Predictors of Severe Perineal Tear during Delivery in Yenagoa, Southern Nigeria

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Authors' contributions

This work was carried out in collaboration between both authors. Author IEH designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author IJSA managed the analyses of the study and literature search. Both authors read and approved the final manuscript.

Original Research Article

ABSTRACT

Background: Perineal tear is a very common complication of vaginal delivery, and it is often mild. However, when severe, it could result in torrential life threatening hemorrhage and anal sphincter injury, with fecal incontinence.
Objective: The objective of this study is to determine the predictors of severe perineal tear (3rd and 4th degree tear), using mild perineal tear (1st and 2nd degree) as control. It would also determine the rate of perineal tear, and the maternal and fetal demographic risk factor associated with it.
Materials and Methods: This was an analytic observational study of 186 women who had perineal tear during vaginal delivery. Out of these, 19 women had severe (3rd and 4th degree) perineal tear, also known as obstetrics anal sphincter injury (OASI). This was compared to 167 women who had mild perineal tear (1st and 2nd degree) during the study period.
Maternal demographic information retrieved was maternal age, parity, educational level, and occupation. Obstetrics factors were booking status, gestational age at delivery, mode of delivery, rank of the accoucheur (nurse or doctor), and degree of perineal tear. Fetal demographic data was birth weight and fetal sex.

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Categorical variables were compared with odds ratio, difference in mean was compared with student's t-test, and the degree of association for quantitative variables was determined using Pearson's correlation coefficient. Predictor variables were determined using simple logistic regression, and multivariate analysis. Confidence interval was set at 95%, and statistical significance was set at p value of < 0.05.

Results: The prevalence of OASI (3rd and 4th degree perineal tear) in Yenagoa was 1.1%. The significant risk factors were women of younger age, odds ratio = 1.04(0.37, 2.87) with p = 0.04, low parity, odds ratio = 0.20(0.07, 0.55) with p = 0.008, low educational background, odd ratio = 18.9(5.92, 60.81), and birth weight ≥ 4kg, odds ratio = 0.30[0.09, 1.06] with p = 0.04.

Using simple liner regression, the most significant predictors for severe perineal tear were mode delivery (r^2 = 65.5%), and educational level (r^2 = 30.0%). However, on stepwise multivariate analysis, these two factors accounted for 68.5%.

Conclusion: The rate of severe perineal tear is relatively low in Yenagoa, Nigeria, and comparable to what obtains in many countries. The most significant predictors were mode of delivery and educational level. Careful selection of the mode of delivery, especially instrumental vaginal deliveries, and women empowerment could minimize the rate in our environment.

1. INTRODUCTION

Maternal injury during childbirth is a very common obstetrics complication, and includes perineal tear, vaginal and cervical lacerations, and injury to the pelvic floor [1]. Though episiotomy is a deliberate incision to widen the vulva outlet during childbirth, it is widely regarded as perineal trauma [1,2].

Perineal tear is classified into first, second, third and fourth degree. According to the Royal College of Obstetricians and Gynecologists (RCOG), first degree perineal tear is the mildest form, which is a small tear affecting only the skin, and could involve the vagina, labia, and clitoris [3]. In second degree perineal tear, the injury has gone beyond the skin, and has involved the perineal muscles [3]. With respect to 3rd and 4th degree perineal tear, also known as obstetric anal sphincter injury (OASI), the laceration is severe, and has involved the external anal sphincter, and anal mucosa respectively [3,4].

The prevalence of genital tract laceration in Yaoundé Central Hospital was reported as 12%, [5] and as much as 24.8% from a previous study in Yenagoa, Nigeria [6]. With respect to OASI, RCOG in the UK has reported an overall prevalence of 3rd and 4th degree perineal as 2.9%, [3] and a population based cohort study in the US reported a prevalence of 3.3% for 3rd and 1.1% for 4th degree tear respectively [7]. Evidence from the Australian birth registry reported rates of 1.5% and 0.1 for 3rd and 4th degree respectively [4].

Various risk factors for OASI have been reported globally, some of these are maternal demographic factors like parity and maternal age. Obstetrics factors are instrumental vaginal delivery, precipitate labour, primigravida, and direct occipito-posterior position [8]. The most consistent fetal factor is delivery of birth weight ≥ 4.0 kg (fetal macrosomia) [9].

