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Umbilical Cord Prolapse and Perinatal Outcomes in a Tertiary Hospital in Yenagoa, South-South Nigeria: A 5-Year Review

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Authors' contributions

This work was carried out in collaboration among all authors. Author PCO conceptualized and designed the study, collated data, wrote the introduction, results and the first draft of the manuscript. Author DOA wrote the protocol of the study and supervised the entire research. Author DCB wrote the discussion. Author MNC managed literature searches. Author AEU wrote the abstract and contributed to the writing of the discussion. Author CEU participated in literature searches. Author GA collected the data for the research. All authors read and approved the final manuscript.

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ABSTRACT

Background: Umbilical cord prolapse is an obstetric emergency when the foetus is still alive, and it is associated with high foetal morbidity and mortality. If umbilical cord prolapse occurs outside the hospital, mortality rate can be as high as 44% - 70%, and as low as 3% when it occurs in the hospital.



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Objective: To determine the incidence of umbilical cord prolapse and the perinatal outcomes associated with it at the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria over 5 years. **Materials and Methods:** This retrospective survey was carried out between 1st January, 2016 and 31st December, 2020. Data were retrieved, entered into a pre-designed proforma, and analysed using IBM SPSS version 25.0. Results were presented in frequencies and percentages for categorical variables and mean and standard deviation for continuous variables.

Results: Forty-one women had umbilical cord prolapse out of 4,571 deliveries, giving a case incidence rate of 8.9 per 1,000 deliveries. About three-quarters (75.6%) of the women were multiparous. A fifth (21.9%) of the foetuses died in-utero, while 27 (65.9%) babies survived. Five (15.6%) babies had severe birth asphyxia, and died (early neonatal death) in the special care baby unit. Decision-to-delivery interval was \leq 30 minutes in only 12.5% of patients.

Conclusion: Umbilical cord prolapse is associated with significant perinatal morbidity and mortality. Prompt diagnosis and intervention are very key in preventing adverse perinatal outcomes.

Keywords: Umbilical cord prolapse; emergency; morbidity; mortality; Caesarean section.

1. INTRODUCTION

Umbilical cord prolapse is defined as the presence of the umbilical cord below the presenting part of the foetus with ruptured membranes [1]. It is an obstetric emergency when the foetus is still alive, and it is associated with high foetal morbidity and mortality. A large study of 56,283 deliveries carried out over a 9year period in John Radcliffe Hospital, Oxford, reported a perinatal mortality rate of 91/1000 deliveries (9.1%) [2]. If umbilical cord prolapse occurs outside the hospital, mortality rate can be as high as 44% - 70%, [3,4] and as low as 3%when it occurs in the hospital [4]. The presence of the umbilical cord below the presenting part with intact foetal membranes is called umbilical cord presentation. Umbilical cord prolapse may be occult, when the umbilical cord lies adjacent to the foetal presenting part, or overt, when the cord lies below the foetal presenting part. cord prolapse is Umbilical an obstetric emergency, because of the risk of umbilical cord compression, which may occlude the umbilical vein, and cause the umbilical artery to go into spasm, consequently causing foetal hypoxia [5]. The incidence of umbilical cord prolapse has been reported by many studies as 0.14% -0.62% [2,6-10]. Umbilical cord presentation and prolapse are associated with 0.5% each of frank breech and cephalic presentations, 5% of complete breech presentations, 15% of footling breech presentations, [1] and may be as high as 20% in transverse lie [11].

The plausible explanations for umbilical cord prolapse include high-pressure flow of amniotic fluid following rupture of foetal membranes, and this carries the umbilical cord beyond the unengaged presenting part. Another explanation is that the umbilical cord may prolapse following disengagement of the presenting part during obstetric procedures. The common thing among these two is that any condition that interferes with the snug-fitting of the foetal presenting part to the lower uterine segment and the pelvic brim can predispose to umbilical cord prolapse. Therefore, the risk factors associated with umbilical cord prolapse could either be maternal, foetal or iatrogenic (usually from obstetric interventions). Foetal factors include foetal malpresentation. low birth weight. multiple prematurity. placentation. pregnancies, low lying polyhydramnios, foetal anomalies, long umbilical cord, unengaged foetal presenting part and spontaneous rupture of foetal membranes [5,12,13] Maternal factors include pelvic deformities. uterine malformations/tumours, contracted pelvis, multiparity and prolonged labour [5,12,13]. latrogenic factors include artificial rupture of foetal membranes, cervical ripening with intracervical extra-amniotic Foley's catheter, induction of labour, application of a foetal scalp electrode, manual rotation of the foetal head, amnioinfusion, external cephalic version, internal podalic version, application of forceps or vacuum [5,13].

