"Clinical Profile and Short-Term Outcomes of Neonates with Congenital Anomalies Admitted to a Level 3 Tertiary Care Hospital: A Retrospective Cohort Study."

Background

Congenital anomalies are a major contributor to neonatal morbidity and mortality. Evaluating their clinical profiles and short-term outcomes is essential for guiding management and improving survival.

Objectives

To describe the clinical characteristics, types of anomalies, early outcomes, and factors associated with adverse outcomes among neonates with congenital anomalies in a level 3 tertiary care center.

Methodology

A retrospective cohort study was conducted at BJMC in year 2024. Neonates with structural or chromosomal anomalies were included; those with incomplete records, stillbirths, or loss to follow-up were excluded.

Results

Eighty-three neonates were included (61.4% males); 37.3% were preterm, 8.4% had very low birth weight (VLBW), and the mean birth weight was 2416.5±612.2 g. Frequent anomaly groups included cleft lip/palate (12.0%), cardiac anomalies (e.g., VSD, 8.4%), and congenital diaphragmatic hernia (7.2%). Surgical intervention was required by 18.1% of neonates. Antenatal scanning was performed 89.2%, with 35 scans (42.2%) accurately correlating to postnatal diagnoses, while 39 scans (47.0%) missed anomalies later detected at birth. Overall mortality was 14.5%, with VLBW (41.7% mortality $p<0.0001$) and prematurity (50% vs. 32.4% of survivors, $p=0.025$) significantly linked to higher risk of death. Of the survivors, 56.6% were discharged, 27.7% left against medical advice, and 1.2% were transferred out. Mean antibiotic duration was 6.1±5.8 days, and the average hospital stay was 9.3±8.0 days.

Conclusion

Neonates with congenital anomalies exhibit diverse clinical profiles with VLBW and prematurity strongly influencing mortality.

Keywords

Congenital anomalies, Neonates, Short-term outcomes, Prematurity, Very low birth weight, Retrospective cohort

2. Introduction

Congenital anomalies, defined as structural or functional abnormalities present at birth, are a significant cause of neonatal and infant morbidity and mortality worldwide. According to the World Health Organization (WHO), congenital anomalies affect approximately 1 in 33 infants globally, accounting for an estimated 303,000 neonatal deaths annually (1). These anomalies encompass a wide spectrum of conditions, including cardiovascular, gastrointestinal, genitourinary, and central nervous system defects, as well as chromosomal abnormalities such as Down syndrome (2). The burden of congenital anomalies is particularly high in low- and middle-income countries (LMICs), where limited access to prenatal screening, diagnostic facilities, and specialized care exacerbates poor outcomes (3).

In tertiary care hospitals, particularly those with level 3 neonatal intensive care units (NICU) with congenital anomalies often require multidisciplinary care, including surgical interventions, advanced diagnostics, and prolonged hospitalization. Despite advancements in neonatal care, congenital anomalies remain a leading cause of neonatal mortality, contributing to nearly 20% of neonatal deaths in some regions (4). Early diagnosis, timely intervention, and specialized care are critical to improving survival and reducing long-term disability. However, the clinical spectrum, management challenges, and short-term outcomes of these conditions in tertiary care settings are not well-documented, particularly in resource-limited settings.

Past studies have shown that cardiovascular and central nervous system anomalies are associated with higher mortality rates, while timely surgical interventions can significantly improve outcomes (5,6). However, data on the prevalence, types, and outcomes of congenital anomalies in level 3 tertiary care hospitals remain scarce, particularly in LMICs. This study aims to address this gap by analyzing the clinical profiles, management patterns, and short-term outcomes of neonates and infants with congenital anomalies admitted to a level 3 tertiary care hospital. The findings will contribute to a better understanding of the burden of congenital nomalies in this setting and guide the development of targeted interventions to improve care and outcomes.

3. Objectives

Primary Objectives

1. Describe the clinical profile of neonates with congenital anomalies admitted to a level 3 tertiary care hospital.
2. Assess short-term outcomes (survival, complications, mortality) during hospitalization.

Secondary Objectives

1. Identify the most common types of congenital anomalies.
2. Evaluate factors associated with poor outcomes (e.g., prematurity, type of anomaly, access to surgery).
3. Determine the mortality rate and causes of death.

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4. Methodology

Study Design

- Retrospective observational cohort study.

Setting

- Level 3 neonatal/pediatric intensive care unit (NICU) and pediatric wards of BJ Medical college and Sassoon General Hospital,Pune.

