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# **BMJ Open** Time to death and predictors of mortality among asphyxiated neonates in southwest Ethiopia, 2022: prospective cohort study

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#### ABSTRACT

**Objective** This study aimed to determine the time to death and predictors of mortality among asphyxiated neonates admitted to public hospitals in the southwest region of Ethiopia.

Design An institution-based prospective cohort study was conducted.

Setting Public hospitals in southwest Ethiopia. Participants A total of 144 asphyxiated neonates, who were admitted to the neonatal intensive care unit, and their mothers participated from March 2022 to 30 September 2022. Data were entered into EpiData V.4.4.2.1 and exported to STATA V.16 for analysis. The Cox proportional hazards model using bivariate (p<0.25) and multivariate (p<0.05) analyses was used to identify the predictors of mortality. The median survival time was estimated using Kaplan-Meier survival estimates.

Primary outcome Time to death from asphyxia and its predictors in neonates.

**Results** The mortality incidence rate of asphyxiated neonates was 9.1 deaths per 1000 person-days of observation (95% CI: 7.11 to 11.52) with a median survival time of 8 days, and 45.83% (95% CI: 37.81% to 54.08%) of asphyxiated neonates died. Being male (adjusted HR (AHR) 0.32 (95% CI: 0.14 to 0.76)). neonatal sepsis (AHR 0.321 (95% CI: 0.13 to 0.77)), not receiving kangaroo mother care (AHR 0.16 (95% CI: 0. 07 to 0.39)) and vaginal delivery (AHR 0.39 (95% CI: 0.16 to 0.95)) were independent predictors of mortality of asphyxiated neonates.

Conclusions In this study, asphyxiated neonates had a higher incidence of mortality with a median survival time of only 8 days. Being male, vaginal delivery, not receiving kangaroo mother care and comorbidities such as neonatal sepsis were independent predictors of mortality among asphyxiated neonates. Therefore, healthcare providers and other stakeholders should provide timely initiation of advanced diagnosis and appropriate therapeutic interventions for neonates with asphyxia to reduce neonatal mortality.

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STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ This multicentre study used prospective follow-up and primary data, which increased the accuracy and reliability of the data.
⇒ This study used a multivariate Cox regression analysis to control all likely confounders.
⇒ Owing to the relatively small sample size, it is difficult to generalise the results to all asphyxi-ated neonates.
⇒ It cannot be generalised for the asphyxiated ne-onates admitted to private health institutions.
MTRODUCTION
The WHO defines prenatal asphyxia as a failure to initiate and sustain breathing at birth and inadequate oxygen perfusion to with an inadequate oxygen perfusion to birth and inadequate oxygen perfusion to vital organs.<sup>1</sup> Birth asphyxia is probably the most common cause of prenatal brain ≥ injury associated with high morbidity and mortality.<sup>1 2</sup> Neonatal asphysia is one failed of the three leading causes of neonatal death worldwide, especially in developing **g** countries, where approximately 700000 neonates die each year from neonatal S asphyxia.<sup>13</sup>

Prenatal asphyxia is an event with farreaching consequences that can lead not only to the development of neonatal encephalopathy but also to multiple organ failure, such as the heart, brain and **g** adrenal glands, at the expense of other 8 organs in newborns, followed by a fatal outcome or severe life-long pathologies.<sup>45</sup>

A 4-year prospective study conducted at the Enugu State University Teaching Hospital, Enugu, Nigeria revealed that the case fatality rate of prenatal asphysia was approximately 18%.<sup>6</sup> Prenatal asphyxia is a serious problem in neonates, especially in developing countries

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Mr Belete Fenta Kebede; belete121wy@gmail.com including Ethiopia.<sup>78</sup> It is also a major cause of morbidity and mortality in Ethiopia.