Parity as a prominent risk factor for OASI has been reported in various studies. In the UK, an incidence of 6.1% was reported among primiparous women, but in multiparous, it was as low as 1.7%. [3] It was observed from a study in Scotland (using multivariate analysis), that multiparty significantly reduces the odds of OASI (OR 0.52; 95% CI: 0.30–0.90) [10].

A very common factor associated with OASI is gestational age at delivery; gestational age > 40 weeks was identified as a risk factor for severe perineal tear [8]. Using multivariate analysis, a similar study in another centre identified gestational age > 39 weeks as a significant risk factor for severe perineal tear (OR 1.18, 95% CI [1.02; 1.35] [11].

The role of advanced maternal age as a risk factor has also been reported in many studies globally. A study in Security Forces Hospital, Riyadh, Saudi Arabia identified advanced maternal age (> 40 year) as a risk factor for severe perineal tear [12]. Another study on risk factors for perineal tear in Limbe Regional Hospital in Cameroon identified advanced maternal age as an independent risk factor, (OR 2.6, 95% CI: 1.1-4.3;P = 0.02) [13]. In Sweden, evidence from the Medical Birth Register

indicates that the risk of severe perineal tear doubles from ≥ 35 years, when compared to women less than 35 years old [14]. A similar result was published in another study where maternal age of 35 years was reported as a risk factor for 3rd and 4th degree perineal tear [15].

Instrumental vaginal delivery (use of obstetrics forceps or vacuum extractor to expedite delivery) is one of the most consistent risk factors for OASI globally; they frequently cause direct trauma to maternal soft tissues during child birth. A study in South East England reported a strong association between severe perineal tear and forceps delivery (OR 4.43; 95% CI: 2.02–9.71) [16]. A similar result was also reported in another study (OR = 12.5, CI 2.3–66.2) [8]. In a multicentre study involving 10 public hospitals in Ethiopia, vacuum delivery was significantly associated with severe perineal tear (aOR 5.356; 95% CI; 3.200-8.963) [17]. However, there is evidence that forceps delivery cause more perineal trauma than vacuum. In a study comparing forceps and vacuum delivery, the rate of severe perineal injury was significantly higher among women who had forceps delivery, RR 1.89, 95% CI 1.51-2.37 [18]. This, in addition to fetal injuries during childbirth is the main reasons why the practice of forceps delivery is rapidly losing popularity [19].

Fetal macrosomia (estimated fetal weight ≥ 4.0kg) has been reported by various studies as a significant risk factor for OASI. A study in Sweden on pelvic floor in pregnancy and childbirth (POPRACT), reported a highly significant association with an odds ratio of 6.02 (2.32, 15.6) [20]. Another study in San Gerardo Hospital in Italy reported risk factors for 3rd and 4th degree perineal tear as birth weight > 4kg, shoulder dystocia, prolonged second stage of labour, and delivery after 40 weeks gestation [21]. Vaginal delivery, with the fetal head in persistent occipito-posterior position has also been reported to cause significant perineal tear (OR = 2.6, CI 1.6–4.3) [8]. These factors (fetal macrosomia and persistent occipito-posterior position) pose a fetal head diameter too wide to pass through the vulva outlet during delivery, which could lead to perineal tear.

Though severe perineal injury has been well studied, with widespread publications globally, it has not been given proper attention in Yenagoa, Bayelsa State in Nigeria, as publications are very scanty. The intent of this study is to determine the factors responsible for severe perineal trauma in Yenagoa, using the Niger Delta University teaching Hospital (NDUTH) as a case study.

1.1 Objective

The objective of this study is to determine the predictors of severe perineal tear (3rd and 4th degree tear), using mild perineal tear (1st and 2nd degree) as control. It would also determine the rate of perineal tear, and the maternal and fetal demographic risk factor associated with it.

2. MATERIALS AND METHODS

2.1 Study Site

The study was carried out in the delivery suit and obstetrics theatre of the department of obstetrics and gynaecology, Niger Delta University Teaching Hospital (NDUTH) Yenagoa, Bayelsa State in Southern Nigeria. Being an apex hospital, it serves as a referral centre, and received patients form primary, secondary and tertiary health institutions in Bayelsa State. It also receives patients from parts of our neighboring states like Rivers State, Imo and Delta States.