Study Population

- **Inclusion Criteria**: Neonates diagnosed with congenital anomalies (structural or chromosomal) admitted between January 2024 and December 2024
- **Exclusion Criteria**: Incomplete medical records, stillbirths, or neonates lost to follow-up before discharge.

Data Collection

- **Variables**:
    - **Demographics**: Gestational age, birth weight, sex, maternal age, antenatal care.

- **Clinical Profile**: Type of anomaly (classified by ICD-10 codes), system involved (e.g., cardiovascular, gastrointestinal), timing of diagnosis (antenatal/postnatal).
- **Management**: Diagnostic modalities (ultrasound, echocardiography), surgical/non-surgical interventions, complications.
- **Outcomes**: Survival to discharge, mortality, length of stay, referral status.

- **Data Sources**: Electronic medical records, admission/discharge registers, and operative reports.

Sample Size

The formula used is as follows:

$n=Z_{1-\alpha/2}{}^2 \times p \times (1-p)/ d^2$

$n= (1.96)^2 \times 0.025 \times (1-0.025)/ (0.05)^2$

n=37.45 rounded off to 38.

Adjustments for Incomplete Records:To account for potential missing or incomplete medical records, the sample size was inflated by **25%**.

Adjusted sample size=38/0.75=50.7 rounded off to **51.** Thus minimum required sample size is 51 cases.

Where:

- n = Minimum sample size required.
- $Z1-\alpha/2Z1-\alpha/2$ = Z-score corresponding to the 95% confidence level (Type 1 error = 5%), which is **1.96**.
- **Prevalence (p)**:The prevalence of congenital anomalies in India was estimated at **2.5%** (0.025) based on a meta-analysis by Bhide and Kar (2018) (3). This value was chosen as it reflects the pooled prevalence from multiple studies across India, ensuring generalizability to the study population.
- *d* = Margin of error (precision), set at **5%** (0.05).

Statistical Analysis

- Raw data was collected from medical records and entered in Microsoft excel 2016. The statistical analysis was performed using IBM SPSS Version 25. Categorical variables were presented as numbers and percentages and proportions were compared using Chi-square test. Continuous variables were represented as mean and standard deviations and were compared using independentsample t test. Significance was considered at cut off value of 0.05.

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5. Ethical Considerations

- Institutional Ethics Committee approval will be obtained.
- Patient confidentiality ensured via anonymized data collection.

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6. Expected Study Outcomes

1. **Clinical Profile**: The study will provide a comprehensive description of the types and frequencies of congenital anomalies among neonates admitted to a level 3 tertiary care hospital. It is anticipated that cardiovascular and gastrointestinal anomalies will be the most common, consistent with findings from similar studies (5,7).
2. **Short-Term Outcomes**: The study will quantify survival rates, complications, and mortality during hospitalization. Based on existing literature, the mortality rate is expected to be higher among infants with complex anomalies such as hypoplastic left heart syndrome and neural tube defects (8).
3. **Predictors of Poor Outcomes**: The study will identify risk factors associated with poor outcomes, such as prematurity, low birth weight, and delayed access to surgical interventions. These findings will help prioritize high-risk groups for targeted interventions.
4. **Mortality and Causes of Death**: The study will document the mortality rate and primary causes of death, which are expected to include sepsis, respiratory failure, and complications of surgical procedures (9).
5. **Implications for Practice**: The findings will inform the development of clinical guidelines for the management of congenital anomalies in tertiary care settings,

emphasizing the importance of early diagnosis, timely intervention, and multidisciplinary care.

RESULTS AND OBSERVATIONS

Table No. 1: Demographic and Perinatal Characteristics of Neonates by Survival Outcome