According to the report from a systematic review, the overall pooled prevalence of prenatal asphysia in Ethiopia was 24.06%<sup>2</sup> and 22.8%,<sup>9</sup> and associated factors included prolonged labour, low birth weight and meconium-stained amniotic fluid. Moreover, according to a study conducted in Jimma Medical Center, Ethiopia, the magnitude of prenatal asphyxia was accounted for 18%.

According to previous studies conducted in the neonatal intensive care units (NICUs) of Debre Markos Referral Hospital,<sup>10</sup> Dessie Specialized Hospital<sup>11</sup> and Ayder Comprehensive Specialized Hospital,<sup>12</sup> in Ethiopia, birth asphyxia causes 23-40%, 32% and 37.5% of neonatal deaths, respectively.

Despite advances in healthcare to improve neonatal survival rates and complications, neonatal mortality due to asphyxia remains high and neonatal asphyxia is the leading cause of morbidity and mortality in Ethiopia. Although studies on the prevalence and mortality rate of neonatal asphyxia have been conducted in different hospitals in Ethiopia, few studies have been conducted on the time to death and predictors of mortality among asphyxiated neonates. Therefore, this study aimed to determine the time to death and predictors of mortality among asphyxiated neonates admitted to governmental hospitals in southwest Ethiopia.

# METHODS AND MATERIALS

### Study area and period

This study was conducted in public hospitals in the southwest region of Ethiopia. The southwest region is one of the newly established regions in Ethiopia, with three well-known public hospitals: Mizan-Tepi University Teaching Hospital (MTUTH), Tepi General Hospital and G/tsaddik Shewa General Hospital. MTUTH is located 584 km from Addis Ababa and served as a referral centre. Tepi General Hospital is located 622 km from Addis Ababa. G/tsaddik Shewa General Hospital is located in Keffa zone, Bonga town, which is 464 km from Addis Ababa. All the hospitals provided neonatal intensive care services. The study was conducted from 1 March 2021 to 30 September 2022 in the three selected governmental hospitals.

#### Study design

An institution-based prospective cohort study was conducted among asphyxiated neonates admitted to the NICU wards of public hospitals in the southwest region of Ethiopia (multicentre).

#### **Study participants**

All asphyxiated neonates admitted to the NICU were considered as the source population. All sampled asphyxiated neonates admitted to the NICU in governmental hospitals, southwest Ethiopia were the study population.

### **Exclusion criteria**

Asphyxiated neonates who had incomplete observations during the follow-up and unknown dates of admission were excluded.

#### Sample size determination

The required sample size for this study was determined using the STATA statistical package V.14 (Cox model) using the following assumptions:

Margin of error (0.05), 95% CI, 80% power, variability (SD)=0.5, HR=2.11, probability of failure (event)=0.32 (32%) taken from previous study copyright conducted at Dessie Specialized Hospital.<sup>11</sup> The estimated number of events and the sample size (N) were 45 and 139, respectively. After adding 10% of nonresponse rate, the final sample size was 153. including

#### Sampling technique and procedure

Prior to data collection, a secondary data source (card review) was used to estimate the number of asphyxiated ð neonates admitted to the NICU at each hospital. Finally, r uses the total sample size of the study was allocated proportionally using the formula:  $ni=\frac{n}{N} \times Ni$  for each hospital Pe based on the previous number of asphyxiated neonates lated admitted to the NICU.

Where Ni=sample size (153), N=total number of asphyxtex iated neonates (625) and n=the total number of asphyxiated neonates at each hospital.

and Finally, 68 neonates from MTUTH, 43 from G/ tsaddik Shewa General Hospital and 42 from Tepi 🔓 General Hospital were asphyxiated neonates. All study ລິ participants were followed up on a daily basis for 28 days of neonatal age. Among the 153 asphyxia cases, 9 cases were lost to follow-up, withdrew and referred Al training, to other hospitals. A total of 144 asphyxia cases were included in the final analysis.

#### Variables of the study

The dependent variable was the survival status of the asphyxiated neonates dichotomised as survived or died.

