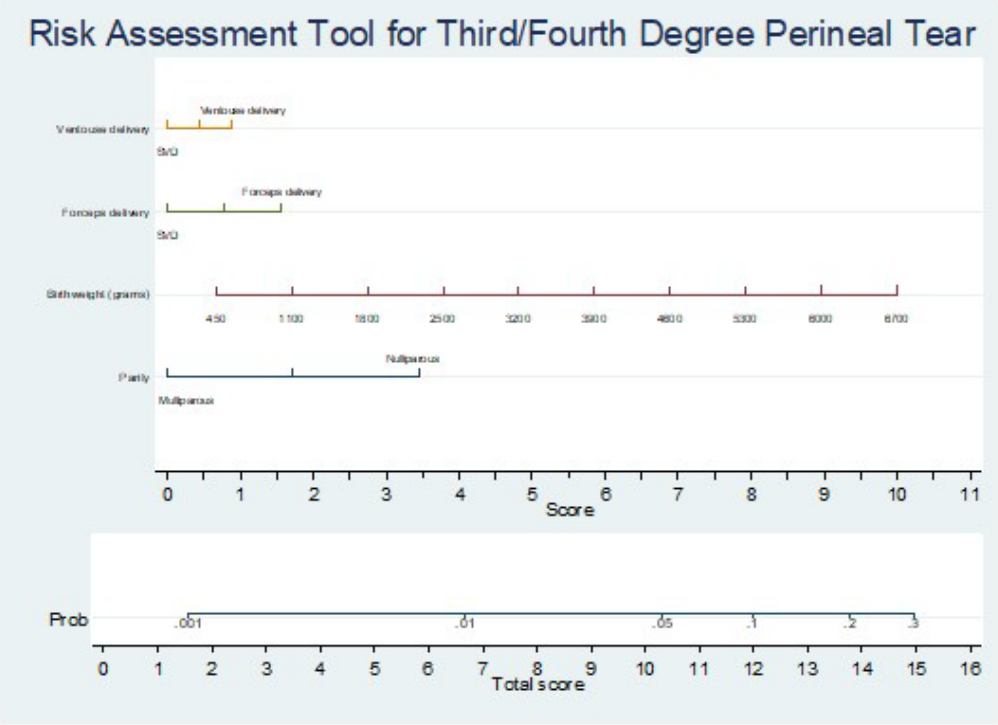

Figure 1. Nomogram providing individualised risk assessment of third/fourth degree perineal tear. For example, a forceps delivery (score 1.5), birthweight of ~4,600 grams (score 7), and nulliparous woman (score 3.5), the total score is 12, corresponding to an ~10% risk of third/fourth degree perineal tear.

the deciles are clustered in the bottom left, suggesting most women have low risk of third/fourth degree tears. There is some miscalibration at the individual level in the higher risk individuals as suggested by the LOWESS smoother. However, there is very little data at the higher risk probabilities as indicated by the spike plot towards the bottom of the graph (Figure A2, found as *Extended data*[8]).

The original apparent C-statistic was 0.75 (95% CI: 0.71, 0.79). After bootstrapping, there was minimal optimism adjustment to the C-statistic, suggesting good internal performance (optimism adjusted C-statistic: 0.74). The miscalibration in CITL and C-slope were small indicating that overfitting was unlikely to be an issue (Table 2).

Discussion

We developed and internally validated a risk prediction model for third/fourth degree perineal tears using antepartum and intrapartum data from a general obstetric Irish population.

During model development, we identified three variables that were considered the best combined predictors of third/fourth degree tears, including nulliparity, mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight. Our model had good internal performance, with an original apparent C-statistic of 0.75, which was minimally adjusted after bootstrapping (optimism adjusted C-statistic: 0.74). Finally, overall calibration of our model was good as suggested by the CITL, C-slope and calibration plot.

Risk prediction models in other geographical locations have been developed using data available before and after delivery, with some similarities to the current study. For example, a single-site model developed in a tertiary hospital in the US (with a ROC curve estimate of 0.83) identified nulliparity, operative vaginal delivery and estimated foetal weight >3,500 grams as risk factors for third/fourth degree tears, while African American ethnicity and tobacco use showed a protective effect[13]. This study did not differentiate between different types of operative vaginal delivery, however. Separately, a risk stratification tool developed in the US used a scoring system to predict third/fourth degree tears, identifying parity, duration of second stage of labour, vacuum delivery, history of anal sphincter injury, maternal age, gestational age and maternal ethnicity as important risk factors for model development[14].