Umbilical cord prolapse usually presents with the abrupt onset of severe, prolonged foetal bradycardia or moderate to severe variable decelerations in a patient with previously normal cardiotocographic tracing [5]. Less commonly, the pulsating umbilical cord is palpated incidentally by the care provider during vaginal examination to assess the labour progress. A patient with ruptured foetal membranes may also report seeing or feeling of an overtly prolapsed umbilical cord. The diagnosis of overt umbilical cord prolapse is based on visualisation or palpation of the umbilical cord ahead of the presenting part [5]. For occult cord prolapse, abrupt onset of severe, prolonged foetal bradycardia or moderate to severe variable decelerations in a patient with previously normal cardiotocographic tracing is the basis for diagnosis [5]. Differential diagnoses for occult cord prolapse include maternal hypotension. tachysystole, placental abruption, uterine rupture and vasa praevia [5]. These conditions can cause foetal heart rate changes similar to occult umbilical cord prolapse, and so can be confused with it.

The optimal obstetric management of umbilical cord prolapse is prompt delivery to avoid foetal compromise or death from compression of the cord between the presenting foetal part and the birth canal. A practical approach to managing a confirmed or suspected cord prolapse includes the following steps: call for help and prepare for emergency delivery; initiate manoeuvres for intrauterine resuscitation which includes manual elevation of the foetal presenting part. Trendelenburg or knee chest position, rapidly filling the urinary bladder with 500 - 700 ml of normal saline, administration of a tocolytic, monitoring of foetal heart tones, and manual replacement of the prolapsed umbilical cord into the vagina, to keep it moist with wet gauze, to prevent umbilical artery spasm, which may exacerbate poor foetal perfusion [5].

The baby should be delivered as an emergency through the most feasible and safest route. This is usually by emergency Caesarean section. However, there is still a place for vaginal delivery in umbilical cord prolapse in selected cases when the foetus is alive, especially if the cervix is fully dilated and delivery is imminent. This is accomplished by assisted vaginal usuallv delivery, with forceps or vacuum. This mode of delivery should be considered as an alternative to Caesarean section when the condition is suitable without compromising the mother and the baby. This is of utmost importance in the region where this study was carried out, where there is strong aversion to Caesarean section in a majority of the patients [14].

The baby's survival depends on its maturity, the duration of umbilical cord prolapse, cervical os dilatation, decision-to-delivery interval, the presence of a neonatologist during delivery and

efficient special care baby unit. Perinatal mortality associated with umbilical cord prolapse varies from 0% - 3% for events occurring among patients monitored in a labour and delivery unit [5] and up to 44% when occurring outside the hospital [15]. Asphyxia and complications related to prematurity and congenital anomalies are the major causes of poor outcomes, [5] with complications of prematurity and low birth weight responsible for most of the perinatal mortalities [12].

Prevention of iatrogenic umbilical cord prolapse would include anticipating and managing the risk factors, [16] and minimising risk from obstetric manoeuvres by performing amniotomy only when the foetal head is well applied to the cervix, or 'controlled' amniotomy when the foetal head is not well applied and amniotomy is very necessary. Disengaging the foetal presenting part when performing procedures such as foetal scalp sampling, forceps application and manual rotation of the foetal head should be avoided [16]. Furthermore, early resort to Caesarean section, proper and effective prenatal care, properly supervised hospital delivery and the presence of neonatologist at delivery are recommended to reduce or prevent the complications associated with umbilical cord prolapse [16]. The objective of this retrospective survey was to determine the incidence and perinatal outcomes of umbilical cord prolapse at the Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria, over a 5-year period.

2. MATERIALS AND METHODS

This retrospective study was conducted at the Obstetric Unit of the Federal Medical Centre, Yenagoa, Bayelsa State, South-South, Nigeria, between 1st January 2016 and 31st December 2020.