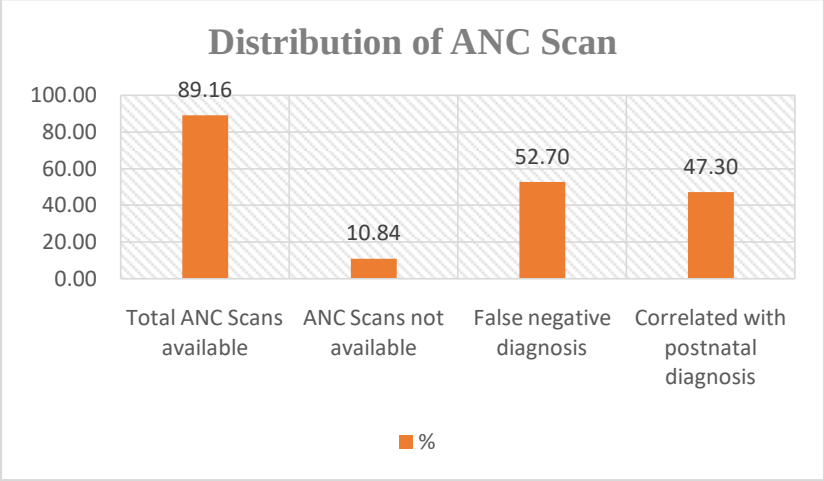
Demographic characterstics			Death (N=12)	Survivor (N=71)	Total	P
SEX	FEMALE	Number	5	27	32	0.81
		%	41.7%	38.0%	38.6%	
	MALE	Number	7	44	51	
		%	58.3%	62.0%	61.4%	
Mother age	Upto 20 Years	Number	5	13	18	0.19
		%	41.7%	18.3%	21.7%	
	21 to 30 Years	Number	6	51	57	
		%	50.0%	71.8%	68.7%	
	31 to 40 Years	Number	1	7	8	
		%	8.3%	9.9%	9.6%	
Gravida	1.00	Number	7	39	46	0.56
		%	58.3%	54.9%	55.4%	
	2.00	Number	5	19	24	
		%	41.7%	26.8%	28.9%	
	3.00	Number	0	11	11	
		%	0.0%	15.5%	13.3%	
	4.00	Number	0	1	1	
		%	0.0%	1.4%	1.2%	
	5.00	Number	0	1	1	
		%	0.0%	1.4%	1.2%	
Birth Weight category	Very Low Birth Weight (VLBW)(<1500 gm)	Number	5	2	7	<0.0001
		%	41.7%	2.8%	8.4%	
	Low Birth	Number	2	29	31	

	Weight (LBW)(<2500 gm)	%	16.7%	40.8%	37.3%	
	Normal Birth Weight(Between 2500 to 4000 gm)	Number	5	40	45	
		%	41.7%	56.3%	54.2%	
GESTATIONAL AGE	Preterm (<36 weeks)	Number	6	25	31	0.025
		%	50.0%	35.2%	37.3%	
	Term (37 to 41 weeks)	Number	5	46	51	
		%	41.7%	64.8%	61.4%	
	Post Term (42 weeks)	Number	1	0	1	
		%	8.3%	0.0%	1.2%	

The table interprets among the 83 neonates, 12 (14.5%) died, and 71 (85.5%) survived. Males constituted a higher proportion in both groups (58.3% in deaths vs. 62.0% in survivors, p=0.81). A higher percentage of deceased neonates were born to mothers aged ≤20 years (41.7% vs. 18.3%), whereas most survivors were born to mothers aged 21-30 years (71.8%), though this was not statistically significant (p=0.19). Primigravida mothers were more common in both groups (58.3% in deaths vs. 54.9% in survivors, p=0.56). Birth weight was significantly associated with mortality, with 41.7% of deceased neonates being Very Low Birth Weight (VLBW) compared to only 2.8% in survivors (p<0.0001). Preterm birth was also significantly associated with mortality (50.0% in deaths vs. 35.2% in survivors, p=0.025).

Table No.2 : Distribution of ANC Scan

ANC Scan	Number	%
Total ANC Scans available	74	89.16
ANC Scans not available	9	10.84
False negative diagnosis	39	52.70
Correlated with postnatal diagnosis	35	47.30



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167 The table presents that among the 83 cases, antenatal care (ANC) scan records were available
168 for 74 (89.16%) neonates, while 9 (10.84%) lacked ANC scan data. Among those with
169 available scans, 39 cases (52.70%) had a false-negative diagnosis, meaning the antenatal scan
170 did not detect the condition later confirmed postnatally. In contrast, 35 cases (47.30%) had
171 findings that correlated with the postnatal diagnosis.