The independent variables of the study include the following:

- Sociodemographic characteristics: date of birth, date of admission, gender of the neonate, maternal date of admission, gender of the neonate, maternal age, age of the neonate at admission, residence of the mother and place of delivery.
- Neonatal characteristics: newborn weight, Apgar score, gestational age at birth, feeding status, kangaroo mother care utilisation and fetal presentation (cephalic/non-cephalic) at delivery.
- Neonatal morbidities: neonatal sepsis, respiratory distress syndrome (RDS), jaundice, necrotising enterocolitis, congenital anomalies, hypothermia and hypoglycaemia.
- Maternal obstetric and medical problems during pregnancy: maternal chronic disease, obstetric

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complications, pregnancy-induced hypertension, antenatal care status, parity of the mother and pregnancy type (multiple and singleton).

### **Operational definitions**

Birth asphyxia: the failure to initiate and sustain breathing at birth, and diagnosis was confirmed based on the physician's diagnosis of using Apgar score <7 in the first and fifth minutes of birth.

*Time scale:* the survival time was measured in days.

Incomplete observation: the full duration could not be observed if the patient left against medical advice or was transferred to another health institution.

*Survival status:* the outcome of asphyxiated neonates who died or were discharged with improvements/ survival.

Survival time/time to event/time to death: the time from admission of the newborn to the NICU until the occurrence of an event (death) during the follow-up period.

Event: the event in this study was death of asphyxiated neonates after admission to the NICU during the hospitalisation period.

Censored: in this study, asphyxiated neonates were considered censored if they remained alive until the end of the study period (beyond 28 days), which is considered right censoring.

### **Data collection tools and procedures**

After reviewing the literature,<sup>11 13-16</sup> the tool was adapted and prepared in English and translated into the local language Amharic, and retranslated back into English. Data were collected through face-to-face interviews with the mother and day-to-day neonatal follow-up with a neonatal chart (ie, from the time of admission to 28 days of neonatal age).

#### **Data processing and analysis**

After coding, editing and cleaning, the data were entered into the EpiData Manager (V.4.4.2.1) and exported to STATA (V.16) for analysis. The median survival time was estimated using Kaplan-Meier survival estimates, and predictors of mortality were identified using the Cox proportional hazards model. The assumptions of the Cox proportional hazards model were assessed using the Schoenfeld residual/ global test (0.22). Multicollinearity was checked using the variance inflation factor (1.231). Based on the bivariate analysis, variables with p<0.25 were transferred to the multivariate analysis. Variables with p<0.05 at a 95% confidence level in the multivariate analysis were considered as independent predictors of mortality.

#### **Data quality assurance**

A pretest was conducted on 5% of the sample size before the actual data collection period, then editions, wording and sequencing were made on the tool. Training was provided to the data collectors and

supervisors regarding the techniques and objectives of data collection and ethical issues. The supervisors regularly checked the completed questionnaires.

### Patient and public involvement

The participants were not involved in the development of the research question or design, conduct, reporting, implementation or dissemination plans, or evaluation.

### RESULTS

Protected In this study, from the total sample of 153 neonates by copyright, includ diagnosed with asphyxia, only 144 of them completed the follow-up and were included in the final analysis with a response rate of 94.12%.

#### Sociodemographic characteristics of neonates and their mothers

In this study, more than half of the asphyxiated neonates were male (54.86%) and more than half of βu the neonates were more than 24 hours of age at the ð time of admission (54.2%). Most neonates were born uses related to text to mothers aged 20–35 years. In this study, the median age of the mothers was 27 years with an IQR of 23-30. Approximately 73.61% of mothers were from urban residences (online supplemental table 1).

#### Neonatal comorbidity with asphyxia factors/additional diagnosis

In this study, the majority (73.6%) of the asphyxiated neonates were diagnosed with neonatal sepsis, whereas approximately 70.1% were diagnosed with RDS. Fifteen (10.4%), 26 (18.1%) and 60 (41.7%) of asphyxiated neonates were diagnosed with jaundice, hypoglycaemia and hypothermia, respectively (table 1).