2.2 Study Design

It was a retrospective analytic study of 186 women who were admitted in labour, delivered in NDUTH, and were diagnosed with perineal tear. Out of these, 19 had severe perineal tear (3rd and 4th degree perineal tear), while 168 women had mild perineal tear (1st and 2nd degree). The study was carried out from January 2015 to January 2019.

2.3 Inclusion Criteria

Women who were admitted in labour in NDUTH, delivered vaginally and were diagnosed with perineal tear.

2.4 Exclusion Criteria

Excluded from this study were women who were in labour, and were delivered by emergency caesarean section. Also excluded were women who did not have perineal tear during delivery, and women with perineal tear but information in their case notes was poorly documented.

2.5 Data Collection

Data from a total of 1786 women who delivered vaginally during the study period was retrieved from the registry of the delivery suit, and labour ward theatre. A total 194 women who had

perineal tear were identified, out of these, 19 had severe perineal tear (3rd and 4th degree), and 175 had minor perineal tear (1st and 2nd degree). In 8 women who had minor perineal tear, the documentation in their case notes was poor, and they were excluded. Therefore 167 women with minor trauma were used, giving the total number of women used in this study as 186.

Maternal demographic information retrieved was maternal age, parity, educational level, and occupation. Obstetrics factors were booking status, gestational age at delivery, mode of delivery, rank of the accoucheur (nurse or doctor), and degree of perineal tear. Fetal demographic data was birth weight and fetal sex. Data on treatment given was not collected because it was beyond the scope of this study.

2.6 Data Analysis

Data collected from each subject was entered into SPSS version 25 for windows, and EPI info version 7 software. Categorical variables were compared with odds ratio, difference in mean was compared with student's t-test, and the degree of association for quantitative variables was determined using Pearson's correlation coefficient. Predictor variables were determined using simple logistic regression, and multivariate analysis. Confidence interval was set at 95%, and statistical significance was set at p value of < 0.05.

3. RESULTS

Out 1786 women who had vaginal delivery during the period of study, 186 had perineal tear, giving a prevalence of 10.4% in Yenagoa. Nineteen (19) of these women had 3rd and 4th degree perineal tear (OASI), giving a rate of 1.1%.

The mean birth weight was significantly higher among women who had major degree perineal tear, when compared to minor degree, with P = 0.0001.

Most of the women who had perineal tear in Yenagoa were young women age 25 – 29.9 years, and they were also more vulnerable to major degree tear, odds ratio = 1.04[0.37, 2.87], with p = 0.04. Similarly women with low parity (Para 1) had more perineal tear in this study, and were more prone to major degree perineal tear, odds ratio = 0.20[0.07, 0.55], with p = 0.0008.

High educational level seems to protect against major degree tear; women with tertiary education were 18 times more likely to have minor degree perineal tear, odds ratio = 18.9 [5.92, 60.81].

However, the role of some variables as risk factors seems to be weak, as there effects were not statistically significant. There include: unemployment, being unbooked, the rank of the accoucheur, and sex of the baby.

Significantly more women who delivered at term (37 – 42 weeks gestation) had more severe perineal tear in this study, 4.76 [2.24, 10.09] with p = 0.0001. However, postterm delivery had very little influence as only 0.5% of the women delivered postterm.

Evidence from this study indicates that birth weight ≥ 4.0 kg (fetal macrosomia) predisposes to major degree perineal tear, odds ratio = 0.30[0.09, 1.06] with p = 0.04.

With respect to severe perineal tear, the correlation coefficient with mode of delivery is very strong r = 0.810, while that for educational level is moderate r = - 0.552. For mild perineal tear, all the correlation coefficients are relatively weak, the best being fetal sex, r = - 0.298, and rank of the accoucheur r = 0.226.

The strongest and most significant predictors for severe perineal tear was mode of delivery r^2 = 65.5%, followed by educational level r^2 = 30.0%. All the rest were not significant.

