

Clinical Profile, Outcome and Risk Factors for Mortality of Neonates Requiring Mechanical Ventilation at Tertiary Care Centre of Central Gujarat, India

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ABSTRACT

Introduction: Mechanical ventilation is an important factor contributing to the reduced neonatal mortality in NICU. However, many ventilated babies are left with detrimental sequelae. This study was undertaken to know the prognostic predictors and survival outcome in the ventilated neonates. We assessed the clinical profile, outcome of mechanical ventilation and analysed the risk factors for mortality and complications resulting from mechanical ventilation.

Methods: A prospective study was conducted at the NICU of a tertiary care hospital in India. The study period was from May 2015 to April 2016. Neonates who underwent mechanical ventilation and met the inclusion criteria were enrolled in the study. Their demographic profile, outcomes and risk factors were documented and analysed using appropriate statistical methods.

Results: 285 neonates required mechanical ventilation during the study period. Among them, 190 were included in the study. Overall mortality was 99 out of the 190 enrolled (52%). The most common indications for mechanical ventilation were Respiratory Distress Syndrome (RDS), Meconium Aspiration Syndrome (MAS) and apnea. Risk factors contributing significantly to higher mortality of ventilated neonates were very low birth weight (VLBW), gestation of less than 32 weeks, shock, ventilator-associated complications like pneumothorax and pulmonary haemorrhage. In multiple regression analysis, very low birth weight, circulatory disturbances, pneumothorax, pulmonary haemorrhage, and higher initial FiO₂ requirement were found to be independent risk factors of mortality.

Conclusions: The commonest indications for mechanical ventilation were RDS and MAS. Significantly higher mortality was seen amongst VLBW, preterm neonates. Co-morbidities like circulatory disturbance, and complications like pneumothorax and pulmonary haemorrhage contributed to adverse outcomes.

Keywords: mechanical ventilation; neonates; outcome



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INTRODUCTION

As per the Sample Registration System (SRS) 2017 report, the present Infant Mortality Rates (IMR) of our country and Gujarat are 37 and 30 per 1000 live births respectively,¹ against targeted 27/1000 live births under Millennium Development Goals-4, which was to be achieved by 2015,^{2,3} despite a plethora of measures taken by the Government with focus on neonatal health.

The improved access to neonatal mechanical ventilation is an important factor contributing to the reduced neonatal mortality in today's age. However, significant number of ventilated babies who survive, do so with detrimental sequelae due to their turbulent NICU stay; due to many economic and infrastructural hurdles in a low-income country like India.

Various Indian studies report a survival rate of 40% to 60%.⁴ Thus, this study was undertaken with the objectives of studying the clinical profile, outcome of mechanical ventilation in neonates and analysing the risk factors for mortality and complications resulting from mechanical ventilation and their effect on survival.

METHODS

A prospective, hospital-based study was conducted at the NICU of Kashiben Gordhandas Patel Children Hospital (KGP), Vadodara, Gujarat, India. The study period was from May 2015 to April 2016. The study was commenced following approval from the Institutional Ethical and Scientific Committee. The sample size of 232 was derived by applying formula $N = 4 \times pq / L^2$; N = sample size; p = positive factor i.e. proportion, $q = 100 - p$; $L = 20\%$ allowable error, precision, variability.

During the study period of one year, 285 (21.9%) neonates of total 1299 admissions were mechanically ventilated, of which 232 (17.8%) neonates fulfilling the inclusion criteria were enrolled after taking a written informed consent from the parents.

Forty-two babies took discharge against medical advice during the study or were ventilated prior to admission, thus they were excluded. Finally, 190 (14.6%) cases requiring ventilator support were analysed.