Prediction models using data available before delivery only have also been developed. One Danish model used single-site data available prior to delivery to develop and internally validate a prediction model for obstetric anal sphincter injuries (third-and-fourth-degree tears)[6]. Variables identified as predictors of third/fourth degree tears (with a C-statistic of 0.71) included suspected macrosomia, nulliparity, increasing maternal age, occiput posterior foetal position and induction/augmentation of labour[6]. A US-based study developed and validated a prediction model for obstetric anal sphincter injuries using data available at the time of admission for labour only. Out of 30 candidate risk factors identified, 15 remained in the final model. These included parity, maternal age, ethnicity, marital status, insurance status, maternal smoking, gestational age, prior caesarean section, prior operative delivery, anaemia, cardiovascular disease, gestational diabetes, white blood cell and haematocrit values and whether a creatinine lab test was conducted, resulting in a C-statistic of 0.77[15]. Although authors had a large number of candidate predictors included in the model, this did not significantly improve model accuracy in comparison to our model. Additionally, we used data available in both the antepartum and intrapartum period to examine any additional potential risk occurring from medical interventions such as mode of delivery (including spontaneous vaginal delivery with and without episiotomy, forceps delivery and ventouse delivery).

Strengths and limitations

This study contained some limitations that are important to note. First, we did not have access to data on previous history of third/fourth degree tears, length of second stage of labour, birthing position, or indication for instrumental delivery, which may have improved the accuracy of our model. However, before additional candidate predictors are added to a prediction model it is important to consider availability of an appropriate sample size to minimise overfitting. Additionally, regarding a lack of data on previous history of third/fourth degree tears, evidence examining risk of recurrence of third/fourth tears in subsequent pregnancies is inconsistent, and women who had an anal sphincter injury in their first pregnancy are more likely to have a caesarean section in their subsequent pregnancy to avoid a recurrent tear[16–19]. Second, to minimise overfitting and maximise the number of events and total sample size for the current study, we grouped third and fourth degree tears together and used data from all singleton vaginal deliveries at CUMH during 2019 and 2020 to develop and internally validate our model. Ideally, we would have used 2020 data to conduct a temporal external validation in order to examine reproducibility of our model. However, despite this limitation, a geographical external validation would still be needed to assess generalisability of our findings. As it is recommended that external validation is carried out by an independent research team, we included the estimates needed to calculate the linear predictor of our model to allow for an independent external validation and objective evaluation of model performance[20]. Third, previous evidence suggests that third/fourth degree tears may be subject to overdiagnosis potentially as a result of anxiety or fear of missing a diagnosis[21]. However, the rate of third/fourth degree tear reported in the current study (1.53%) was similar to that of the national estimate for 2019–2020 (1.6%–1.9%), reducing the possibility of misclassification of the outcome[22]. Fourth, there are many benefits of using secondary data for research purposes, in particular regarding the need for fewer resources. In addition to this, the data used in the current study are real world data and while it has deficits, it reflects outcome in practice. However, a reliance on existing data can be a limitation in terms of data availability, unmeasured variables, and uncertainty around data quality. For example, we did not have access to data on why episiotomies were performed, and while episiotomy was defined according

to standard practice at CUMH (i.e., right mediolateral incision), this data could not be validated as we were reliant on secondary data only for the current study. Episiotomies angled at 40–60° are associated with a reduced risk of third and fourth degree tears compared to episiotomies with a more acute angle[23]. Therefore, a validated measure of episiotomy is necessary to maximise model performance. Finally, this study was limited to singleton deliveries only, therefore results of the prediction model should not be generalised to multiple pregnancies.

There are also several strengths in this study. First, we conducted an internal validation of our model allowing us to assess overfitting and calculate an optimism adjusted C-statistic. Second, the amount of missing data for model development was small (<1%), minimising the likelihood of selection bias driven by missing data. Third, we conducted an appropriate sample size calculation to ensure a sufficiently large sample size in order to minimise overfitting. Finally, we developed a nomogram to graphically represent our prediction model. This provides an individualised risk assessment enabling the user to quickly and easily estimate the probability of sustaining a third/fourth degree tear.