Table 1. Mean values of the risk factors for minor and major degree perineal tear

Risk factor	Minor degree perineal tear	Major degree perineal tear	Student's t	Mean difference	P value
Maternal age	27.77 ± 5.64	28.74 ± 3.46	0.73	0.97 [-1.64, 3.58]	0.46
Parity	1.56 ± 1.33	1.05 ± 0.62	1.65	0.51 [-0.10, 1.12]	0.10
Gestational age at delivery	38.33 ± 2.01	38.89 ± 1.05	1.19	0.56 [-0.37, 1.49]	0.23
Birth weight	3.32 ± 0.48	3.75 ± 0.24	3.84	0.43 [0.21, 0.65]	0.0001

Table 2. Frequency distribution of the demographic and obstetric factors

Variable	Minor degree perineal tear	Major degree perineal tear	Total	Odds Ratio	P Value
Maternal age					
< 25 years	56 (30.1%)	3(1.6%)	59(31.7%)		
25 – 29.9 years	54(29.0%)	6(3.2%)	60(32.3%)	1.04[0.37, 2.87]	0.04
30 – 34.9 years	37(19.9%)	8(4.3%)	45(24.2%)		
35 – 39.9 years	14(7.5%)	2(1.0%)	16(8.6%)		
≥ 40 years	6(3.2%)	-	6(3.2%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Parity					
Para 0	42(22.6%)	3(1.6%)	45(24.2%)		
Para 1	47(25.3%)	12(6.5%)	59(31.7%)	0.20[0.07, 0.55]	0.0008
Pare 2	40(21.5%)	4(2.2%)	44(33.7%)		
Para 3	24(12.9%)	-	24(12.9%)		
Para 4	8(4.3%)	-	8(4.3%)		
≥ Para 5	6(3.2%)	-	6(3.2%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Educational level					
Non formal	-	-			
Primary	5(2.7%)	3(1.6%)	8(4.3%)		
Secondary	27(14.5%))	12(63.2%)	39(21.0%)		
Tertiary	135(72.6%)	4(21.1%)	139(74.7%)	18.9 [5.92, 60.81]	0.0001
Total	167(89.8%)	19(10.2%)	186(100%)		
Occupation					
House wife	57(30.6%))	8(4.3%)	65(34.9%)	0.97 [0.87, 1.09]	0.62
Civil servant	48(25.8%)	6(3.2%)	54(29.0%)		
Petty trader	32(17.2)	4(2.2%)	36(19.4%)		
Student	25(13.4%)	1(0.5%)	26(14.0%)		
Company staff	5(2.7%)	-	5(2.7%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Booking status					
Unbooked	46(24.7%)	8(4.3%)	54(29.0%)	0.93 [0.82, 1.05]	0.18
booked	121(65.0%)	11(5.9%)	132(71.0%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Gestational age at delivery					
< 37 weeks (preterm)	28(15.0%)	-	28(15.0%)		
37 – 42 weeks (term)	138(74.2%)	19(10.2%)	157(84.5%)	4.76 [2.24, 10.09]	0.0001
> 42 weeks (postterm)	1(0.5%)	-	1(0.5%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Mode of delivery					
Spontaneous vaginal delivery	156(83.9%)	16(8.6%)	172(72.5%)		
Breech delivery	5(2.7%)	2(1.1%)	7(37.6%)		
Vacuum extraction	4(2.2%)	1(0.5%)	5(2.7%)		
Forceps delivery	2(1.1%)	-	2(1.1%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Degree of perineal tear					
1st degree	113(60.8%)	-	113(60.8%)		
2nd degree	54(29.0%)	-	54(29.0%)		
3rd degree	-	18(9.7%)	18(9.7%)		
4th degree	-	1(0.5%)	1(0.5%)		

Variable	Minor degree perineal tear	Major degree perineal tear	Total	Odds Ratio	P Value
Total	167(89.8%)	19(10.2%)	186(100%)		
Rank of the accoucheur					
Delivery by nurse	97(52.2%)	12(6.5%)	109(58.6%)	0.81 [0.30, 2.16]	0.67
Delivery by doctor	70(37.6%)	7(3.8%)	77(41.4%)	1.24 [0.46, 3.30]	0.68
Total	167(89.8%)	19(10.2%)	186(100%)		
Fetal sex					
Female	64(34.4%)	9(4.8%)	73(39.2%)	0.6 [0.27, 1.79]	0.44
Male	103(55.4)	10(5.4%)	113(60.8%)		
Total	167(89.8%)	19(10.2%)	186(100%)		
Birth weight					
Low birth weight (< 2.5kg)	10(5.4%)	-	10(5.4%)		
Normal birth weight (2.5 – 3.9 kg)	147(79.0%)	15(8.1%)	162(87.1%)		
Fatal macrosomia (≥ 4.0 kg)	10(5.4%)	4(2.2%)	14.0(7.5%)	0.30[0.09, 1.06]	0.04
Total	167(89.8%)	19(10.2%)	186(100%)		