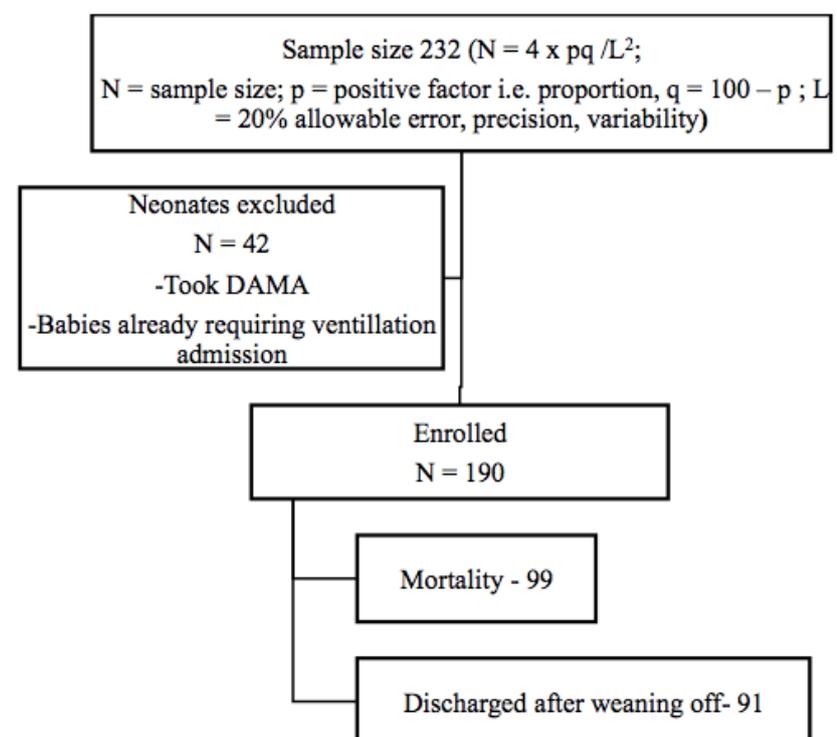


Figure 1. Study flowchart

Table 1. Demographic variables of the enrolled neonates requiring ventilation

Demographic variables	Distribution	Number of cases (N = 190)	Percent of total Cases (%)
Area	Rural	109	57.4
Place of birth	KGP Hospital (Inborn)	13	6.8
	Out born	177	93.2
Age on admission	< 24 hours	120	63.2
	1 – 7 days	51	26.8
	> 7 days	19	10.0
Gestation	< 32 weeks	32	16.8
	32 – 36 weeks	60	31.5
	> 37 weeks	98	51.5
Birth weight	< 1000 grams	15	7.9
	1000 - 1500 grams	26	13.7
	1500 - 2500 grams	83	43.7
	> 2500 grams	66	34.7
Gender	Male	124	65.3

For all included neonates, a thorough history was taken as per a set proforma, then they were examined and gestational age was established by using the expected date of delivery and / or expanded new Ballard score. Neonates presenting with respiratory distress were assessed by Downe or Silverman Anderson score (SAS). A provisional diagnosis was made based on the clinical condition and initial blood gas report, and a decision was taken for mechanical ventilation.

Treatment of ventilator related complications, and other supportive management were undertaken as per standard NICU protocols. Outcome was determined in terms of survival and days of hospitalisation. The collected data was computerised and analysed using appropriate

Table 2. Distribution of clinical diseases

Disease at presentation	Number (N = 190)	Percentage (%)
RDS	67	35.3
MAS	35	18.4
Apnoea	33	17.4
Persistent pulmonary hypertension of newborn (PPHN)	15	7.9
Birth asphyxia	11	5.8
CNS related – Intracranial haemorrhage and raised ICP	9	4.7
Septicaemia	8	4.2
Pneumonia	8	4.2
CHD	4	2.1

statistical methods like Chi-square test, t - test, multivariate analysis, etc.

RESULTS

Of the 285 neonates needing mechanical ventilation during the study period, 190 cases were finally analysed, meeting the inclusion and exclusion criteria (Figure 1).

Majority of the neonates included were born outside KGP (93.2 %). The percentage of babies who got admitted within the first 24 hours of life was 63.2%. Among the babies, 48.3% were preterm and 21.6% were very low birth weight (Table 1).

Overall mortality was 99 out of the 190 enrolled (52%), of which 81 (43%) died while receiving mechanical ventilation; the rest died after weaning off from the ventilator due to some other cause (e.g. aspiration, acute renal failure, sepsis with refractory shock). Among the ventilated babies, 91 (47.9 %) were successfully weaned off from the ventilator and discharged from the NICU (Figure 1).

As shown in Table 2 below, the most common indication for mechanical ventilation was Respiratory Distress Syndrome (RDS) (35.3%), followed by Meconium Aspiration Syndrome (MAS) (18.4%) and apnea (17.4%).

Table 3. Risk factors affecting survival of the mechanically ventilated neonates

Risk factor	Number (N = 190)	Percentage (%)	Survival group		Non survival group		p value
			Number of cases	Percentage (%)	Number of cases	Percentage (%)	
Baseline characteristics							
Low Birth weight (< 1500 grams)	41	21.6	12	29.3	29	70.7	0.007
Preterm (GA < 32 weeks)	32	16.8	9	28.1	23	71.9	0.014
Male gender	124	65.3	60	48.4	64	51.6	0.852
Morbidity							
Sepsis	115	60.2	59	51.3	56	48.7	0.244
DIC	46	24.2	17	37	29	63	0.088
Shock	62	32.6	21	33.9	41	66.1	0.007
Mechanical ventilation related complications							
Ventilator Associated Pneumonia	40	21.1	18	45	22	55	0.680
Endotracheal tube related complications	43	22.6	23	53.5	20	46.5	0.404
Pulmonary Haemorrhage	25	13.6	1	4	24	96	0.000
Pneumothorax	28	14.7	6	21.4	22	78.6	0.002

High mortality was found in babies ventilated for Congenital Heart Disease (CHD) (100%), sepsis (87.5 %), Persistent Pulmonary (PPHN) (60%) and MAS (50%). Table 3 shows that 21.6% babies were VLBW, with a mortality rate of 70.7%, while the mortality was 47% in babies who weren't VLBW (statistically significant $p = 0.007$). Similarly, mortality was higher in babies of gestation < 32 weeks ($p = 0.014$). As shown in table 3 below, related morbidities like shock, ventilation associated complications like pulmonary

haemorrhage and pneumothorax contributed significantly to adverse outcome (p values 0.007, 0.000 and 0.002 respectively).