#### **Neonatal characteristics**

ing, Al training, In this study, most of the asphyxiated neonates had first-minute Apgar score of less than 7 (78.5%), and approximately 95.1% of the asphyxiated neonates were delivered to health institutions. Approximately 65.3% of asphyxiated neonates were receiving

Stare (KMC) during their hospitalstay (table 2).Maternal obstetric and medical characteristicsIn this study, the majority (77.1%) of the mothersgave birth through vaginal mode of deliveryimately85%85%95%85%9 imately 85% of the mothers had antenatal care visits/contacts during pregnancy. More than half of the mothers (53.5%) were multipara. Most (66.7%)of the neonates were from singleton births (online supplemental table 2).

In this study, approximately 45.83% (95% CI: 37.81% to 54.08%) of neonates diagnosed with asphysia have died, whereas the majority (54.17%; 95% CI: 45.92%

Characteristics	Category	Frequency	Percentage
Respiratory distress syndrome	No	43	29.9
	Yes	101	70.1
Jaundice	No	129	89.6
	Yes	15	10.4
Congenital anomaly	No	139	96.5
	Yes	5	3.5
Hypoglycaemia	No	118	81.9
	Yes	26	18.1
Hypothermia	No	84	58.3
	Yes	60	41.7
Sepsis	No	38	26.4
	Yes	106	73.6
NEC	No	128	88.9
	Yes	16	11.1

NEC, Necrotizing enterocolitis; NICU, Neonatal Intensive Care Unit.

to 62.19%) of them survived and were discharged with improvement (figures 1).

In this study, each neonate diagnosed with asphyxia had different lengths of hospital stay, with a median survival time of 8 days. Among 144 asphyxiated neonates followed for 729 neonatal days, the mortality incidence rate was 9.1/1000 person-days of observation (95% CI: 7.11 to 11.52).

In this study, there were survival differences among covariates such as gender and neonatal sepsis (online supplemental figure 1). Time from birth until all-cause mortality using Kaplan-Meier survival and failure curves indicated that around 50% of neonates died below the median time of 8 days and 50% survived after a median survival time of 8 days (figure 2).

#### Predictors of time to death in asphyxiated neonates

The independent variables with a significance level of <0.25 during the bivariate analysis were transferred to multivariate analysis, and variables with a significance

Characteristics	Category	Frequency	Percentage
Place of delivery	Health institution	137	95.1
	Home	7	4.9
Weight of neonate (g)	Low birth weight (<2500g)	52	36.1
	Normal birth weight (≥2500g)	92	63.9
Gestational age (GA)	Preterm (<37 weeks of GA)	53	36.81
	Term (≥37 weeks of GA)	91	63.19
Apgar score in 1st minute	<7	113	78.5
	≥7	31	21.5
Apgar score in 5th minute	<7	39	27.1
	≥7	105	72.9
KMC applied	Yes	94	65.3
	No	50	34.7
Feeding status at admission	Breast milk	110	76.4
	Formula feeding	5	3.5
	Not initiated at all	29	20.1

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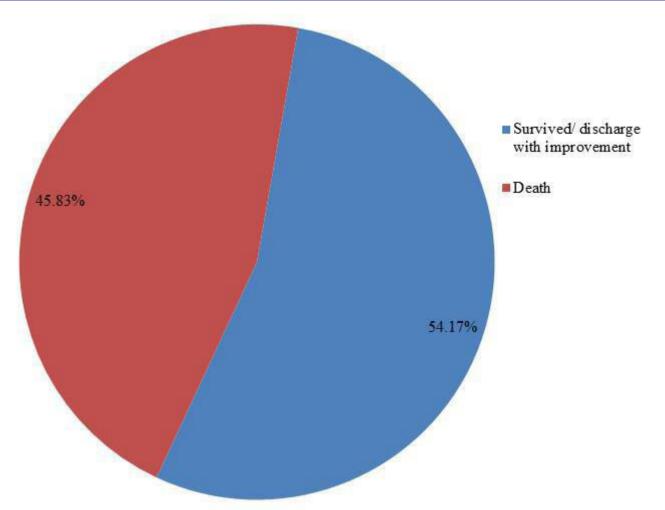


Figure 1 Survival status of asphyxiated neonates admitted to the neonatal intensive care unit of public hospitals in southwest Ethiopia (N=144).

level of 0.05 during multivariate analysis were considered as predictors of mortality.