Conclusions

We developed and internally validated a risk prediction model to predict third/fourth degree perineal tears using antepartum and intrapartum data from a general obstetric population. Three routinely collected variables were considered the best combined predictors, including nulliparity, mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight. Use of our nomogram can provide an individualised risk assessment of third/fourth degree tears and potentially aid counselling of women on their potential risk. However, before a risk prediction model can be applied in clinical practice, an independent external validation is needed to assess reproducibility and an impact study is needed to assess its clinical usefulness.

Data availability

Underlying data

The data used in this study are not publicly available due to data protection issues. It is the policy of The National Perinatal Epidemiology Centre (NPEC) that all requests for data for research purposes are first considered by a Data Access Committee. More information on the conditions under which access will be granted and who can request data can be found on their Data Access Committee page (https://www.ucc.ie/en/npec/dataaccesscommittee/dataaccesscommittee/). The datasets used in this study are from The Maternal and Newborn Clinical Management System (MN-CMS) of the Cork University Maternity Hospital (CUMH) from January 2019 to December 2020 and can be found on the NPEC website at https://www.ucc.ie/en/. Request for data access is available from NPEC by completing their Data Access Request Form and returning it to npec@ucc.ie.

Extended data

Zenodo: Predicting Perineal Trauma during Childbirth using data from a General Obstetric Population. https://doi.org/10.5281/zenodo.8379770[8].

This project contains the following extended data:

- TRIPOD checklist
- Obstetric characteristics of study participants by parity (Table A1)
- Univariable analysis (Table A2)
- Linear function for birthweight plotted against spline function for birthweight (Figure A1)
- Calibration plot (Figure A2)

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 03 November 2023

https://doi.org/10.21956/hrbopenres.15117.r36502

✔ **Emilia Rotstein**

[1] Department of Clinical Science, Intervention and Technology - CLINTEC, Karolinska Institutet, Stockholm, Sweden

[2] Karolinska University Hospital, Stockholm, Sweden

Thank you for your responses to my questions and to your amendments to the manuscript.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Urogynaecology, pelvic floor dysfunction, pelvic floor ultrasound

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 01 September 2023

https://doi.org/10.21956/hrbopenres.14934.r35699

? **Emilia Rotstein**

[1] Department of Clinical Science, Intervention and Technology - CLINTEC, Karolinska Institutet, Stockholm, Sweden

[2] Karolinska University Hospital, Stockholm, Sweden

Thank you for giving me the opportunity to review this interesting study.

This is a register-based study with the overarching aim of developing and internally validating a risk prediction model of obstetric anal sphincter injuries. A total of 8,367 vaginal deliveries were included with a total frequency of 128 (1.53%) cases of third/fourth degree tear, a number which is quite low in western countries today. As result, nulliparity, mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight (per 100- gram increase) were the important factors.

The study resulted in a risk prevention model identifying nulliparity, mode of delivery (divided into spontaneous vaginal delivery with or without episiotomy, ventouse or forceps delivery) as risk factors of obstetric trauma. Even though this is not novel information, the resulting nomogram displaying individual risk prediction shows promise.

I would like to congratulate the authors on a nicely thought-through and executed study, however, I do have some questions for the authors:

- How did you choose the candidate predictors and why? You mention several others in your discussion, and whereas information on previous perineal trauma and e.g. foetal head circumference were not available to you, others such as length of second stage or birthing position may well have been included, as well as indication for instrumental delivery.

- Why were episiotomy rate for ventouse and forceps deliveries not included? The risk reducing effect of episiotomies is still being discussed and as such this would have added valuable information.

- How was the diagnosis made? What was the rationale of not subdividing the degree of tear?

- Was there any information on manual perineal support?

- Are there any indications on how and why the episiotomies were performed?

- I find it quite difficult to navigate Table 1 as the background characteristics and obstetric data are all in the same table. May I suggest at least dividing the obstetric variables into primi- and multiparas? I believe this would facilitate the overview.

- Finally, you mention possible overdiagnosis in your section on limitations even though your frequency falls well within your stated national injury rate but fail to mention the limitations of a registry-based study as far as reliability of data is concerned such as the data not having been collected by the researcher, lacking information on confounders, missing information on data quality to highlight a few. Could you please comment?

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?

Partly

If applicable, is the statistical analysis and its interpretation appropriate?
I cannot comment. A qualified statistician is required.