In multiple regression analysis, factors such as birth weight <1500 grams, complications such as circulatory disturbances, pneumothorax, pulmonary haemorrhage and higher initial FiO₂ requirement were found to be independent risk factors for mortality in the mechanically ventilated neonate (Table 4).

Table 3. Multiple Logistic Regression Analysis of the risk factors contributing to mortality

Variables	B	S.E.	P value	OR	95% C.L. for OR	
					Lower	Upper
Circulatory disturbances	1.024	0.367	0.005	2.784	1.356	5.713
Pneumothorax	1.322	0.536	0.014	3.750	1.313	10.711
Pulmonary Haemorrhage	3.353	1.056	0.001	28.596	3.609	226.552
Birth weight < 1500 grams	1.255	0.452	0.005	3.509	1.447	8.508
Initial FiO ₂	2.036	0.762	0.008	7.659	1.719	34.125

DISCUSSION

The use of mechanical ventilation is an integral part of any nursery catering to sick neonates in both developed and developing countries. However, even today, mechanically ventilated neonates have a high fatality reported all over the world,⁵⁻⁷ the fatality being higher in the tertiary referral neonatal units receiving most cases as out born neonates.⁸ Results of the present study are discussed below along with comparison with other studies.

Various studies reported 3.5 to 13 percent of newborns who were mechanically ventilated from all NICU admissions, depending upon the centre, drainage area, cost, man power and infrastructure.^{4,9} The percentage is higher in this study because our centre caters to more out born neonates who need tertiary care in NICU and referred from the city and rural areas adjoining. In this study, 17% neonates were of less than 32 weeks of gestation, 31% were between 32 to 36 weeks as per expanded new Ballard score applied to find out gestational age. Other Indian studies reported a similar cohort with 16 to 17% for < 32 weeks gestation, 30% to 40% for 32 to 37 weeks respectively.^{10,11} Preterm babies suffer from RDS, apnea, sepsis, pneumonia, pulmonary haemorrhage etc. and they need mechanical ventilation more than term neonates.¹²

Overall mortality in this study was 52.1%. Among them, 43% had died while on ventilator and 9% died after successful weaning from ventilator due to other causes such as aspiration, sepsis with refractory shock, ARF. 47.9% babies were successfully weaned from ventilator and discharged. A study conducted in Surat in 2009 reported similar mortality of 54% among which 52% expired while on ventilator and 2% after successful weaning from ventilator due to other causes.¹⁰

RDS, MAS and apnea were common indications for mechanical ventilation in our study. Similar results were seen in the studies conducted in Nepal (indications - birth asphyxia, sepsis and MAS),¹³ and in Karnataka (indications- birth asphyxia, RDS, sepsis).¹⁴

On comparing complications in survival and non-survival group, p value was statistically significant with complications such as circulatory disturbances, pneumothorax and pulmonary haemorrhage, for contributing to adverse outcome. A study conducted in Puducherry reported similar mortality pattern in relation to complications. They found that, the highest mortality was seen with pneumothorax and pulmonary haemorrhage in 100% and 94% respectively followed by 83.4% in DIC, 65.6% in pneumonia / sepsis and 43% in shock.¹⁵

On multiple regression analysis, risk factors like very low birth weight, higher initial FiO₂ and complications such as pneumothorax, pulmonary haemorrhage and circulatory disturbances were found to be significant independent predictors of fatality in the mechanically ventilated neonates. A study conducted in Kerala also reported pulmonary haemorrhage and DIC as the independent risk factors for the fatality.¹⁶

From the present study, risk factors mentioned below were identified as predictors of adverse outcome in the mechanically ventilated neonates, whose knowledge can help deduce prognosis at the outset, or help strengthen efforts by earmarking high-risk cases. The major risk factors and significant predictors for high mortality that we noted were VLBW and pre-terms less than 32 weeks. Complications like pneumothorax and pulmonary haemorrhages were the major significant predictors of deaths in the mechanically ventilated neonates.

Although our study has tried to look into various factors which required ventilation among neonates, and significant factors which predicted mortality in ventilated NICU babies, there are various limitations in our research. Some of the limitations of our study include a small sample size, limited to a single centre, which caters to a major population of referrals for tertiary care. Hence the extrapolation of data has been difficult and our findings may not be generalised to the entire population. However, we recommend further more comprehensive, multi-centric study in the future to divulge further into the subject.

CONCLUSIONS

The commonest indications for mechanical ventilation in neonates were RDS followed by MAS and apnea in our study. The mortality was significantly high amongst VLBW neonates and preterm neonates with ≤ 32 weeks. Co-morbidities like circulatory disturbance, and ventilator associated complications like pneumothorax and

pulmonary haemorrhage contributed to the adverse outcome.

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