All cases of umbilical cord prolapse managed in the Unit within the study period were included in the study. The patients in labour were monitored with the use of partograph, and were on continuous electronic usually foetal monitoring. These, coupled with findings on vaginal examination, aided in the diagnosis of umbilical cord prolapse. A bedside ultrasound scan in the labour ward was also used, when indicated. Our patients' case records are manually stored at the medical records department of the institution, with regular quality checks. The electronic database for medical records in our institution is not functional yet. All the case records of the patients that were managed for umbilical cord prolapse during the five years under review were manually retrieved from the medical records department and reviewed manually, one after the other. Relevant data were extracted from these case records, using a purpose-designed proforma. These data included age, marital status, level of education, state of residence, occupation, parity, booking status, number of foetuses, risk factors, gestational age at presentation, foetal outcome, duration of stay in hospital after surgery and the total number of deliveries during the period under review.

The data were analysed using the Statistical Package for the Social Sciences version 25.0. Results were presented in frequencies and percentages for categorical variables and mean and standard deviation for continuous variables.

3. RESULTS

3.1 Sociodemographic Characteristics of Parturients with Cord Prolapse

Forty-one women had umbilical cord prolapse out of 4,571 deliveries in the five years under review, giving a case incidence rate of 8.9 per 1,000 deliveries. Of the 41 women who had umbilical cord prolapse in labour, 24 (58.5%) were aged 35 years and above (Table 1). Most (95.1%) of them were married, and with secondary education (58.5%). They were artisans (4.9%), farmers (12.2%), civil servants (17.1%) and traders (39.0%) by occupation (Table 1).

3.2 Obstetric Features of Parturients with Cord Prolapse

Three-quarters (75.6%) of the women were multiparous, with parity ranging between 1 and 11, with a median parity of 3 (Table 2). No nulliparous woman in the period under review had cord prolapse. Most (80.5%) of the women were unbooked patients with singleton pregnancies (90.2%). Thirteen women (31.7%) had cephalic, while 17 (41.5%) had breech presentation. Most (68.3%) of the pregnancies were 38 weeks (39.0%) and 39 weeks (29.3%) at the onset of labour. Emergency Caesarean section was the most (73.2%) deployed mode of delivery for these women with umbilical cord prolapse.

3.3 Risk Factors among Women with Umbilical cord Prolapse

Multiparity (92.7%) and spontaneous rupture of foetal membranes (95.1%) were the risk factors found in almost all the women who had umbilical cord prolapse (Table 3).

Table 1. Sociodemographic characteristics of parturients with cord prolapse

Characteristics	Frequency N = 41	Percent (%)
Age Group		
< 30 years	10	24.4
30 - 35 years	7	17.1
> 35 years	24	58.5
Mean age ± SD in	33.3 ± 4.5	
years		
Marital Status		
Single	2	4.9
Married	39	95.1
Level of		
Education		
None	4	9.8
Primary	9	22.0
Secondary	24	58.5
Tertiary	4	9.8
Occupation		
Unemployed	11	26.8
Civil Servant	7	17.1
Trader	16	39.0
Farmer	5	12.2
Artisan	2	4.9

3.4 Perinatal Outcomes of Umbilical Cord Prolapse

Table 4 shows that a fifth (21.9%) of the foetuses died in-utero, while 27 (65.9%) babies survived. Five (15.6%) babies had severe birth asphyxia, and died (early neonatal death) in the special care baby unit. Decision-to-delivery interval was \leq 30 minutes in only 12.5% of patients.

4. DISCUSSION

Umbilical cord prolapse is an uncommon and mostly unpredictable obstetric emergency with the potential to cause significant adverse neonatal outcomes. We report that in this 5-yearreview, the incidence of cord prolapse, was 0.89% (8.9 per 1,000 deliveries or 1 in 112 deliveries). This was similar to the 0.82% (1 in 122 deliveries) reported by Lamina et al. [17] in Ogun state. However, it is higher than the incidence of cord prolapse ranging from 2.0 per 1000 [18] in Kaduna to 3.8 per 1000 [19] in Lagos. It is also higher than the incidence rates ranging from 0.16% to 0.47% [14,20-29] reported by other tertiary facilities across Nigeria. It unsurprisingly, is also higher than the reported global incidence which ranges between 0.14% -0.62% [2,6-10,30]. Although, our finding also corroborates the rarity of umbilical cord prolapse, the higher incidence in this study may be due to a variety of factors, including differences in mothers' healthcare-seeking behaviour and utilization of antenatal care services. In Bayelsa State, preference for traditional birth attendants' homes, where abdominal massages in pregnancy are done, contributes to adverse outcomes in pregnancy [31].