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Urogynaecology, pelvic floor dysfunction, pelvic floor ultrasound

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 27 Sep 2023

Gillian Maher

Dear Prof Emilia Rotstein,

We thank you for your helpful review of our manuscript entitled *"Predicting perineal trauma during childbirth using data from a general obstetric population"*.
Please find below an itemized reply addressing each comment in your Reviewer's Report.

1. I would like to congratulate the authors on a nicely thought-through and executed study, however, I do have some questions for the authors: How did you choose the candidate predictors and why? You mention several others in your discussion, and whereas information on previous perineal trauma and e.g. foetal head circumference were not available to you, others such as length of second stage or birthing position may well have been included, as well as indication for instrumental delivery.

We thank you for your positive comment regarding our study.
When choosing candidate predictors, we were reliant on what data was available to us in the Maternal and Newborn Clinical Management System (MN-CMS). We chose candidate predictors by reviewing existing literature and through discussion with obstetricians, epidemiologists, and experts on the MN-CMS. We also examined the distribution of the candidate predictor in the data (for example, we excluded any variables with <5 exposed cases).

This is outlined in our Methods as follows:
"In order to identify candidate predictors, we reviewed existing literature, used expert opinion (comprising obstetricians, epidemiologists and experts on the MN-CMS), and examined the distribution of the predictor in the data available to us, (for example, we

excluded any variables with <5 exposed cases) to identify routinely measured candidate predictors for third and fourth degree tears."

With regards to your second comment, we agree that access to variables such as length of second stage of labour, birthing position, and indication for instrumental delivery may have improved the accuracy of our model. We have now acknowledged this in our Discussion as follows:

"We did not have access to data on previous history of third/fourth degree tears, length of second stage of labour, birthing position, or indication for instrumental delivery, which may have improved the accuracy of our model. However, before additional candidate predictors are added to a prediction model it is important to consider availability of an appropriate sample size to minimise overfitting."

2. Why were episiotomy rate for ventouse and forceps deliveries not included? The risk reducing effect of episiotomies is still being discussed and as such this would have added valuable information.

We grouped ventouse delivery (with and without episiotomy) and forceps delivery (with and without episiotomy) together due to the small number of these instrumental deliveries that occurred without episiotomy. For example, there was only 1 case of perineal trauma for forceps delivery without episiotomy.

We have now added this information to our Methods as follows:
"Mode of delivery (with manual support technique(1)) was categorised into four different groups as follows: spontaneous vaginal delivery with episiotomy, spontaneous vaginal delivery without episiotomy, forceps delivery and ventouse delivery. We grouped ventouse delivery (with and without episiotomy) and forceps delivery (with and without episiotomy) together due to the small number of these instrumental deliveries that occurred without episiotomy."

3. How was the diagnosis made? What was the rationale of not subdividing the degree of tear?

Degree of tear was diagnosed by an obstetrician or midwife at time of birth and recorded in the MN-CMS. Third/fourth degree tears were tears that extended into the anal sphincter complex or involved both the anal sphincter complex and anorectal mucosa. We have outlined this information in our Methods.

Regarding your second point, we grouped third- and fourth-degree tears together (n=128) to ensure an appropriate number of events in our data so as to minimise overfitting. This decision was made upon completion of our sample size calculation, as outlined in our Methods as follows:
"*Sample size calculations:* We used the pmsampsize command to calculate the minimum sample size and number of events required for model development to minimise overfitting. Assuming an outcome event proportion (prevalence) of 0.015, a c-statistic of 0.75, a target shrinkage factor of 0.9, and 12 predictors/categories, then a minimum sample size of 7,995 (with 120 events) would be required to minimise overfitting."

We have now acknowledged the limitation of not subdividing the degree of tear in our Discussion as follows:
"To minimise overfitting and maximise the number of events and total sample size for the current study, we grouped third and fourth degree tears together and used data from all singleton vaginal deliveries at CUMH during 2019 and 2020 to develop and internally validate our model."

4. Was there any information on manual perineal support?

As outlined to Reviewer 1 (point 2, above), standard practice at CUMH is to use manual support technique for vaginal deliveries. We have incorporated this into our manuscript as follows and referenced the Hals et al study which describes perineal support in detail:

"Mode of delivery (with manual support technique (1)) was categorised into four different groups as follows: spontaneous vaginal delivery with episiotomy, spontaneous vaginal delivery without episiotomy, forceps delivery and ventouse delivery."