172 **Table No. 3: Distribution of Outcome**

OUTCOMES	Number	%
DAMA	23	27.7
DEATH	12	14.5
DISCHARGED	47	56.6
TRANSFER	1	1.2
Total	83	100.0

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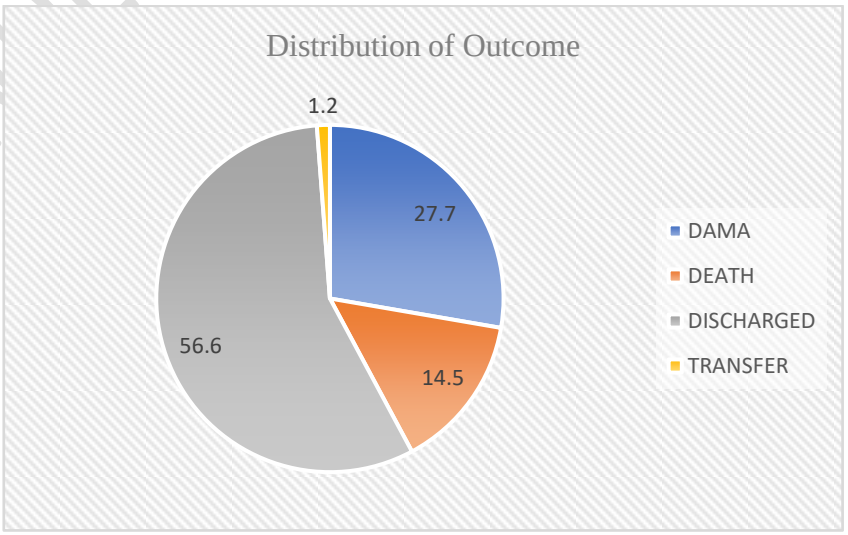

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The table presents that among the 83 neonates, the majority (47, 56.6%) were discharged, while 12 (14.5%) succumbed to their illness. A significant proportion (23, 27.7%) were discharged against medical advice (DAMA), indicating potential concerns regarding follow-up care and treatment adherence. Only one case (1.2%) was transferred to another facility.

Table No. 4: Distribution of Congenital Anomalies Across Organ Systems in Neonates

SYSTEM	CONGENITAL ANOMALIES	Number	%
CLEFT LIP/ CLEFT PALATE	CLEFT LIP/ CLEFT PALATE	10	12.05
Skeletal	CTEV	4	4.82
Cardiac	VSD	7	8.43
	DORV	2	2.41
	TETRALOGY OF FALLOT	3	3.61
	HYPOPLASTIC RIGHT VENTRICLE	1	1.20
	TRICUSPID ATRESIA	1	1.20
	BILATERAL MILD VENTRICULOMEGALY	1	1.20
	CARDIOMEGALY/MILD TR	1	1.20
	TRANSPOSITION OF GREAT ARTERIES	1	1.20
	VENTRICULAR SEPTAL DEFECT,ATRIAL SEPTAL DEFECT	1	1.20
	LEFT HYPOPLASTIC HEART DISESASE	3	3.61
	SEVERE TRICUSPID REGURGITATION	1	1.20
	TAPVC	1	1.20
	SMALL PDA (LT. TO RT. SHUNT)	1	1.20
	PDA	1	1.20
	TGA	1	1.20
Renal	Absent Kidney	2	2.41
	PUJ OBSTRUCTION	4	4.82
	HORSHOE KIDNEY	4	4.82
	HYDRONEPHROSIS	8	9.64
	HYDROCEPHALUS	1	1.20
	LEFT KIDNEY IN PELVIS	2	2.41
	BARTTER SYNDROME	1	1.20
	URINOMA	1	1.20

	CONGENITAL HYDROCELE	1	1.20
GastroIntestinal	DUODENAL ATRESIA	2	2.41
	ANOREACTAL MALFORMATIONS WITH MULTIPLE CONGENITAL ANOMALIES	1	1.20
	SMALL BOWEL OBSTRUCTION	1	1.20
	TRACHEOSEOPHAGEAL FISTULA	4	4.82
	ANORECTAL MALFORMATION	1	1.20
	OMPHALOCELE	1	1.20
CNS	DANDY WALKER MALFORMATION	2	2.41
	ANENCEPHALY	1	1.20
	MENINGOMYELOCOELE	3	3.61
Genetic disorder	DOWNS SYNDROME	1	1.20
Respiratory	PULMONARY HYPOPLASIA	1	1.20
	RIGHT LUNG CPAM	1	1.20
	CONGENITAL DIAPHRAGMATIC HERNIA	6	7.23
Reproductive	HYPOSPADESIS	3	3.61

