

Neonatal Characteristics Associated with Congenital Anomalies and Mortality in a Tertiary Neonatal Unit: A Three-Year Retrospective Study.

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ABSTRACT

Background: In tertiary neonatal centres congenital anomaly (CA) forms part of the causes of neonatal morbidity and mortality when it is combined with other factors such as premature birth, respiratory failure, sepsis, birth asphyxia and/or surgical referral.

Methods: 1200 neonatal admissions to neonatal unit were included as an analytical cohort in this 3-year retrospective study. Neonatal characteristics, maternal factors, congenital anomaly status, clinical morbidities, interventions and mortality were analysed using descriptive statistics, bivariate tests, crude odds ratios and multivariable logistic regression. Each variable for the regression was considered a priori and not entered by a stepwise method.

Results: Congenital anomalies were recorded in 89 (7.4%) of 1,200 neonates. Overall mortality was 171/1,200 (14.2%). The mortality rate in neonates with anomalies was higher than in neonates without anomalies (21.3% vs 13.7%). Antenatal ultrasound was documented in 60/89 anomaly cases (67.4%), but when records were available a confirmed antenatal detection rate could not be computed. In adjusted analysis, mortality was associated with congenital anomaly status, low birth weight, low five-minute Apgar score, birth asphyxia, respiratory distress and mechanical ventilation.

Conclusion: Congenital anomalies were found to be more clinically complex and associated with higher mortality. Small sample sizes of anomaly subgroups are only presented descriptively. Results suggest the need for better documentation during pregnancy, more complete diagnostics, neonate to surgery referrals, and a structured mortality review....

Keywords: congenital anomalies; neonatal mortality; neonatal surgery; antenatal ultrasound; neonatal unit; logistic regression

INTRODUCTION

The first 28 days of life focus physiological vulnerability, diagnostic ambiguity, and the greatest requirement for prompt decision-making and action making neonatal mortality a sensitive measure of performance of both mothers and their offspring, as well as the hospital system. Neonatal period has been continuously named as a critical priority on improving child survival by the World Health Organization (WHO) [1] and also by UNICEF who recognized that the reduction in deaths have not been sufficiently achieved after neonatal period [2]. The United Nations Inter-agency Group for Child Mortality Estimation also indicates that neonate mortality is still a significant proportion of under-five mortality, specifically in places where the leading causes are prematurity, birth asphyxia, infection, and congenital disorders [4].

An anomaly that occurs in intrauterine life and is found to be either structural or functional and is diagnosed either at birth or in the neonatal admission or by the prenatal Registry. WHO identifies congenital disorders as one of the major causes of neonatal mortality and long-term disability and health system burden [3]. Yang et al. [7] found that congenital anomalies are still closely related to neonatal death pathways, and Sabry et al. [8] found anomaly patterns in neonatal intensive care units to be clinically heterogeneous with outcome relevance. These are among the research findings that compel the use of local studies of tertiary units in addition to national mortality estimates...

It is not only as to frequency that the clinical importance of congenital anomalies is to be estimated. Cardiovascular, central nervous system, gastrointestinal, abdominal-wall and urogenital and multiple-system defects all may need expedient diagnosis and stabilisation, with specialist intervention [9-14]. Ayfokru et al. [9] showed that mortality rates are high in the case of neonatal CHD. Yan et al. [15] and Yue et al. [16] independently estimated the global burden of digestive and urogenital congenital anomalies, respectively, based on newer global-burden frameworks. These studies demonstrate that the anomaly-system distribution directly impacts in neonatal surgery, cardiology, imaging, transport and counselling pathways.

Recent facility-based studies reveal that neonatal mortality most often is related to a combination of clinical features, minimal or absent data of which is gathered by birth defect registries. Taye et al. [5] and Tembo et al. [6] found important predictors that include low birth weight, pre-term and ill severity of the neonates in the intensive care settings. A high level of early neonatal mortality pattern at the tertiary level was highlighted by past studies and it was observed that low birth weight neonates remained vulnerable [17-21]. These results are important because congenital abnormalities do co-occur with immaturity, failure of transition, respiratory failure, sepsis and feeding problems requiring advanced feeding support.

Facility-level prediction and outcome studies further reinforce this pattern: preterm neonates admitted to specialized units continue to show substantial mortality risk [22,23]. Perinatal asphyxia and respiratory failure remain among the most consistently reported proximate causes of neonatal death across tertiary and intensive-care settings. Structured clinical prediction tools built from routinely collected admission variables have also been proposed to identify high-risk neonates earlier in their hospital course [24-29]. Thus, it reinforces the rationale for examining locally available clinical characteristics in the present cohort.

