Abstract

Objective: To investigate a possible association between the intensity of staff workload and intermediate adverse events, such as accidental extubation, obstruction of the endotracheal tube, and accidental disconnection of the ventilator circuit, during neonatal mechanical ventilation in high-risk neonatal units.

Method: This prospective cohort study analyzed data of 543 newborns from public neonatal intensive care units (NICUs) in the city of São Luís, state of Maranhão, Northeastern Brazil, for 6 months, during which 136 newborns were submitted to mechanical ventilation in 1,108 shifts and were observed a total of 4,554 times.

Results: Adverse events occurred 117 times during this period. The associations between workload and adverse events were analyzed by means of generalized estimating equations. The adjustment variables were: birth weight, gender, maternity unit, Clinical Risk Index for Babies score, and care demand, the latter measured by the Northern Neonatal Network Scale. The larger the number of newborns classified by care demand (NCCD) per nurse and nursing technician, the more likely the occurrence of intermediate adverse events linked to mechanical ventilation. A number of NCCD > 22 per nurse (relative risk [RR] = 2.86) and > 4.8 per auxiliary nurse (RR = 3.41) was associated with a higher prevalence of intermediate adverse events.

Conclusions: The workload of NICU professionals seems to interfere with the intermediate results of neonatal care and thus should be taken into consideration when evaluating NICU outcomes.


Introduction

Since the 1980s, several studies have investigated the relationship between excessive workload and the occurrence of adverse neonatal outcomes.\textsuperscript{1-5} Most of these studies have investigated the association between workload in neonatal intensive care units (NICUs) and the occurrence of adverse clinical events, e. g. sepsis, neurological sequelae, and death.\textsuperscript{6-11}

However, when technologies like mechanical ventilation are used, the occurrence of intermediate adverse events (IAEs), such as accidental extubation, obstruction of the endotracheal tube, and accidental disconnection of the ventilator circuit, can play an important role in triggering the chain of events.

In research conducted in a pediatric intensive care unit in a university-affiliated children's hospital, Marcin et al.\textsuperscript{12} observed that a nurse-to-patient ratio of 1:2 relative to a nurse-to-patient ratio of 1:1 increased 4.24 times the odds of an accidental extubation. Veldman et al.\textsuperscript{13} found
an average of 3.85 newborns per nurse during shifts when IAEs occurred (range: 1.8-5.0 patients per nurse). This workload was higher than the average of 3 newborns per nurse (range: 1.6-6.0 newborns per nurse) observed during the study period. In a prospective cohort study, Carvalho et al. demonstrated that the higher the number of patient-days ventilated, the higher the risk of accidental extubation, and that it was probably determined by the greater need of nursing care, which exceeds the service capacity.

In this study, the main objective was to examine the hypothesis of a possible association between staff workload intensity and the occurrence of three IAEs during mechanical ventilation, taken as a set, in NICUs in the city of São Luís, state of Maranhão, Brazil. Recently, the Brazilian government has made efforts to reduce neonatal mortality, the main component of infant mortality in our country. Studies like this can give an important contribution to achieving this goal.

Methods

Population

This prospective cohort study was conducted in two public neonatal units in the city of São Luís, state of Maranhão, Brazil. All newborns admitted to both units between August 1999 and February 2000, of all gestational ages and birth weights, who received conventional mechanical ventilation were included in the study. Patients who were hospitalized for less than 6 hours and those who were readmitted to hospital were excluded. All newborns were orally intubated.

Units

Two intensive care units were studied: the Hospital Universitário Materno Infantil (HUMI) and the Maternidade Estadual Marly Sarney (MEMS). In 2000, the HUMI NICU had 12 intensive care beds and an average of 14.5±5.08 patients/day, with a mean bed occupancy rate of 120.8%. The number of admissions ranged from 600 to 700 a year. In 2000, the MEMS NICU admitted between 40 and 45 newborns (6.6 to 7.5% of deliveries) a month and almost 500 newborns a year. Fifteen beds were available, and the average patient/day number was 12.95±4.08, reaching a maximum of 19 on busy occasions. The mean bed occupancy rate was 99.7%. The mortality rate was 10.8% in the HUMI NICU and 14.4% in the MEMS NICU.