The table interprets that among the congenital anomalies identified in 83 neonates, cleft lip/palate was the most common (10 cases, 12.05%). Skeletal anomalies included congenital talipes equinovarus (CTEV) in 4 cases (4.82%). Cardiac anomalies were diverse, with ventricular septal defect (VSD) being the most frequent (7 cases, 8.43%), followed by tetralogy of Fallot (3 cases, 3.61%) and left hypoplastic heart disease (3 cases, 3.61%), among others. Renal anomalies were also prevalent, with hydronephrosis (8 cases, 9.64%), pelvi-ureteric junction (PUJ) obstruction (4 cases, 4.82%), and horseshoe kidney (4 cases, 4.82%) being the most common. Gastrointestinal anomalies included tracheoesophageal fistula (4 cases, 4.82%) and duodenal atresia (2 cases, 2.41%). CNS anomalies included Dandy-Walker malformation (2 cases, 2.41%) and meningomyelocele (3 cases, 3.61%). Additionally, congenital diaphragmatic hernia was observed in 6 cases (7.23%), while Down syndrome was diagnosed in 1 case (1.20%).

196 Table No. 5: Clinical Parameters, Management, and Follow-Up Outcomes in Neonates

Clinical Parameters			Death (N=12)	Survivor (N=71)	Total	P
O2 SUPPORT	BCPAP	Number	1	9	10	0.094
		%	8.3%	12.7%	12.0%	
	NIV	Number	1	2	3	
		%	8.3%	2.8%	3.6%	
	NO	Number	1	29	30	
		%	8.3%	40.8%	36.1%	
	O2 HOOD	Number	3	17	20	
		%	25.0%	23.9%	24.1%	
	SMIV	Number	6	14	20	
		%	50.0%	19.7%	24.1%	
MEDICAL MANAGEMENT	NO	Number	0	8	8	0.221
		%	0.0%	11.3%	9.6%	
	YES	Number	12	63	75	
		%	100.0%	88.7%	90.4%	
SURGICAL MANAGEMENT	NO	Number	9	59	68	0.5
		%	75.0%	83.1%	81.9%	
	YES	Number	3	12	15	
		%	25.0%	16.9%	18.1%	
FOLLOW UP	CVTS SURGERY	Number	0	12	12	<0.0001
		%	0.0%	16.9%	14.5%	
	NEUROSURGERY	Number	1	8	9	
		%	8.3%	11.3%	10.8%	
	NO	Number	7	5	12	
		%	58.3%	7.0%	14.5%	
	ORTHOPEDICS SURGERY	Number	0	3	3	
		%	0.0%	4.2%	3.6%	
	PAEDIATRIC SURGEY	Number	4	38	42	
		%	33.3%	53.5%	50.6%	
	PLASTIC SURGERY	Number	0	5	5	
		%	0.0%	7.0%	6.0%	

The analysis of clinical parameters in neonates with congenital anomalies reveals significant differences between survivors (n=71) and non-survivors (n=12). Higher mortality was associated with increased reliance on invasive respiratory support, with 50.0% of non-survivors requiring synchronized intermittent mandatory ventilation (SMIV) compared to 19.7% of survivors ($p = 0.094$). Non-invasive ventilation (NIV) use was also higher among non-survivors (8.3% vs. 2.8%). While medical management was implemented in nearly all cases (100% in non-survivors, 88.7% in survivors), surgical intervention was slightly more common in non-survivors (25.0% vs. 16.9%). A critical finding was that cardiothoracic surgery (CVTS) was exclusively performed in survivors (16.9%, $p < 0.0001$), indicating its potential role in improved outcomes. Neurosurgery, orthopedics, and plastic surgery were also only performed in survivors, while pediatric surgery, the most common follow-up procedure (50.6%), was more frequent in survivors (53.5%) than non-survivors (33.3%). Notably, 58.3% of non-survivors had no follow-up interventions compared to only 7.0% of survivors, underscoring the significant association between lack of follow-up and mortality.

Table No. 6: Maternal, Neonatal, and Clinical Factors Associated with Neonatal Outcomes

OUTCOME		Mother age	Weight	Gestational Age	Duration of Antibiotics days	Duration of Hospital Stay days
Death (N=12)	Mean	22.8	2020.0	35.8	11.3	13.2
	SD	4.0	729.4	3.8	13.6	16.3
Survivor (N=71)	Mean	24.6	2483.5	36.9	5.3	8.6
	SD	4.4	569.2	1.9	4.4	8.5
Total	Mean	24.3	2416.5	36.7	6.1	9.3
	SD	4.4	612.2	2.3	6.8	10.0
P		0.175	0.014	0.113	0.003	0.146