Maternal and antenatal factors continue to be paramount for prevention and detection. Folic-acid intake has shown to have protective effects in a recent systematic review and meta-analysis by Moges et al. [13] against congenital anomalies. Belama et al. [11] and Geda et al [10] have identified maternal and neonatal factors associated with structural congenital anomalies and Narapureddy et al. [30] have studied maternal risk profile in neonates with anomalies. These sources help in applying all the parameters, such as maternal age, diabetes, hypertension, consanguinity, documentation of folic-acid and antenatal-care visits, and antenatal ultrasound-documentation in the present analysis.

The key for neonatal surgery is not only the question of the presence or not of a congenital anomaly, but also the question of whether the care pathway is able to identify and stabilise the neonate before deterioration of physiologic conditions. Radiology, neonatology, obstetrics, surgery, cardiology, nursing and nutrition will all require coordinated action in the case of a neonate with intestinal obstruction, gastroschisis, diaphragmatic hernia, anorectal malformation, neural tube defect, or complex cardiac disease. This study therefore assessed neonatal variables relevant to that of congenital anomalies and neonatal unit death, focusing particularly on those parameters that could be used to facilitate the detection of anomalies and their early transport of referral, neonatal unit death audit and service planning, and that are clinically interpretable.

2. METHODS

2.1 Study design and setting

This was a three-year retrospective analytical cohort study of neonates admitted to Neonatal Services, Department of Pediatrics, Georgetown Public Hospital Corporation, Guyana (hereafter, the neonatal unit). The study was designed in the form of a clinical research article, original research. The neonatal unit is a tertiary referral unit for sick babies, high-risk deliveries and babies requiring high-level neonatal, surgery, radiological, or specialist assessment.

2.2 Study population

The study population included all neonates aged 0-28 days admitted during the study with complete core information for congenital anomaly status and discharge outcome. Both inborn and "outborn" neonates were eligible. Multiple records, records with admissions outside the neonatal period and records where a discharge record was not documented were excluded. A total of 1200 neonatal admission records made up the final analytic set.

2.3 Variables and operational definitions

The main exposure studied was congenital anomaly status, which was either present or absent. Anomaly cases were properly bucketed by body system and also by the specific type of anomaly, where applicable. Major anomaly was defined as an anomaly with an expected clinically significant impact, which was one of potential life-threatening, surgical, cardiology, neurosurgical, genetic or other specialist evaluation, or one of likely long-term extensive functional impairment. The minor isolated findings, which were not considered to have any impact on management other than specialist services or survival, were not considered to be major anomalies. The main outcome was early neonatal death; the mortality cut-off was defined as in-hospital death during the admission episode. Preterm birth was defined as gestational age under 37 completed weeks, very preterm birth was defined as gestational age under 32 weeks, low birth weight was defined as a birth weighs less than 2,500 g and very low birth weight was defined as birth weight less than 1,500 g. Low 5-minute Apgar score was considered an Apgar score of less than 7. Main clinical data analyzed were respiratory distress, suspected sepsis, birth asphyxia, mechanical ventilation, use of surfactant, feeding difficulty, surgery and length of stay as well as the main recorded cause of

death.

2.4 Antenatal ultrasound and diagnostic completeness

The documentation of the ultrasound images during the antenatal period was singled out as an independent variable. The latter reliability did not apply to the distinction between the anomalies detected in utero and the first documentation of the anomaly being after birth, so the figure for antenatal ultrasound was not considered to be a true figure for detection of anomaly antenatally. Similarly, the number of deaths before completion of the diagnostic work-up including surgical review, radiology, genetic assessment and echocardiography could not be estimated. However, the interpretability of anomaly-system distribution and cause-of-death categories was taken into consideration.