Characteristics of the professionals working in the NICUs

The auxiliary nurse category consisted of individuals with a secondary-level qualification (i.e., without a university degree), who were responsible for the practical work of nursing, such as venipuncture, patient hygiene, administration of drugs, control of infusion devices, and checking of vital signs. Nurses had a degree-level qualification, and their work essentially involved supervising auxiliary nurses and managing the NICU infrastructure. They were called by auxiliary nurses whenever necessary. In addition, nurses checked the timetables for medications and prescribed procedures, made contact with relatives and medical specialists, and checked materials and equipment. Not all nurses were specialists in neonatology. Physicians only had clinical duties, and all were neonatology specialists. Only one of the two units had medical trainees, who were present on a limited number of shifts.

Sample size

A sample size of 122 individuals would be required to estimate a relative risk of 2, with 95% confidence and 80% power, assuming that the study showed a within-subject correlation of 0.5 and that each individual was observed on six occasions. A total of 136 newborns were studied over a 6-month period.

Variables and data collection

The main characteristics of the studied children were: birth weight, defined as the weight of the newborn at the moment of birth and measured in grams; gestational age, calculated from the first day of the last normal menstrual period as reported by the mother and measured in weeks and days; Apgar score at the 1st and 5th minutes; and length of stay, measured in days.

The following events were considered adverse events during mechanical ventilation: accidental extubation, obstruction of the endotracheal tube, and accidental disconnection of the ventilator circuit. Accidental extubation was noted when the endotracheal tube was out of the trachea; the endotracheal tube was considered to be obstructed when the physician was obliged to replace a blocked endotracheal tube with a new one; and accidental disconnection of the ventilator circuit consisted of disconnection of any part of the ventilation circuit, except the orotracheal tube. These three variables were chosen based on studies that showed they were the most frequent adverse events during mechanical ventilation in a public Brazilian NICU.

The three events associated with mechanical ventilation were analyzed as a set because of their low frequency. Occurrences of these events were registered after being confirmed by a diagnosis given by a physician or nurse. These data were obtained daily from the auxiliary nurses in interviews that took place on three occasions: in the morning, at the end of the night shift; at the end of the morning shift; and at night, at the end of the afternoon shift. Trained medical students conducted the interviews, supervised by the research coordinator. Data from each patient were registered on individual worksheets.
Workload indicators were determined by dividing the number of newborns present during each shift (classified by care demand) by the number of professionals in each category. The adjustment for care demand was based on the Northern Neonatal Network (NNN) Scale, developed and validated by the NNN in 1993,18 which classifies newborns into two categories: the high-care-demand category (category A) and the low-care-demand category (category B). All newborns receiving ventilatory assistance (including nasal prong) and those receiving 40% or more oxygen were classified into category A. The newborns in group A required twice as much care time as those in group B. Thus, the number of newborns classified by care demand (NCCDs) was calculated by adding the number of group B babies to the number of group A babies multiplied by two.18

The chief nurse collected data classifying the newborns according to the NNN Scale at the beginning of each shift. At the end of the shift, the same nurse also noted the number of professionals present on each shift. These two procedures were carried out every 12 hours. The following workload indicators were determined when the number of professionals and the number of NCCDs in each shift had been obtained: number of NCCDs/number of auxiliary nurses on duty; number of NCCDs/number of nurses on duty; number of NCCDs/number of physicians on duty; number of NCCDs per shift.

Statistical methods

Student’s t test was used for comparison between hospitals characteristics in case variables were normally distributed. Otherwise they were compared by the Mann-Whitney non-parametric test. Generalized estimating equations (GEEs) were chosen to analyze the association between workload and adverse events during mechanical ventilation.19,22 GEEs are used to analyze longitudinal or naturally grouped data in such a way that observations of a given subject form a cluster and are correlated, but those that belong to different individuals are considered to be independent. In this study, the observations were conducted in the same cluster in different shifts. Thus, the unit of analysis was not different individuals at a single time but several individuals at different times, here represented by each shift. The fact that multiple observations were made for each individual increases the ability of the study to identify statistically significant differences. In this model, the incidence rate ratio and its respective 95% confidence interval were calculated.

The following four variables were used to adjust for confounding: gender, Clinical Risk Index for Babies score,21 birth weight, and the maternity unit under study.

Because the variables related to workload were not normally distributed, all the variables were divided into quartiles. The same procedure was adopted for the variable birth weight. The significance level used in this study was 5% (p < 0.05). Each workload was assessed under a different model because of the high colinearity between them. P-value for trend was calculated by the chi-square test for trend.

This study was approved by the Ethics Committee on Research of the HUMI, Universidade Federal do Maranhão.

Results

Birth weights, gestational ages, and Apgar scores at 5 minutes were similar for the populations in both NICUs. There was no significant difference in gender distribution between maternity hospitals. However, the 1st-minute Apgar score and length of hospitalization were significantly different (Table 1).