The analysis of maternal and neonatal factors associated with outcomes in neonates with congenital anomalies showed notable differences between survivors (n=71) and non-survivors (n=12). The mean maternal age was slightly lower in non-survivors (22.8 ± 4.0 years) compared to survivors (24.6 ± 4.4 years, $p = 0.175$). Birth weight was significantly lower in non-survivors (2020.0 ± 729.4 g) than in survivors (2483.5 ± 569.2 g, $p = 0.014$), indicating that lower birth weight may be a predictor of poor outcomes. The mean gestational age was slightly lower in non-survivors (35.8 ± 3.8 weeks) than in survivors (36.9 ± 1.9

weeks, p = 0.113). Antibiotic duration was significantly longer in non-survivors (11.3 ± 13.6 days) compared to survivors (5.3 ± 4.4 days, p = 0.003), suggesting that prolonged antibiotic use may be associated with higher mortality. The mean hospital stay was also longer in non-survivors (13.2 ± 16.3 days) than in survivors (8.6 ± 8.5 days, p = 0.146), though this difference was not statistically significant

Discussion

The findings of this retrospective cohort study provide critical insights into the clinical profiles and short-term outcomes of neonates with congenital anomalies admitted to a level 3 tertiary care center. Congenital anomalies remain a leading cause of neonatal morbidity and mortality globally, contributing to approximately 20% of neonatal deaths in low- and middle-income countries (10). Our study highlights the significant association of very low birth weight (VLBW) and prematurity with adverse outcomes, aligning with existing evidence while also underscoring gaps in antenatal detection and postnatal management.

Mortality and risk factors

The overall mortality rate of 14.5% in our cohort is consistent with rates reported in similar settings, such as a Nigerian study documenting 16% mortality among neonates with major congenital anomalies (11). The starkly elevated mortality in VLBW neonates (41.7%) and preterm infants (50%) reinforces the well-established link between low birth weight, prematurity, and poor neonatal survival (12). These findings corroborate global data indicating that preterm birth complications and congenital anomalies collectively account for over 35% of under-five deaths (13). The vulnerability of VLBW infants may stem from physiological immaturity, increased infection risk, and limited reserves to withstand surgical or medical interventions (14).

Spectrum of Anomalies and antenatal detection

The predominance of cleft lip/palate (12.0%) and cardiac anomalies (e.g., ventricular septal defects, 8.4%) in our cohort mirrors global trends, where musculoskeletal and cardiovascular defects are among the most common structural anomalies (15). However, congenital diaphragmatic hernia (CDH), observed in 7.2% of cases, had a disproportionately high mortality in our cohort compared to international reports (16), suggesting potential disparities in access to advanced respiratory or surgical care.

Notably, antenatal scans detected anomalies in 89.2% of pregnancies, but only 42.2% of these scans correlated accurately with postnatal diagnoses. This discrepancy aligns with studies

demonstrating variable sensitivity of prenatal ultrasounds, particularly for cardiac and genitourinary anomalies (17). For instance, Khoo et al. (18) reported that 30–40% of congenital heart defects are missed antenatally, often due to technical limitations or late gestational screening. Improved training in anomaly scanning and routine fetal echocardiography could enhance detection rates (19).

Interventions and outcomes

Surgical intervention was required in 18.1% of neonates, a proportion lower than the 25–30% reported in high-resource settings (20). This gap may reflect differences in anomaly severity, resource availability, or delayed referrals. The mean hospital stay of 9.3 days and antibiotic duration of 6.1 days suggest significant healthcare utilization, consistent with studies highlighting prolonged admissions for neonates with complex anomalies (21).

Comparison with existing Literature

Our findings on mortality risk factors align with Tennant et al. (22), who identified prematurity and low birth weight as key predictors of poor outcomes in neonates with anomalies. However, the higher DAMA rate in our study contrasts with data from high-income countries, emphasizing the role of contextual factors in neonatal outcomes (23). Furthermore, the predominance of gastrointestinal and cardiac anomalies in our cohort diverges from studies in sub-Saharan Africa, where neural tube defects are more prevalent (24), suggesting regional variability in anomaly patterns.

Limitations

This study has limitations inherent to its retrospective design, including potential selection bias and reliance on documented records. The single-center focus limits generalizability, and the small sample size may reduce statistical power for rare anomalies. Future prospective, multi-center studies are needed to validate these findings and explore long-term outcomes.

Conclusion

This study underscores the critical impact of VLBW and prematurity on mortality in neonates with congenital anomalies, while highlighting challenges in antenatal detection and postnatal care accessibility. Strengthening prenatal diagnostics, optimizing neonatal intensive care, and addressing socioeconomic barriers are essential to improving outcomes in this vulnerable population.

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