Table 2. Obstetric features of parturients with umbilical cord prolapse

Characteristics	Frequency N = 41	Percent
Parity		(/0)
Primiparity	3	7.3
Multiparity	31	75.6
Grand-multiparity	7	17.1
Median parity	3 (1 – 11)	
(Range)		
Booking Status		
Booked	8	19.5
Unbooked	33	80.5
Number of		
foetuses		
Singleton	37	90.2
Twins	4	9.8
Presentation/Lie		
Cephalic	13	31.7
Breech	17	41.5
Transverse	11	26.8
Gestational age at		
presentation		
36 weeks	3	7.3
37 weeks	8	19.5
38 weeks	16	39.0
39 weeks	12	29.3
40 weeks	2	4.9
Mode of Delivery		
Emergency	30	73.2
Caesarean section		
Assisted vaginal	7	17.1
breech delivery		
Vacuum delivery	2	4.9
Spontaneous	2	4.9
vaginal delivery		

The identifiable obstetric risk factors for umbilical cord prolapse in this study were advanced maternal age > 35 years, multiparity, premature of membranes and non-cephalic rupture presentations. The highest incidence of umbilical cord prolapse occurred in about two-thirds of parturients' aged above 35 years and is comparable to the mean ages of 30 - 35 years reported by other studies conducted in Nigeria [23,32]. In this review, both multiparity and premature rupture of membranes were found in over 90% of cases. The occurrence of umbilical cord prolapse among predominantly multiparous women has also been highlighted by other authors in Nigeria, with proportions ranging from 40.9% to 94.3% [19,22,23,25,26]. It is plausible that our finding of a preponderance of umbilical cord prolapse among multiparous women could be due to the usually delayed engagement of the foetal head in most multiparas, from slackness of the uterine muscles, causing a slipping down of the cord through the cervix in case of rupture of the foetal membranes [10]. Furthermore, the high occurrence of premature rupture of membranes among the parturients in this study, despite having term gestations, as earlier alluded to, may be due to unsafe practices performed routinely at traditional birth attendants' homes like abdominal massages, which could induce uterine contractions, and fingering of the cervix. However, in contrast to our study, other authors reported prematurity [18,25,26,29] to be the most commonly identified obstetric risk factor. While prematurity has an increased risk for umbilical cord prolapse, probably due to poor application of the presenting part to the cervix, several other studies [29,33,34] have demonstrated that umbilical cord prolapse can occur in term gestations, which was consistent with our finding.

The relationship between non-cephalic presentations (such as breech and transverse lie) and umbilical cord prolapse is replete in literature, and is thought to be due to poor or non- engagement of the presenting part into the maternal pelvis, allowing space for the umbilical cord to prolapse [10]. In this study, breech presentation was the commonest form of presentation (41.5%) and has been equally reported in other Nigerian studies [19,25]. Albeit, our finding, differs from the reports of 44.7% by Nana et al. [35] in Cameroun, 64.9% by Faiz et al. [36] in Saudi Arabia and 65% by Allagoa et al. [30] in Port Harcourt, Nigeria, and 64% by presentation was the most common form of presentation. Cervical ripening using intracervical extra-amniotic Foley's catheter was also an

Characteristics	Frequency N = 41	Percent (%)
Prematurity	3	7.3
Multiparity	38	92.7
Premature rupture of membranes	39	95.1
Cervical ripening with a balloon catheter	2	4.9

Table 3. Frequency of occurrence of risk factors with umbilical cord prolapse

	Table 4. Foetal	outcomes of	umbilical cord	prolapse and	decision-to-delivery	v interval
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Characteristics	Frequency N = 41	Percent (%)
Foetal Outcome		
Alive	27	65.9
Intrauterine foetal death	9	21.9
Early neonatal death	5	12.2
Admission into Special care baby unit	N = 32	
Mild birth asphyxia	12	37.5
Moderate birth asphyxia	15	46.9
*Severe birth asphyxia	5	15.6
Decision-to-delivery interval (minutes)	N = 32	
≤ 30	4	12.5
> 30	28	87.5

*Five (15.6%) babies had severe birth asphyxia, and died (early neonatal death)

observed risk for umbilical cord prolapse in our series and accounted for 4.9% of iatrogenically induced umbilical cord prolapse. Cervical ripening has been similarly reported by Hasegawa et al. [37] in a study in Japan, which revealed an increased risk of umbilical cord prolapse during orfollowing intracervical extraamniotic Foley's catheterisation for cervical ripening.