5. Are there any indications on how and why the episiotomies were performed?

We do have information on *how* episiotomies were performed – "Episiotomies were performed using a right mediolateral incision (i.e., a cut made by the doctor or midwife during childbirth that begins in the middle of the vaginal opening and extends down toward the buttocks at a 45-degree angle)." This information is outlined in our Methods.

Conversely, we do not have access to data on *why* episiotomies were performed. We have included this in our Discussion and acknowledged the limitation that data on episiotomy was not validated (as outlined to Reviewer 1 in point 1, above):
"A reliance on existing data can be a limitation in terms of data availability, unmeasured variables, and uncertainty around data quality. For example, we did not have access to data on why episiotomies were performed, and while episiotomy was defined according to standard practice at CUMH (i.e., right mediolateral incision), this data could not be validated as we were reliant on secondary data only for the current study. Episiotomies angled at 40–60° are associated with a reduced risk of third and fourth degree tears compared to episiotomies with a more acute angle (2). Therefore, a validated measure of episiotomy is necessary to maximise model performance."

6. I find it quite difficult to navigate Table 1 as the background characteristics and obstetric data are all in the same table. May I suggest at least dividing the obstetric variables into primi- and multiparas? I believe this would facilitate the overview.

Apologies for this – In table 1 we have outlined the characteristics of our study participants according to those who did and did not sustain a third/fourth degree tear. We are very limited in how we can further subdivide this data due to data protection issues (i.e., subdividing by primiparous and multiparous will result in very small cell counts for those who sustained a third/fourth degree tear). Taking mode of delivery as an example, further

subdividing our table by parity will result in <10 exposed cases for SVD with episiotomy, forceps, and ventouse delivery among multiparous women. Similarly, it would result in <10 exposed cases for induction of labour and private antenatal care among multiparous women.

However, to facilitate a clearer overview of our participants, we have now created an additional table in our extended data (Table A1: https://doi.org/10.5281/zenodo.8379770) outlining our obstetric data by parity.

7. Finally, you mention possible overdiagnosis in your section on limitations even though your frequency falls well within your stated national injury rate but fail to mention the limitations of a registry-based study as far as reliability of data is concerned such as the data not having been collected by the researcher, lacking information on confounders, missing information on data quality to highlight a few. Could you please comment?

There are many benefits of using secondary data for research purposes, in particular regarding the need for fewer resources. Furthermore, the data used in the current study are real world data and while it has deficits, it reflects outcome in practice. However, we agree that a reliance on existing data can be a limitation in terms of data availability, unmeasured variables, and uncertainty around data quality.

We have edited our Discussion and incorporated this into our manuscript as follows: "There are many benefits of using secondary data for research purposes, in particular regarding the need for fewer resources. In addition to this, the data used in the current study are real world data and while it has deficits, it reflects outcome in practice. However, a reliance on existing data can be a limitation in terms of data availability, unmeasured variables, and uncertainty around data quality."

We hope these amendments address the suggestions raised. Should any further amendments be necessary, we would be happy to address them accordingly.

Sincerely,

Dr Gillian Maher, Dr Laura O'Byrne, Dr Joye McKernan, Dr Paul Corcoran, Prof Richard Greene, Dr Ali Khashan and Dr Fergus McCarthy

References

1. Hals E, Øian P, Pirhonen T, Gissler M, Hjelle S, Nilsen EB, et al. A Multicenter Interventional Program to Reduce the Incidence of Anal Sphincter Tears. Obstetrics & Gynecology. 2010;116(4):901-8.
2. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. BJOG : an international journal of obstetrics and gynaecology. 2012;119(6):724-30.

Competing Interests: No competing interests to disclose.

Reviewer Report 02 August 2023

https://doi.org/10.21956/hrbopenres.14934.r35280

Jouko Pirhonen
University Hospital of North Norway, Tromsø, Norway

In this manuscript from Ireland the authors developed and internally validated a risk prediction model to predict third- and fourth-degree perineal tears using data from a general obstetric population. They used univariable and multivariable logistic regression with backward stepwise selection to develop the models. Totally 8,367 cases (singleton vaginal deliveries) completed data on predictors for model development. A total frequency of 128 women (1.53%) had a third/fourth degree tear, the number which is quite low in western countries today. As result, nulliparity, mode of delivery (specifically forceps delivery or ventouse delivery) and increasing birthweight (per 100-gram increase) were the important factors.