A total of 543 newborns were studied over a 6-month period; 136 of them were submitted to mechanical ventilation during a total of 1,108 shifts, with 4,554 observations. Adverse events related to mechanical ventilation occurred 117 times during this period. The numbers of disconnections of the ventilator circuit, accidental extubations, and obstructions of the endotracheal tube, expressed as percentages of the total number of patients studied, were 9.98, 5.37, and 4.61%, respectively. The staff on each shift consisted, on average, of 5.28 auxiliary nurses, 1.45 nurses, and 3.54 physicians.

The adjusted analysis showed an association between the number of NCCDs per nurse or auxiliary nurse and adverse events: the greater the ratio of the number of NCCDs to the number of nurses or auxiliary nurses, the greater the risk of adverse events occurring (p-values for trend < 0.05). The number of NCCDs per physician was not associated with adverse events during mechanical ventilation. However, the total number of NCCDs was strongly linked to adverse events during neonatal ventilation. The larger this number, the greater the risk of adverse events occurring (p-value for trend = 0.002) (Table 2).

Discussion

The hypothesis of an association between excessive workload and adverse events in neonatal mechanical ventilation was confirmed in this study for most of the workload indicators. These results confirm the findings of several studies suggesting that excessive workload is a risk factor for undesirable outcomes in NICUs and adult intensive care units.4-6,22 In developing countries, many undesirable outcomes are preceded by unplanned adverse events, such as accidental extubation, obstruction of the endotracheal tube, and accidental disconnection of the ventilator circuit. The rate of these adverse events has been used as an indicator of the quality of care.17
### Table 1 - Comparison between the main characteristics of the samples from the two neonatal intensive care units, São Luís, MA, Brazil, 2000

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HUMI Mean ± SD</th>
<th>MEMS Mean ± SD</th>
<th>p</th>
<th>Total Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>335</td>
<td>208</td>
<td>543</td>
<td></td>
</tr>
<tr>
<td>Weight (g)</td>
<td>2,196±813</td>
<td>2,112±932</td>
<td>0.26*</td>
<td>2,163±861</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>35±4 and 6/7</td>
<td>34 and 4/7±5</td>
<td>0.29†</td>
<td>34 and 6/7±5</td>
</tr>
<tr>
<td>1st-minute Apgar score</td>
<td>5.78±2.63</td>
<td>5.12±2.76</td>
<td>0.01*</td>
<td>5.52±2.69</td>
</tr>
<tr>
<td>5th-minute Apgar score</td>
<td>7.49±1.76</td>
<td>7.45±1.77</td>
<td>0.83*</td>
<td>7.48±1.77</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>19.11±16.79</td>
<td>27.53±21.91</td>
<td>&lt; 0.05*</td>
<td>23.09±19.35</td>
</tr>
</tbody>
</table>

HUMI = Hospital Universitário Materno Infantil; MEMS = Maternidade Estadual Marly Sarney; SD = standard deviation.

* Student's t test.
† Mann-Whitney's test.

### Table 2 - Non-adjusted and adjusted analyses of the associations between workload indicators and adverse events in newborns submitted to mechanical ventilation

<table>
<thead>
<tr>
<th>Non-adjusted analysis</th>
<th>Adjusted analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IRR*</td>
</tr>
<tr>
<td>Number of NCCDs per physician</td>
<td></td>
</tr>
<tr>
<td>2.7-6</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 6-10.5</td>
<td>0.93</td>
</tr>
<tr>
<td>&gt; 10.5-19</td>
<td>1.08</td>
</tr>
<tr>
<td>&gt; 19-32</td>
<td>1.34</td>
</tr>
<tr>
<td>Number of NCCDs per nurse</td>
<td></td>
</tr>
<tr>
<td>5.6-11</td>
<td>3.44</td>
</tr>
<tr>
<td>&gt; 11-13.5</td>
<td>2.27</td>
</tr>
<tr>
<td>&gt; 13.5-22</td>
<td>2.36</td>
</tr>
<tr>
<td>Number of NCCDs per auxiliary nurse</td>
<td></td>
</tr>
<tr>
<td>2-3.8</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 3.8-4.2</td>
<td>2.31</td>
</tr>
<tr>
<td>&gt; 4.2-4.8</td>
<td>1.38</td>
</tr>
<tr>
<td>&gt; 4.8-8.5</td>
<td>3.19</td>
</tr>
<tr>
<td>Number of NCCDs</td>
<td></td>
</tr>
<tr>
<td>12-20</td>
<td>1</td>
</tr>
<tr>
<td>21-22</td>
<td>1.22</td>
</tr>
<tr>
<td>23-24</td>
<td>1.92</td>
</tr>
<tr>
<td>25-34</td>
<td>2.57</td>
</tr>
</tbody>
</table>

95%CI = 95% confidence interval; IRR = incidence rate ratio; NCCDs = newborns classified by care demand.