2.5 Statistical analysis

The data of continuous variables were expressed as mean and standard deviation while that of categorical variables as frequency and percentage. Comparisons of neonates with and without congenital anomalies were performed using the Welch independent-samples t test for continuous variables, and the chi-square test for categorical variables (Fisher exact test was used when the expected cell counts were small). IBM SPSS Statistics 26.0 was used for analyses. Records were kept with maximum core exposure data and outcomes information; covariate values which were absent from records were not imputable but were treated as missing with complete-case analysis conducted for each comparison based on data availability which is displayed on the denominators. Some anomaly types were only descriptively presented because when results in the tables are presented in sub-groups, the numbers of cells with counts of five or less makes the inferential sub-group comparisons unstable. There was no prospective power calculation, as this was a retrospective cohort including all eligible admissions; however, the sample of 1200 admissions were only 89 cases of anomaly, so the power of the subgroups (particularly multiple anomaly and body-system) analyses was limited. Crude odds ratios and 95% confidence intervals were reported for the mortality predictors. For mortality a Multivariable binary Logistic regression was then performed. The selection of variables was done on clinical and theoretical bases and not by a stepwise procedure. Congenital anomaly status, the preterm birth, low five-minute Apgar score, birth asphyxia, respiratory distress, suspected sepsis and mechanical ventilation were included in the model, in addition to parental consanguinity. The need for surgery was assessed for crude analysis but was not included in the adjusted model given that it was a downstream management variable, was well correlated with the congenital anomaly status value and had limited exposure as only 36 neonates had the surgery which could have destabilised the model and resulted in overadjustment. Variance inflation factors were used to diagnose multicollinearity and all were found to be less than 3.49. The Hosmer-Lemeshow goodness-of-fit test ($P=0.456$) was used to determine model fit and the area under the receiver operating characteristic curve ($AUC=0.783$) was used to determine discrimination.

2.6 Ethical considerations

Retrospective data from the neonatal-unit for de-identified study. The authors must explain prior to submission to the Journal that a suitable ethics committee has approved the research and add the name, approval number and date of the ethics committee to the manuscript. They must also include a statement indicating whether or not informed consent of the individuals was waived when requested by the ethics committee. All information should be kept on password protected, institutionalized data and only be reported in the aggregate.

3. RESULTS

A total of 1200 neonates were included in the analysis over the three years. 89 neonates (7.4%) had congenital anomalies and overall in-hospital neonatal mortality rate was 171/1,200 (14.2%). Neonates with congenital anomalies had a higher rate of mortality compared to those without congenital anomalies (21.3% vs. 13.7%). The study flow is illustrated in Figure 1, and the characteristics of baseline measurements for the anomaly and non-anomaly studies are presented in Table 1.

For all neonates, 871/1200 (72.6%) had an antenatal ultrasound recorded, while 60/89 (67.4%) with congenital anomalies had an antenatal ultrasound. This figure is for antenatal ultrasound documentation and not necessarily for confirmed antenatal anomaly detection rates, as some antenatal ultrasound records did not consistently show if the anomaly was detected before or after admission. In addition, records were not always complete enough to quantify the impact of determining an anomaly when death occurred prior to completion of some diagnostic studies, including echocardiography, radiology, genetic assessment, and/or surgical review.

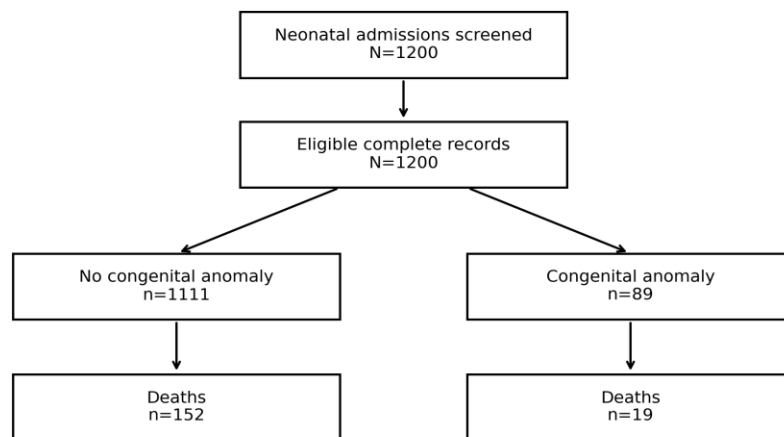


Figure 1. Study flow diagram.