In this study, the independent variables such as gender, maternal residency, KMC, sepsis, RDS, mode of delivery, weight, hypoglycaemia and fifth-minute Apgar score were significant in the bivariate analysis, while gender, sepsis, KMC and vaginal delivery were predictors of mortality for asphyxiated neonates in the multivariate regression.

In this study, female asphyxiated neonates had 68% times lower risk of death than male neonates (adjusted HR (AHR) 0.32 (95% CI: 0.14 to 0.76)). Asphyxiated neonates who received KMC had 84% times lower hazards of death than those who did not receive KMC (AHR 0.16 (95% CI: 0. 07 to 0.39)). Asphyxiated neonates without diagnosis of neonatal sepsis had 67.9% times lower hazard of death as compared with asphyxiated neonates with neonatal sepsis (AHR 0.321 (95% CI: 0.13 to 0.77)). Asphyxiated neonates delivered via caesarean section had 61% times lower hazard of death than neonates delivered with a vaginal mode of delivery (AHR 0.39 (95% CI: 0.16 to 0.95)) (table 3).

#### DISCUSSION Background

A prospective cohort study was conducted to determine the time to death among asphyxiated neonates and to identify predictors of mortality.

#### General findings of the study

In this study, the incidence of death among asphyxiated neonates was 9.1/1000 person-days of observation [95% CI: 7.11 to 11.52) with a median survival time of 8 days. Approximately 45.83% (95% CI: 37.81% to 54.08%) of neonates diagnosed with asphyxia died during the follow-up period. Gender variation, sepsis, KMC and vaginal delivery were independent predictors of mortality in asphyxiated neonates admitted to intensive care units.

### **Comparison with similar studies**

In this study, approximately 45.83% of neonates diagnosed with asphyxia died during the follow-up period, which was higher than the studies conducted at Dessie Comprehensive Specialized Hospital,<sup>11</sup> northwest Ethiopia,<sup>14</sup> Addis Ababa<sup>13</sup> and Nigeria,<sup>15</sup>

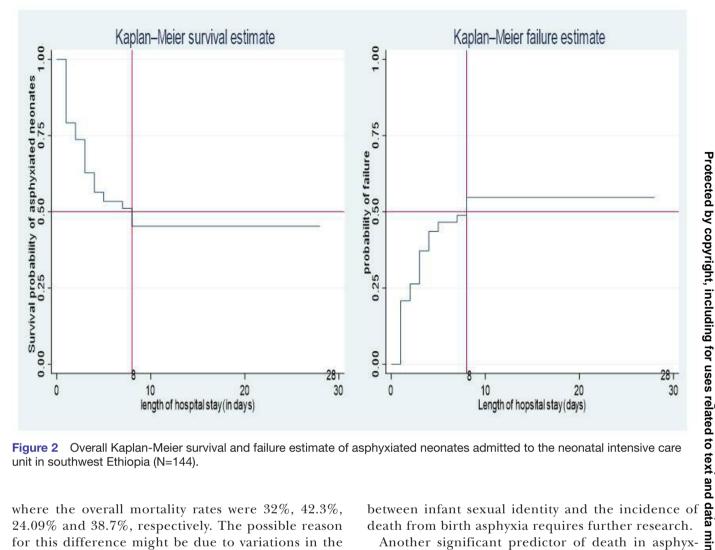


Figure 2 Overall Kaplan-Meier survival and failure estimate of asphyxiated neonates admitted to the neonatal intensive care unit in southwest Ethiopia (N=144).