Umbilical cord prolapse is an acute obstetric emergency that requires delivery of the foetus within the shortest possible time and via the quickest route. It is generally recommended that the decision-to-delivery interval (DDI) be less than 30 minutes to optimise the foetal outcome [38]. Most (73.2%) of the women in this study delivered via emergency Caesarean section, as has similarly been reported by several authors in Nigeria, with Caesarean section rates ranging from 59% to 84.6% [19,23,26]. Caesarean section rates as high as 93.5% has been reported by another study in Saudi Arabia [36]. Hence, within and outside Nigeria, Caesarean section is the predominant mode of delivery for women with umbilical cord prolapse, and this agrees with the view of Esike et al. [27], that this obstetric emergency contributes substantially to high Caesarean section rates with its attendant complications. The Caesarean section rate in our Centre, as reported in a recent study, is 42.4% [39], and this is mainly due to unbooked patients referred from TBAs and private clinics. This rate

is quite higher than that of a number of Centres [39,40].

In this study, the DDI was more than 30 minutes in majority (87.5%) of the cases. The most plausible explanation for the delayed DDI is a delay in obtaining a written informed consent from the mother, accompanying spouse or relatives, due to marked and widespread aversion for Caesarean section in our setting, as has been previously noted. Other reasons for delayed DDI are the distance to the main theatre. and uncommonly, unavailability of theatre space at the time decision to deliver is taken. This brings to bear the numerous challenges obstetricians and neonatologists alike, face working in resource-limited settings when emergencies requiring urgent interventions like umbilical cord prolapse present. Similar reasons for delay in decision-to-delivery time have also been documented by other authors in Nigeria [19,26].

Though immediate abdominal delivery is desired, when possible, other methods of vaginal delivery are still permissible such as was observed in this study – assisted vaginal breech delivery (17.1%), spontaneous vaginal (4.9%) and vacuum extraction (4.9%). These alternative methods of delivery via the vaginal route have also been reported by several authors [23,26,27]. In this study, these were employed mainly when foetal demise was identified and there were no signs of obstruction or when mothers either did not give consent for abdominal delivery or were already fully or near-full cervical dilatation at presentation. In all cases, irrespective of the mode of delivery, mothers were nursed in knee chest position to relieve pressure on the cord by the presenting part and occasionally, manual reduction of the cord was done because of being faced with the challenges of prolonged DDI, to help improve perinatal outcomes, and allow time for preparations to be made for definitive treatment.

Eighty percent of the women who presented with umbilical cord prolapse were unbooked, and this is comparable to findings of several other authors in Nigeria, that had documented that the proportion of unbooked parturients with cord prolapse ranged from 44% to 84% [19,20,23-25]. An earlier study conducted among 46 cases of cord prolapse with 96 controls in Ebonvi state. South-East Nigeria, reported five-fold higher odds of umbilical cord prolapse occurring in unbooked mothers compared to booked counterparts [25]. In our Centre, unbooked status has consistently been associated with adverse perinatal and maternal outcomes [41-43]. In contrast, some authors in Nigeria, such as Umar et al. [26] in Kano and Allagoa et al. [30] in Port Harcourt, reported very low proportions of unbooked cases presenting with cord prolapse. This was because greater proportions, over 70% of the mothers in their series were booked. The authors inferred that lack of a high index of suspicion to identify the risks factors for umbilical cord prolapse amongst the booked mothers may have been the reason for such high levels of occurrence [30].