Table 1. Baseline neonatal and maternal characteristics by congenital anomaly status

Characteristic	Overall (N=1200)	No anomaly (n=1111)	Anomaly (n=89)	P value
Gestational age, weeks, mean $\pm$ SD	36.2 $\pm$ 4.3	36.1 $\pm$ 4.3	36.9 $\pm$ 3.7	0.058
Birth weight, g, mean $\pm$ SD	2662.2 $\pm$ 825.7	2657.0 $\pm$ 834.4	2727.6 $\pm$ 709.6	0.375
Apgar score at 1 minute, mean $\pm$ SD	5.9 $\pm$ 1.8	5.9 $\pm$ 1.9	6.1 $\pm$ 1.7	0.227
Apgar score at 5 minutes, mean $\pm$ SD	7.4 $\pm$ 1.6	7.4 $\pm$ 1.6	7.8 $\pm$ 1.4	0.021
Age at admission, hours, mean $\pm$ SD	8.1 $\pm$ 6.7	8.1 $\pm$ 6.7	7.8 $\pm$ 6.2	0.654
Maternal age, years, mean $\pm$ SD	28.1 $\pm$ 5.9	28.0 $\pm$ 5.9	29.5 $\pm$ 5.8	0.016
Antenatal-care visits, mean $\pm$ SD	4.2 $\pm$ 2.1	4.2 $\pm$ 2.1	4.1 $\pm$ 2.3	0.603
Male sex	667 (55.6)	611 (55.0)	56 (62.9)	0.181
Preterm birth <37 weeks	527 (43.9)	493 (44.4)	34 (38.2)	0.309
Very preterm birth <32 weeks	183 (15.2)	174 (15.7)	9 (10.1)	0.212
Low birth weight <2500 g	462 (38.5)	432 (38.9)	30 (33.7)	0.394
Very low birth weight <1500 g	113 (9.4)	111 (10.0)	2 (2.2)	0.027

Low 5-minute Apgar <7	335 (27.9)	318 (28.6)	17 (19.1)	0.071
Inborn delivery	872 (72.7)	808 (72.7)	64 (71.9)	0.966
Antenatal ultrasound documented	871 (72.6)	811 (73.0)	60 (67.4)	0.311
Parental consanguinity	310 (25.8)	283 (25.5)	27 (30.3)	0.377
Maternal diabetes	86 (7.2)	83 (7.5)	3 (3.4)	0.219
Maternal hypertension	124 (10.3)	116 (10.4)	8 (9.0)	0.801
First-trimester folic acid documented	611 (50.9)	568 (51.1)	43 (48.3)	0.689

Note. Values are n (%) unless otherwise stated. P values compare anomaly and non-anomaly groups.

The distribution of congenital anomalies by body system is shown in Table 2 and Figure 2. Cardiovascular anomalies were the most frequent group, followed by musculoskeletal, gastrointestinal and CNS/neural tube anomalies. Table 2 is descriptive only; inferential comparison by anomaly system was not performed because several subgroups contained small cell counts, including categories with five or fewer neonates, which would reduce statistical power and make percentages unstable.

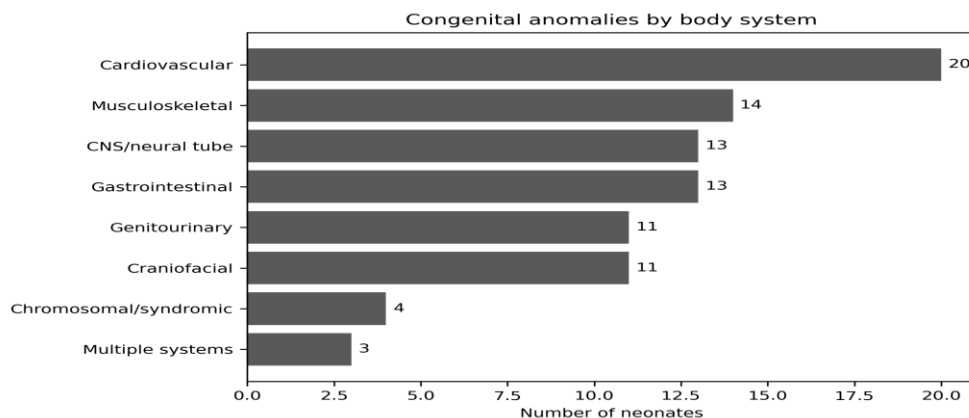


Figure 2. Congenital anomalies by body system.

Table 2. Congenital anomalies by body system and mortality

Anomaly system	n	% among anomalies	Deaths n (%)
Cardiovascular	20	22.5	5 (25.0)
Musculoskeletal	14	15.7	1 (7.1)
Gastrointestinal	13	14.6	2 (15.4)
CNS/neural tube	13	14.6	5 (38.5)
Craniofacial	11	12.4	1 (9.1)
Genitourinary	11	12.4	4 (36.4)
Chromosomal/syndromic	4	4.5	0 (0.0)
Multiple systems	3	3.4	1 (33.3)

Note. Descriptive table only; inferential comparisons by anomaly system were not performed because several categories had small cell counts.