Table 3. Correlation between the risk factors and perineal tear

Risk factor	Pearson's correlation coefficient	
	Mild perineal tear	Severe perineal tear
Maternal age	0.017	0.088
Parity	-0.178	- 0.021
Educational level	-0.054	-0.552
Occupation	0.089	0.209
Booking status	-0.032	0.201
Gestational age at delivery	0.182	-0.207
Mode of delivery	0.087	0.810
Rank of the accoucheur	0.226	-0.180
Birth weight	0.097	0.256
Fetal sex	-0.298	-0.248

Table 4. Simple linear regression of the risk factors for mild and severe perineal tear

Predictor variable	Mild perineal tear			Severe perineal tear		
	r^2 (%)	F-ratio	P value	r^2 (%)	F-ratio	P value
Maternal age	0.0	0,451	0.83	0.8	0.134	0.72
Parity	3.2	5.382	0.02	0.8	0.007	0.93
Educational level	0.3	0.484	0.48	30.0	7.456	0.014
Occupation	0.8	1.32	0.25	4.0	0.773	0.39
Booking status	0.1	0.172	0.68	4.0	0.716	0.40
Gestational age at delivery	3.3	5.623	0.02	4.3	0.758	0.39
Mode of delivery	3.5	5.971	0.016	65.5	32.32	0.000
Rank of the accoucheur	5.1	8.872	0.03	3.2	0.569	0.46
Birth weight	0.9	0.1554	0.22	6.6	1.19	0.29
Fetal sex	8.9	16.043	0.001	6.2	1.118	0.32

For mild perineal tear, the predictors were relatively weak. The most significant was fetal sex r^2 = 8.9%, followed by rank of the accoucheur r^2 = 5.1%, mode of delivery r^2 = 3.5%, gestational age at delivery r^2 = 3.3%, and parity r^2 = 3.2%.

With respect to severe perineal tear, 68.5% of the variation in severe perineal tear was accounted for by the risk factors in this study (mainly mode of delivery and educational level).

Table 5. Stepwise multivariate analysis of the significant predictive factors for perineal tear

Predictor variable	Mild perineal tear					Severe perineal tear	
	Step 1	Step 2	Step 3	Step 4	Step 5	Step 1	Step 2
Mode of delivery	0.187	0.187	0.187	0.187	0.187	0.810	0.810
Educational level		0.195	0.195	0.195	0.195		0.828
Fetal sex			0.360	0.360	0.360		
Rank of the accoucheur					0.394		
Gestational age at delivery							
Parity							
Constant	1.186	-0.053	-0.292	0.096	-0.048	0.347	-0.066
r^2	3.5	3.8	13.0	13.8	15.5	65.5	68.5
F-ratio	5.971	3.236	8.085	6.488	5.926	32.32	17.409
P value	0.016	0.04	0.000	0.000	0.000	0.000	0.000

For mild perineal tear, the risk factors could only explain 15.5% (fetal sex, rank of the accoucheur, mode of delivery, gestational age at delivery and parity).

4. DISCUSSION

Perineal tear has been described as the commonest injury sustained during childbirth, and it has been reported to occur in as much as 85% of women [22]. Fortunately, a great majority of these injuries are mild (with minimal consequences), [22] as the risk of severe perineal tear is as low as 0. 1 – 4.0% [3,7,23].

The prevalence of severe perineal tear in Yenagoa, as obtained in this study was similar to the 0.1 – 1.5% obtained in Australia, [4] and the 2.9% in the UK [3]. The reason why there is minimal disparity may result from the fact that perineal tear during child birth may be independent of advancement in medical technology and sophisticated medical facilities; the determinants may be predominantly demographic and obstetrics factors.