When umbilical cord prolapse occurs, it is often associated with a high risk of foetal demise, which mainly happens as a result of umbilical cord compression resulting in either total acute asphyxia or subacute hypoxic insults with varying adverse neonatal sequelae. The incidence is particularly high among unbooked women, with a high rate of foetal wastage, especially when the prolapse occurs outside of a hospital facility [3,4,10,19,22,24]. Notable in this study is the observation that all the mothers with a clinical diagnosis of umbilical cord prolapse had foetuses already compromised in-utero, as all were asphyxiated. Regrettably, one-fifth (21.9%) of mothers, all of whom were unbooked, presented to this facility with intrauterine foetal deaths. Five neonates also succumbed within the first week of life, from complications of severe birth asphyxia,

which accounted for 12.2% of early neonatal deaths. Hence, in this study, we report a Perinatal Mortality Rate (PMR) of 341/1,000 live births or 34.1%, which is similar to the 36.7% reported in a study by Dare et al. [24] in Ile-Ife, 343.8/1,000 live births in a study by Esike et al. [27] in Afikpo, and 333/1,000 in a study by Adeniran et al. [28] in Ilorin. However, it is higher than the PMRs ranging from 12% to 29.2% noted in other studies in Nigeria [19,21,23,29]. Our finding was also lower than 403/1.000 live births reported by Enakpene et al. [14] in Ibadan and the 413/1,000 live births reported by Kalu et al. [25] in Abakiliki. Nevertheless, our study finding was not comparable to a 10-year review by Faiz et al.

[36] in Saudi Arabia, where there was no perinatal death among the women that presented with cord prolapse. This was plausibly due to the fact that the citizenry benefit from a fully functioning and well-organised healthcare system in Saudi Arabia, where no delays, either at the level of diagnosis to the point of delivery and resuscitation of the newborn resulted in adverse perinatal outcomes. This inference is evidenced by the authors reporting a DDI of 10 to 20 minutes in 49.5% and >20 minutes in 50.5% of the cases, with only 4.5% of babies that had an APGAR score of less than 7 at the 5th minute of life [36].

All babies delivered to mothers with umbilical cord prolapse in this review were admitted into the neonatal intensive care unit for asphyxia, irrespective of the mode of delivery. Our findings are in consonance with what has been reported by other Nigerian authors, with a greater proportion of babies needina neonatal intensive care, with admission rate of about 54.8% [28]. Enakpene and colleagues. [14] in their study, found that babies born to unbooked mothers with umbilical cord prolapse had four-fold greater odds of perinatal morbidity and admissions into neonatal intensive care units and three-fold greater odds of neonatal death when compared to babies born to booked mothers with umbilical cord prolapse. This was evident in this current study, as the babies from unbooked mothers suffered more adverse perinatal events. Our study highlights the importance of neonatologists with skills in advanced neonatal resuscitation and assisted ventilatory support to salvage asphyxiated neonates and commence the appropriate treatment protocols to improve long- term outcomes.

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The findings in this study, therefore, suggests that efforts targeted at preventing umbilical cord prolapse such as educating women to attend regular antenatal care and accept Caesarean sections when medically indicated are needful. Furthermore, obstetricians should have a high index of suspicion, to identify women at risk, and vigilance during obstetric procedures that may increase the risk of umbilical cord prolapse.

5. CONCLUSION

Umbilical cord prolapse is associated with significant perinatal morbidity and mortality. A high index of suspicion for umbilical cord prolapse should be entertained when foetal membranes rupture either spontaneously or artificially, and during other obstetric procedures that increase the risk of umbilical cord prolapse, especially in patients with predisposing factor(s). Continuous electronic foetal monitoring in labour in women with risk factors for umbilical cord prolapse may increase detection rates of occult umbilical cord prolapse. Prompt diagnosis and intervention are necessary to reduce the perinatal morbidity and mortality associated with prolapse. umbilical cord Education and enlightenment of women on the benefits of skilled attendance at delivery, and Caesarean section, when indicated, as well as effective and efficient emergency obstetric care and referral services and systems would improve perinatal outcomes. Women need to be enlightened to recognise danger signs in pregnancy and labour, and a more efficient healthcare system should be put in place to mitigate the delays in accessing obstetric care.

6. LIMITATION

This is a single Centre, hospital-based study. It may therefore, not reflect what is obtainable in other tertiary health institutions in our sub-region. It is also a retrospective study, and may be difficult to estimate the true incidence of umbilical cord prolapse, because some cases of occult umbilical cord prolapse may go undocumented. Therefore, a multicentered, prospective comparative study design will be more informative.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

The research work was examined and approved by the hospital research and ethics committee.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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