The most frequent specific anomaly labels are shown in Table 3. These values describe the clinical case mix rather than subgroup risk estimates. The table was retained because it helps neonatal, surgical and referral teams understand the types of anomalies represented; however, no inferential conclusions are drawn from these sparse categories.

Table 3. Most frequent specific anomaly types

Specific anomaly type	n	% among anomalies
Spina bifida	5	5.6
Critical congenital heart disease	5	5.6
Ambiguous genitalia	5	5.6
Micrognathia	5	5.6
Tetralogy of Fallot	5	5.6
Limb reduction defect	5	5.6
Polydactyly	5	5.6
Ventricular septal defect	5	5.6
Hydrocephalus	4	4.5
Omphalocele	4	4.5
Anorectal malformation	4	4.5
Gastroschisis	3	3.4

Note. Descriptive table only. Percentages are among neonates with congenital anomalies; no inferential claims are made from these small subgroups.

Clinical morbidity and intervention patterns are shown in Table 4. Mechanical ventilation, feeding difficulty, need for surgery and length of stay were higher among neonates with congenital anomalies. These findings indicate that anomaly status was associated with a more complex admission course and greater need for specialist or intensive supportive care.

Table 4. Clinical morbidity and interventions by congenital anomaly status

Characteristic	Overall (N=1200)	No anomaly (n=1111)	Anomaly (n=89)	P value
Respiratory distress	298 (24.8)	279 (25.1)	19 (21.3)	0.507
Suspected sepsis	214 (17.8)	199 (17.9)	15 (16.9)	0.915
Birth asphyxia	88 (7.3)	80 (7.2)	8 (9.0)	0.681
Mechanical ventilation	128 (10.7)	110 (9.9)	18 (20.2)	0.004
Surfactant administered	103 (8.6)	96 (8.6)	7 (7.9)	0.956
Feeding difficulty	188 (15.7)	162 (14.6)	26 (29.2)	<0.001
Surgery needed	36 (3.0)	19 (1.7)	17 (19.1)	<0.001
Length of stay, days, mean $\pm$ SD	7.3 $\pm$ 5.4	6.8 $\pm$ 5.0	12.9 $\pm$ 6.7	<0.001

Note. Values are n (%) unless otherwise stated.

Mortality by selected neonatal risk characteristics is shown in Table 5 and Figure 3. The mortality was mainly in very low

weight neonates with low 5-minute Apgar score, birth asphyxia, respiratory distress and mechanical ventilation. A higher observed mortality proportion (33.3% versus 14.1%) was associated with multiple anomalies, but this comparison was not significant ($P=0.137$). The very low number of neonates with multiple anomalies should not be interpreted as a lack of association, this result is likely underpowered.

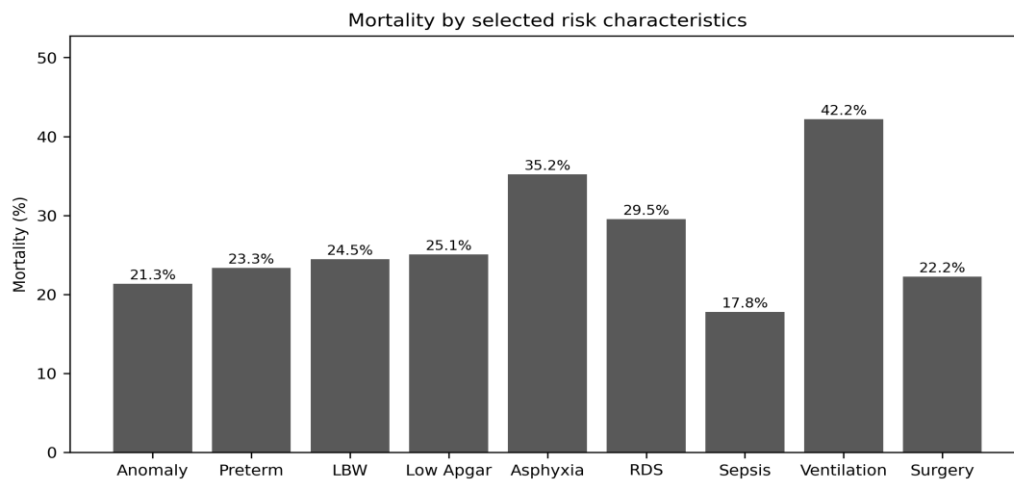


Figure 3. Mortality by selected risk characteristics.