The rate of perineal injury seems to reduce linearly with increase in parity; a previous study reported a decline from 90.4% in nulliparous women to 68.8% in multiparous [24]. With respect to severe perineal tear, a study in Scotland has proven that multiparity significantly reduces the risk (OR 0.52; 95% CI: 0.30–0.90) [10]. This was further validated by another study which reported that the chances of severe perineal tear was 10 times higher in nulliparous than multiparous women, odds ratio = 10.0[3.0 – 33.3] [16]. The result from our study tends to follow the same trend, as the rate of perineal tear in Yenagoa was significantly higher in women with low parity. It has been explained that the

perineum in women with low parity, (especially in nulliparous women) is very rigid and over stressed by the fetal head, with a high tendency to tear during delivery [25]. Prophylactic episiotomy has therefore been advocated [25].

Besides prophylactic episiotomy, evidence from a systematic review indicates that prophylactic physiotherapy (anal sphincter muscle exercises and pelvic floor muscle training) significantly improves the rate of OASI and fecal incontinence by improving muscle strength [26]. Perineal massage during pregnancy has also been reported to reduce the rate of perineal tear, p = 0.0005 [27].

Maternal age as a risk factor for severe perineal tear has also been reported in previous studies; it was observed that the risk of perineal tear doubles as maternal age exceeds 35 years, [14] and another study reported an increased risk after 35 years [15]. The reason why severe perineal tear was commoner among older women in these studies was not clear stated. However, the converse was the case in our study; the risk was significantly higher among younger women. By logical reasoning, younger women are expected to have low parity, with relatively rigid perineum when compared to older women. Therefore they are vulnerable to perineal tear.

With respect to gestational age at delivery, significantly more women in our study with severe perineal tear delivered at term. This is at par with findings from other centers, where the risk was reported to be high at a gestational age of 39 weeks and above, [11] and after 40 weeks [8]. This is because as the gestational age increases, the estimated fetal weight increases, with increased risk of perineal injury during

delivery. Studies in Sweden, [20] and Italy [21] have reported a significant association between fetal macrosomia (birth weight ≥ 4.0kg) and severe perineal tear.

The phenomenon where birth weight increases as gestational age increases, leading to higher rates of perineal tear, has been reported to escalate after term (after 42 weeks gestation). Postterm infants have been reported to be bigger than term infants, [28] and the rate of fetal macrosomia at term was reported as 0.8 – 1%, which increases to 2.5 – 10% postterm. [28] Therefore the rate of perineal tear following postterm birth is expected to be higher than term birth. However, this did not manifest in our study; our postterm delivery rate was very low (0.5%).

The effect of educational level on severe perineal tear has not been given proper attention as publications on this issue are scanty. In our study we observed that high educational level (tertiary education) seems to protect against severe perineal tear; odds ratio = 18.9 [5.92, 60.81]. This may be due to the fact that highly educated women are expected to receive antenatal care in tertiary health institutions, where delivery is conducted by specialists.

Our results indicates that the most important factors that predicts whether perineal tear would be severe among the women in Yenagoa are mode of delivery and educational level, as they accounted for 65.8% of the factors. The various categories that constitute mode of delivery have been reported as predictors of severe perineal tear globally, and they include: forceps delivery, [16] delivery by vacuum extractor [29], persistent occopitoposterior position, and vaginal breech delivery [8].

However as its earlier stated above, the role of educational level as predictor has not been widely studied, and its influence is expected to be more prominent in underdeveloped countries like Nigeria, because of the high level of illiteracy, and the tendency to patronize traditional birth attendants, and quarks. In addition many of these women deliver in primary health care facilities and general hospitals where expertise is deficient. I believe that if this study is carried out outside the teaching hospital setting, the indices would be worse. Further studies are hereby advocated to validate this concept.

5. CONCLUSION

The rate of severe perineal tear is relatively low in Yenagoa, Nigeria, and comparable to what obtains in other countries. The most significant predictors were mode of delivery and educational level. Careful selection of the mode of delivery, especially instrumental vaginal deliveries, and women empowerment could minimize the rate in our environment.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

Ethical approval to proceed with this study was granted by the ethical committee of NDUTH.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sdiarticle4.com/review-history/67768