where the overall mortality rates were 32%, 42.3%, 24.09% and 38.7%, respectively. The possible reason for this difference might be due to variations in the level of quality of care in neonatal services provided to asphyxiated neonates during hospitalisation, sources of data (primary/secondary). This study used primary data sources during follow-up with data that are more accurate and reliable on the outcome status of neonates, whereas other studies used secondary data/cared review, which makes it difficult to obtain the actual outcome status and where not all neonatal outcomes were recorded on their charts; therefore, cases of mortality might be under-reported. The variation with the study conducted at Enugu, southeast Nigeria<sup>15</sup> might also be due to varying methods of clinical practice and contextual factors such as laboratory equipment and sociodemographic differences of the population served between Ethiopia and Nigeria.

In this study, female asphyxiated neonates had lower hazards of death than male neonates, which was supported by studies conducted in India<sup>17</sup> and reports of the United Nations Inter-agency Group for Child Mortality Estimation.<sup>18</sup> This might be because male newborns are more vulnerable to birth asphyxia and have a greater risk of poor cardiovascular and respiratory outcomes.<sup>19 20</sup> However, the relationship

between infant sexual identity and the incidence of death from birth asphyxia requires further research.

Another significant predictor of death in asphyxiated neonates was the lack of KMC. Asphyxiated neonates who received KMC had lower risk of death than those who did not. This might be because asphyxiated neonates who did not receive KMC service may not be stabilised so they had a delay in the initiation of breast feeding during hospitalisation, which may lead to hypoglycaemia, and ultimately to death.

In addition, asphyxiated neonates without a diagnosis of neonatal sepsis have a lower risk of death than those with neonatal sepsis. This finding is supported by other studies.<sup>1421</sup> This might be because asphyxiated neonates with neonatal sepsis have lower immunity and risk of lung collapse leading to hypoxia and death. Therefore, neonatal comorbidities such as sepsis are equally important and should be considered in the management of neonatal asphyxia.

Asphyxiated neonates delivered via caesarean section have a lower risk of death than those delivered vaginally. This result is supported by studies conducted in Japan<sup>22</sup> and Nepal,<sup>23</sup> and a multicountry survey.<sup>24</sup> This is because there is a significant relationship between the mode of delivery and neonatal asphyxia,<sup>25 26</sup> where the action of labour and birth

Table 3	Predictors of time to death of asphyxiated neonates admitted to the NICU of public hospitals in southwest Ethiopia,
2022 (N=	=144)

Characteristics		Outcome status				
	Category	Alive	Death	CHR (95% CI)	AHR (95% CI)	P value
Sex of the neonates	Female	25 (38.46)	40 (61.54)	1	1	
	Male	53 (67.09)	26 (32.91)	0.31 (0.19 to 0.53)	0.32 (0.14 to 0.76)	<0.05
Maternal residency	Urban	18 (47.37)	20 (52.63)	1	1	
	Rural	60 (56.60)	46 (43.40)	0.77 (0.45 to 1.30)	0.86 (0.49 to 1.50)	0.61
KMC applied	No	40 (80.00)	10 (20.00)	0.35 (0.18 to 0.68)	0.16 (0.07 to 0.39)	<0.05
	Yes	38 (40.43)	56 (59.57)	1	1	
Sepsis	No	17 (44.74)	21 (55.26)	1	1	
	Yes	61 (57.55)	45 (42.45)	0.48 (0.28 to 0.83)	0.321 (0.13 to 0.77)	<0.05
RDS	No	28 (65.12)	15 (34.88)	1	1	
	Yes	50 (49.50)	51 (50.50)	1.75 (0.98 to 3.13)	1.28 (0.63 to 2.60)	0.49
Mode of delivery	C/S	25 (75.76)	8 (24.24)	1	1	
	Vaginal	53 (47.75)	58 (52.25)	2.91 (1.39 to 6.12)	0.39 (0.16 to 0.95)	<0.05
Birth weight	<2500 g	62 (67.39)	30 (32.61)	0.35 (0.22 to 0.58)	0.77 (0.39 to 1.49)	0.43
	≥2500g	16 (30.77)	36 (69.23)	1	1	
Hypoglycaemia	No	66 (55.93)	52 (44.07)	1	1	
	Yes	12 (46.15)	14 (53.85)	1.61 (0.89 to 2.91)	1.71 (0.92 to 3.18)	0.09
5th-minute Apgar score	<7	15 (38.46)	24 (61.54)	0.66 (0.40 to 1.10)	1.26 (0.49 to 3.23)	0.63
	≥7	63 (60.0)	42 (40.00)	1	1	