Table 5. Mortality by selected neonatal characteristics

Characteristic	Exposed n	Deaths in exposed n (%)	Unexposed n	Deaths unexposed (%)	P value
Congenital anomaly	89	19 (21.3)	1111	152 (13.7)	0.067
Major anomaly	61	16 (26.2)	1139	155 (13.6)	0.010
Multiple anomalies	12	4 (33.3)	1188	167 (14.1)	0.137
Preterm <37 weeks	527	123 (23.3)	673	48 (7.1)	<0.001
Very preterm <32 weeks	183	79 (43.2)	1017	92 (9.0)	<0.001
Low birth weight <2500 g	462	113 (24.5)	738	58 (7.9)	<0.001
Very low birth weight <1500 g	113	61 (54.0)	1087	110 (10.1)	<0.001
Low 5-minute Apgar <7	335	84 (25.1)	865	87 (10.1)	<0.001
Birth asphyxia	88	31 (35.2)	1112	140 (12.6)	<0.001
Respiratory distress	298	88 (29.5)	902	83 (9.2)	<0.001
Suspected sepsis	214	38 (17.8)	986	133 (13.5)	0.131
Mechanical ventilation	128	54 (42.2)	1072	117 (10.9)	<0.001
Surgery needed	36	8 (22.2)	1164	163 (14.0)	0.251

Note. Exposed means the characteristic is present. The multiple-anomalies subgroup was small and underpowered; absence of statistical significance should not be read as evidence of no association.

Crude odds ratios for mortality are presented in Table 6. The crude odds ratio associated with congenital anomaly was 1.71 (95% CI 1.00-2.92) and stronger crude associations were seen with respiratory distress, birth asphyxia, mechanical ventilation, prematurity and low birth weight.

Table 6. Crude associations with neonatal mortality

Predictor	Crude OR	95% CI	P value
Congenital anomaly	1.71	1.00-2.92	0.067
Preterm <37 weeks	3.96	2.78-5.66	<0.001
Low birth weight <2500 g	3.80	2.70-5.34	<0.001
Low 5-minute Apgar <7	2.99	2.15-4.17	<0.001
Birth asphyxia	3.78	2.36-6.05	<0.001
Respiratory distress	4.13	2.95-5.79	<0.001
Suspected sepsis	1.38	0.93-2.06	0.131
Mechanical ventilation	5.96	3.99-8.88	<0.001
Surgery needed	1.75	0.79-3.92	0.251
Parental consanguinity	0.99	0.69-1.44	1.000

Note. Crude odds ratios were calculated using two-by-two tables.

The multivariable mortality model is shown in Table 7 and Figure 4. Even after these clinical variables were accounted for in the prespecified analyses, mortality was associated with congenital anomaly status, low birth weight, low five-minute Apgar score, birth asphyxia, respiratory distress and mechanical ventilation. Accordingly, surgery required was not adjusted for in the prespecified methodological reasons described in Section 2.5. For the model, Hosmer-Lemeshow test and AUC indicated fair model calibration and moderate model discrimination, respectively. The causes of death which are recorded as Primary are summarised in Table 8.