* IRR estimated by generalized estimating equation adjusted for birth weight (quartiles), Clinical Risk Index for Babies score, gender, and maternity hospital in separate models for each workload indicator.
† p for trend estimated by the chi-square test for trend.
As expected, the association between the higher ratio of the number of NCCDs to the number of auxiliary nurses and a higher risk of adverse events was confirmed in this study. This association is plausible, since it is to be expected that the greater the number of patients under observation, the worse the quality of care. Possibly one of the greatest differences between developed and developing countries is the average number of newborns per nurse or auxiliary nurse. In Brazil, some units reach average ratios as high as 2.86 patients per auxiliary nurse, while developed countries like the United Kingdom usually show average ratios of 0.84 whole time equivalent (WTE) nurses per patient (1.19 patients per WTE nurse) and 0.84–1.0 nurses per patient (1.0–1.19 patient per nurse). Marcin et al. observed that a nurse-to-patient ratio as high as 1:2 increased the risk of accidental extubation. Veldman et al. found that the average of the number of newborns per nurse during shifts when IAEs occurred was higher than the average during the study period. Finally, Carvalho et al. hypothesized that the risk of IAEs was probably determined by the greater need of nursing care.

A number of authors, such as Hamilton et al., have demonstrated associations between high staff workloads and high neonatal mortality in NICUs in the United Kingdom. Their results showed that, among 173 very low birth weight newborns, the risk of survival was reduced by 64% for each extra child attended per nurse on duty. In our study, the risk of adverse events associated with mechanical ventilation occurring doubled when the average number of babies per nursing technician was more than 3.8 and tripled when this proportion reached 4.8 babies per technician. There was a dose-response effect, with a p-value for trend of less than 0.05. Thus, the larger the number of babies supervised per technician, the greater the probability of adverse events occurring.

A similar phenomenon became evident for the variable number of NCCDs per nurse. In this case, when the number of babies was greater than an average of 11 babies per nurse per shift, the risk of adverse events increased three and a half times. A similar dose-response effect was also observed (p-value for trend = 0.001). Tibby et al. showed the importance of having an adequate number of nursing staff available during a shift when they studied risk factors for adverse events in pediatric NICUs in London.

The number of NCCDs also showed an association with adverse events. The risk of these events increased 2.95 times when the number of babies exceeded 24 per shift. As with the other workload indicators, a dose-response relationship was also observed (p-value for trend = 0.002). Tibby et al. also found a similar association in a pediatric NICU in London. Studies by Hamilton et al., Tarnow-Mordi et al., Tucker & the UK Neonatal Staffing Study Group, and Tucker et al. appear to indicate that a greater workload is associated with an increasing occurrence of unfavorable clinical outcomes related to mechanical ventilation.

In this study, no association was found between the number of NCCDs per physician and adverse events. This probably occurred because these professionals play a less important role in the visual monitoring of patients on mechanical ventilation, since this task is not part of their job.

Some limitations of this study must be pointed out. One of them refers to the time the study was conducted. We understand that, although data were collected nearly 10 years ago, the results remain valid. The findings clarify an etiological question that probably shows little variation over time. We can also argue that, although most Brazilian neonatal units have incorporated new technologies during this period, many still face problems in staffing, which may impact on workload, especially in situations of overcrowding in the NICU. Another limitation of the work concerns the qualification/training of staff, particularly of the nursing crew. It is possible that the results would be different if there were a more elaborate training, mainly of auxiliary nurses. At that time all were classified as auxiliary nurses, not nursing technicians.

In conclusion, the presence of a sufficient number of nurses and auxiliary nurses per newborn per shift appears to be important in reducing adverse events linked to neonatal mechanical ventilation.

References

Correspondence:
Fernando Lamy Filho
Departamento de Saúde Pública
Rua Barão de Itapary, 155
CEP 65020-070 - São Luís, MA - Brazil
Tel.: +55 (98) 3301.9674, +55 (98) 3301.9680
Fax: +55 (98) 3301.9674
E-mail: lamyfilho@gmail.com