All the risk factors studied in the manuscript are well known. Secondly, similar articles have been published earlier. However, the manuscript has a potential interest. Further, the modern statistics improves the quality of this study.

The greatest limitation of this register study is the database used. For example, the authors describe the used episiotomy (mediolateral) nicely. However, an information if the episiotomy was cut correctly is missing. The authors could read the study from Stedenfeldt et al. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. BJOG 2012;119:724–73 for their future research. Further, there is no mention if manual support technique was used or not. This affects greatly for the risk factors as well for OASIS rate. Please, read the article from Hals et a. A Multicenter Interventional Program to Reduce the Incidence of Anal Sphincter Tears Obstet Gynecol 2010;116:901–8 for future research. And finally, which kind of support technique was used.

References

1. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, et al.: Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study.*BJOG*. 2012; **119** (6): 724-30 PubMed Abstract | Publisher Full Text
2. Hals E, Øian P, Pirhonen T, Gissler M, et al.: A multicenter interventional program to reduce the incidence of anal sphincter tears.*Obstet Gynecol*. 2010; **116** (4): 901-908 PubMed Abstract | Publisher Full Text

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?

Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Yes

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Fetal medicine. Ultrasound. Prevention of serious perineal tears.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 27 Sep 2023

Gillian Maher

Dear Prof Jouko Pirhonen,

We thank you for your helpful review of our manuscript entitled *"Predicting perineal trauma during childbirth using data from a general obstetric population"*.
Please find below an itemized reply addressing each comment in your Reviewer's Report.

1. The greatest limitation of this register study is the database used. For example, the authors describe the used episiotomy (mediolateral) nicely. However, an information if the episiotomy was cut correctly is missing. The authors could read the study from Stedenfeldt et al. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. BJOG 2012;119:724–73 for their future research.

We thank you for your positive comment regarding the description of episiotomy in our study and for drawing our attention to the Stedenfeldt et al study. As we have outlined in our manuscript, episiotomy was defined as a right mediolateral incision (i.e., a cut made by the doctor or midwife during childbirth that begins in the middle of the vaginal opening and extends down toward the buttocks at a 45-degree angle). However, we agree that it is a limitation that data on episiotomy was not validated.

We have edited our Discussion to acknowledge this limitation and referenced the Stedenfeldt et al study as follows:
"While episiotomy was defined according to standard practice at CUMH (i.e., right mediolateral incision), this data could not be validated as we were reliant on secondary data

only for the current study. Episiotomies angled at 40–60° are associated with a reduced risk of third and fourth degree tears compared to episiotomies with a more acute angle (1). Therefore, a validated measure of episiotomy is necessary to maximise model performance."

2. *Further, there is no mention if manual support technique was used or not. This affects greatly for the risk factors as well for OASIS rate. Please, read the article from Hals et a. A Multicenter Interventional Program to Reduce the Incidence of Anal Sphincter Tears Obstet Gynecol 2010;116:901–8 for future research. And finally, which kind of support technique was used.*

Thank you for bringing the Hals et al study to our attention. Standard practice at CUMH is to use manual support technique for vaginal deliveries. We have incorporated this into our manuscript as follows and referenced the Hals et al study:

Mode of delivery (with manual support technique (2)) was categorised into four different groups as follows: spontaneous vaginal delivery with episiotomy, spontaneous vaginal delivery without episiotomy, forceps delivery and ventouse delivery."

We hope these amendments address the suggestions raised. Should any further amendments be necessary, we would be happy to address them accordingly.

Sincerely,

Dr Gillian Maher, Dr Laura O'Byrne, Dr Joye McKernan, Dr Paul Corcoran, Prof Richard Greene, Dr Ali Khashan and Dr Fergus McCarthy

References

1. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. Episiotomy characteristics and risks for obstetric anal sphincter injuries: a case-control study. BJOG : an international journal of obstetrics and gynaecology. 2012;119(6):724-30.
2. Hals E, Øian P, Pirhonen T, Gissler M, Hjelle S, Nilsen EB, et al. A Multicenter Interventional Program to Reduce the Incidence of Anal Sphincter Tears. Obstetrics & Gynecology. 2010;116(4):901-8.

Competing Interests: No competing interests to disclose.