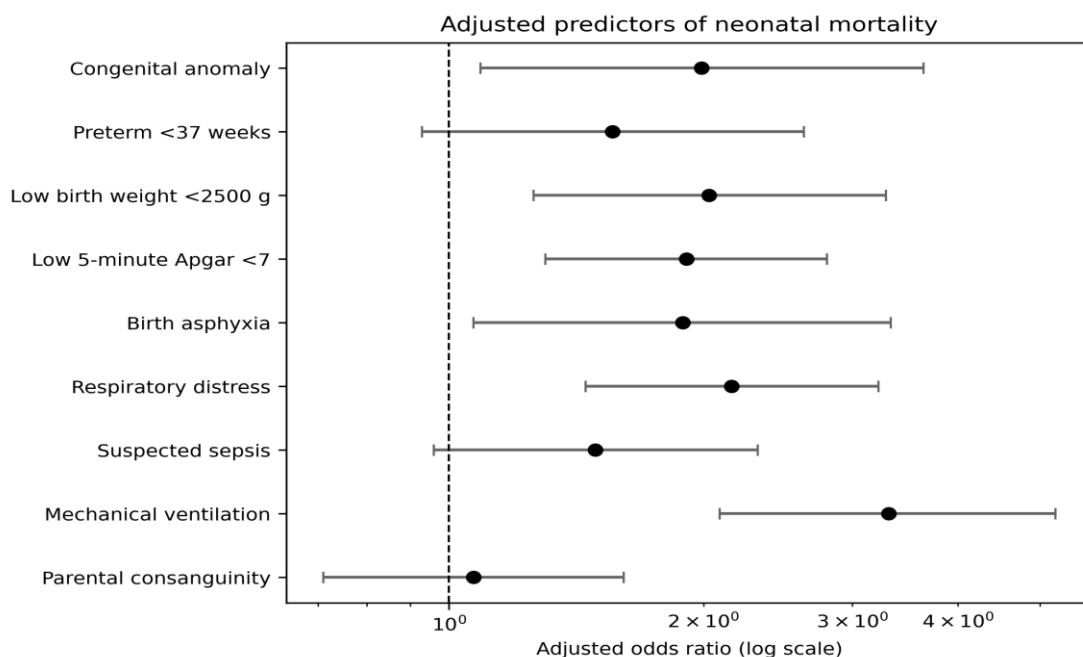


Figure 4. Forest plot of adjusted odds ratios for neonatal mortality.

Table 7. Multivariable logistic regression model for neonatal mortality

Variable	Adjusted OR	95% CI	P value
Congenital anomaly	1.99	1.09-3.64	0.025
Preterm <37 weeks	1.56	0.93-2.63	0.092
Low birth weight <2500 g	2.03	1.26-3.29	0.004
Low 5-minute Apgar <7	1.91	1.30-2.80	0.001
Birth asphyxia	1.89	1.07-3.33	0.027
Respiratory distress	2.16	1.45-3.22	<0.001
Suspected sepsis	1.49	0.96-2.32	0.075
Mechanical ventilation	3.31	2.09-5.22	<0.001
Parental consanguinity	1.07	0.71-1.61	0.741

Note. Dependent variable: mortality. Variables selected a priori. Surgery needed was excluded from the adjusted model because it was a downstream management variable with sparse exposure and risk of overadjustment. VIFs were <3.49; Hosmer-Lemeshow P=0.456; AUC=0.783.

Table 8. Primary recorded causes of death

Primary recorded cause of death	n	% of deaths
Respiratory distress syndrome	50	29.2
Extreme prematurity/ELBW	40	23.4
Other neonatal complication	31	18.1
Neonatal sepsis	28	16.4
Congenital anomaly	11	6.4
Birth asphyxia	11	6.4

Note. Cause categories are based on recorded discharge/death documentation and may represent final common pathways rather than all underlying contributors.

4. DISCUSSION

In this study, congenital anomaly resulted in earlier death in the hospital and greater complexity of the neonatal course in the neonatal unit. This finding is comparable to that of Yang et al. [7] who associated a congenital anomaly with a pathway of neonatal death, as well as that of Sabry et al. [8] who found heterogeneous anomaly patterns in neonates in neonatal intensive care and that of Ayfokru et al. [9] who reported significant mortality risk among neonates with congenital heart disease. Hence, the distribution of the body-systems in Table 2 is clinically relevant for service planning. However, owing to small numbers in the subgroups, caution must be used when applying these to body-system-specific estimates of risk.

Congenital anomaly status, low birth weight, low five-minute Apgar score, birth asphyxia and respiratory distress and mechanical ventilation were important variables associated with mortality in the adjusted model. Low birth weight, low birth order and prematurity are now shown to be relevant factors of mortality in the modern neonatal studies [19, 31-36]. Daka et al. [24] and Wudu et al. [25] reported high mortality rates in neonates of perinatal asphyxia. In the multicenter and tertiary-care studies, respiratory failure and the requirement for intensive support have also been reported as significant causes of neonatal deaths [6,27,28]. These findings suggest clustering of congenital anomalies to acute physiological instability in the current analysis based on tests for relatedness rather than a formal mediation analysis.

From a neonatal-surgical point of view the activation of the pathway upon the diagnosis of congenital anomalies should not be postponed. If necessary, coordinated gastrointestinal, abdominal-wall and urogenital decompression, fluid and electrolyte management, antibiotic, temperature management and imaging and timely surgical review should be utilised with gastrointestinal, abdominal-wall and urogenital anomalies. Early echocardiography and CNS/neural tube assessment cycles, specialist referral and family counselling should be sought for cardiovascular and CNS/neural tube anomalies. The

descriptive anomaly tables were kept for this reason, as that they show and will alert the neonatal unit to be ready to deal with the types of clinical pathways, even though there are few records within them.