injuries contributes to the risk of stress and additional hypoxia and may result in death. Therefore, effective obstetric care and timely resuscitation are important for reducing neonatal deaths at the time of birth.

#### Policy implications and future research

Some trials have attempted to implement novel techniques to prevent morbidity and mortality related to neonatal asphyxia in Ethiopia. High-impact newborn and child health interventions address the particular needs of women and newborns from pre-pregnancy to childhood period, and different interventions are packaged to be delivered at household/community and individualised clinical care levels to improve newborn survival.<sup>27 28</sup>

However, the findings of the current study highlight that the incidence of mortality related to neonatal asphyxia was high, and another study supported this

existing trials and strategies, and emphasise the need for intensified efforts to decrease the proportion of asphyxia and related neonatal mortality. In this study, one of the significant predictors of death for asphyxiated neonates was lack of KMC, and findings in a previous study confirmed that lack of

KMC could affect the survival of neonates.<sup>30 31</sup> Therefore, all the responsible bodies, especially healthcare professionals, newborns' families and mothers, should play a key role in ensuring consistent utilisation of KMC as an essential procedure that can improve newborn survival for eligible hospitalised neonates,

birth asphyxia is low in Ethiopia.<sup>29</sup> Thus, the Federal

Ministry of Health, regional health offices, hospi-

tals, healthcare professionals and non-governmental organisations should focus on the need to strengthen

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but future research should be done to determine how KMC can impact asphyxiated neonates and how long should KMC be applied. Health education should be given for those mothers/families on how to care and apply KMC.

In the current study, gender differences were one of the predictors of mortality. However, this is also open for future follow-up studies to understand the impact of gender on the incidence of death among asphyxiated neonates that help in developing policies and identifying strategies that can reduce gender-specific mortality.

The study was conducted prospectively in multiple centres (three public hospitals) in the southwest region using primary data, thus increasing the accuracy and reliability of the data, and a multivariate Cox regression analysis was used to control all likely confounders. However, this study had some limitations. Using a relatively small sample size and being unable to include asphyxiated neonates admitted to private health institutions make it difficult to generalise the findings to all asphyxiated neonates.

#### **CONCLUSION**

In this study, asphyxiated neonates had a higher incidence of mortality with a median survival time of only 8 days. Being male, vaginal delivery, not receiving KMC and comorbidity with neonatal sepsis were independent predictors of mortality among asphyxiated neonates. Therefore, to reduce neonatal mortality with asphyxia, healthcare providers and other stakeholders should provide timely initiation of advanced diagnosis and appropriate therapeutic interventions for neonates with asphyxia.

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Contributors All authors contributed significantly to the work reported. BFK, AY, EA, KKM and TB contributed to the study planning, conception and design, and drafted the manuscript. YDG, BFK, TB, ES, KKM and EM participated in the acquisition, analysis and interpretation of data. EM, EA, ES and BFK critically reviewed the draft and rewrote the entire manuscript the way it is currently presented. All authors had approved the final version.BFK acting as guarantor.

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#### Patient consent for publication Not required.

Ethics approval This study involves human participants and was approved by the Mizan-Tepi University Ethical Review Board (HSC/00102/2014). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. The data presented in this study are available on request from the corresponding author.

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