Documentation and diagnostic completeness are still an important quality concern in antenatal care. Nearly three quarters of the cohort had antenatal ultrasound documented and about two-thirds of the neonates with the congenital anomalies had the ultrasound documented, but this could not be used in calculating an accurate proportion of anomalies detected antenatally. Alemu et al. [14] highlighted the impact of examination and detection practices of newborns on the recognition of congenital anomalies. Some neonates might also die prior to echocardiography, advanced imaging or genetic evaluation or prior to operative confirmation; in these cases, the cause of death written down could only represent the final clinical course and not be the full answer to all the factors.

The findings for multiple anomalies and surgery need show why there is the importance of being transparent in the specification of a model. Multiple anomalies had a greater proportion of observed mortality with only 12 neonates. However, multiple congenital anomalies, as reported by Thornton et al. [36] and by Shi et al. [37] may make a small subgroup clinically much more complex, and resource-consuming, than statistically significant, which means that caution must be exercised when interpreting non-statistically significant results in small subgroups. Surgery need was associated with mortality in crude analysis but not included in the adjusted model because it was a downstream management variable, was sparse and may have introduced the potential for overadjustment.

The study is relevant for Georgetown Public Hospital Corporation, and findings are not immediately applicable or generalisable to other contexts. Mortality on admission and anomaly burden may not be the best indicator of actual community prevalence or outcomes in lower-level facilities, since these types of hospitals receive high-risk pregnancies, outborn transfers, babies with more severe illness as well as surgical cases. Linking the congenital anomaly registry with delivery records, antenatal ultrasound results, neonatal admissions, echocardiographic and surgery and mortality review would aid in better future surveillance, would enable more effective categorisation of those who were only suspected to have a congenital anomaly and would lead to focused improvement in documentation of antenatal anomalies, early referral and neonatal-surgical preparedness.

5. STRENGTHS AND LIMITATIONS

The primary advantage of this study is its clinically coherent three-year retrospective dimension, as opposed to simply descriptive list of cases. It combines maternal risks, neonatal characteristics, anomaly categories, clinical morbidities, interventions and mortality into a single analysis plan. It also provides descriptive data, crude and multivariable association data, distinguishing overall clinical burden from data on adjusted associations. The principal constraints are those of using retrospective admission data. Documentation quality may differ, complete-case analysis was done for missing covariate values, diagnostic confirmation may be incomplete, and infants that died prior to full workup may have had unrecognised anomalies. Limitations of the study are that only 89 of the neonates had congenital anomalies, which limited the study to perform subgroup analysis. This selected referral population is not necessarily generalisable to other hospitals or settings outside Georgetown Public Hospital Corporation.

6. RECOMMENDATIONS AND FUTURE IMPLEMENTATION

Results are conducive to the establishment of a congenital anomaly register associated to obstetric, neonatal, surgical, imaging, and mortality-review registers. There should be a separation of documentation of routine ultrasound and documentation of suspected imperfection detected antenatally and documentation in the neonatal record of whether each anomaly was suspected before birth or detected at birth or diagnosed later in the neonatal period. Part of death review should be the question of whether the neonate died prior to finishing the planned Diagnostic Workup. It is recommended that there be early surgical referral criteria be adopted for gastrointestinal, urogenital, diaphragmatic and abdominal-wall anomalies and early confirmation of cardiovascular anomaly by echo, and CNS anomaly by neuroimaging/specialist consultation where appropriate. Future studies need to be conducted in a prospective manner with neonatal data captured and birth registry data linked to estimate population-based prevalence and post-discharge outcomes.

7. CONCLUSION

Congenital anomalies were associated with higher mortality and a more complex neonatal course in the neonatal unit. Mortality was also strongly associated with low birth weight, low five-minute Apgar score, birth asphyxia, respiratory distress and mechanical ventilation. There is a lack of cell sizes for some types of anomalies and some small body-system subgroups are reported descriptively. The results have suggested for effective documentation of the antenatal period, early diagnosis confirmation, neonatal surgery referral pathway, systematic death review process and the establishment of a congenital anomaly registry at Georgetown Public Hospital Corporation (GPHC).

8. DECLARATIONS

8.1 Ethics approval and consent to participate: This study was approved by the Ethics Committee of Georgetown Public

Hospital Corporation, with a waiver of individual informed consent granted for this retrospective, de-identified record review.

8.2 Consent for publication: No identifiable patient information is included.

8.3 Availability of data and materials: The de-identified analytic dataset may be available from the corresponding author subject to institutional and ethics restrictions.

8.4 Competing interests: The authors declare no competing interests.

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