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Incidence and risk factors of accidental extubation in a neonatal intensive care unit

Fabiana L. Carvalho,[1] Maria Aparecida Mezzacappa,[2] Roseli Calil,[3] Helymar da Costa Machado[4]

Abstract

Objective: To determine the incidence and risk factors of accidental extubation (AE) in a tertiary neonatal intensive care unit.

Methods: A prospective cohort study was conducted to determine AE incidence density per 100 patient-days, during a 23-month period, in 222 newborns receiving assisted ventilation (AV). Logistic regression analysis was used to determine risk factors for AE. The presence of a cyclical pattern in extubation rates, according to the variables of interest, was investigated by Cosinor analysis.

Results: The mean AE rate was 5.34/100 patient-days ventilated. AE-associated predictive variables were: subsequent use of the oral and nasal routes during AV [relative risk (RR) = 4.73; 95% confidence interval (95%CI) 1.92-11.60], AV duration (per day, RR = 1.03; 95%CI 1.02-1.04), and number of patient-days ventilated (RR = 1.01; 95%CI 1.01-1.02). According to the adjusted multiple regression analysis, total AV time was the only independent predictor of AE in this sample (RR = 1.02; 95%CI 1.01-1.03). AV time of 10.5 days showed an accuracy of 0.79 (95%CI 0.71-0.87) for the occurrence of AE. Cosinor analysis showed significant periodicity in overall AE rate and in the number of patient-days ventilated. There was a significant correlation between the number of patient-days ventilated and AE frequency.

Conclusion: Mean AE density was 5.34/100 patient-days ventilated. AV duration was the only independent predictor of AE. The best accuracy for AE occurrence was achieved at 10.5 days of AV duration.

J Pediatr (Rio J). 2010;86(3):189-195: Mechanical ventilation, risk factors, prematurity, intubation, incidence.

Introduction

Assisted ventilation (AV) through an endotracheal tube is used in the treatment of airway obstruction or respiratory failure[1] and has contributed to the increased survival of newborns.[2] AV-related adverse effects are common, and, among them, accidental extubation (AE) has been reported as the most frequent event in adult patients.[3] In neonatal intensive care units in the United States, AE is the fourth most common adverse event.[4]

AE or unplanned extubation is defined as every unexpected or nonelective extubation[5] resulting from patient restlessness or caregiver activity during procedures at the bedside. Some characteristics should be considered

1. Mestre, Saúde da Criança e do Adolescente. Fisioterapeuta Supervisora, Curso de Especialização em Fisioterapia Neonatal, Centro de Atenção Integral à Saúde da Mulher (CAISM), UNICAMP, Campinas, SP, Brazil.
2. Doutora, Saúde da Criança e do Adolescente. Professora, Departamento de Pediatria, Faculdade de Ciências Médicas, Universidade Estadual de Campinas (FCM/UNICAMP), Campinas, SP, Brazil. Setor de Neonatologia, Centro de Atenção Integral à Saúde da Mulher (CAISM), UNICAMP, Campinas, SP, Brazil.
3. Doutora, Saúde da Criança e do Adolescente. Médica assistente, Setor de Neonatologia, Centro de Atenção Integral à Saúde da Mulher (CAISM), UNICAMP, Campinas, SP, Brazil. Departamento de Pediatria, FCM/UNICAMP, Campinas, SP, Brazil.
4. Mestre, Estatística. Estatístico, Câmara de Pesquisa, FCM/UNICAMP, Campinas, SP, Brazil.

This study was conducted in the Department of Pediatrics, School of Medicine, Universidade Estadual de Campinas (FCM/UNICAMP), Campinas, SP, Brazil, and at the Center of Integral Attention to Women's Health (CAISM), UNICAMP, Campinas, SP, Brazil.

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in the diagnosis of this event, such as: tube displacement, presence of vocalization, sudden and unexplained air escape, gastric distension, radiologic evidence of endotracheal tube malpositioning,[5] sudden cyanosis or desaturation, and absence of respiratory movements or breathing.[2]

AE may require urgent reintubation in less controlled situations, often with repeated attempts, increasing the risk of laryngeal injury, and the consequent stridor,[6] and physiologic changes such as hypoxemia and increased blood and intracranial pressure.[7] Data on the incidence of AE in neonatal intensive care units are scarce. In these units, incidence ranges from 0.72 to 4.8 AE per 100 patient-days ventilated,[2,8-11] values that are higher than those found in pediatric intensive care units (0.11-2.7/100 patient-days).[5,8,12-14]

Given the importance of this potentially preventable adverse effect, AE rate has been used as an indicator in the assessment of the quality of medical care.[15] Taking into consideration AE-associated morbidity,[2] it seems important that neonatal units establish the incidence of this adverse event and be informed about associated risk factors in order to be capable of identifying the need to implement interventions and measure their results.[10,11]

The objective of this study was to establish AE density per 100 patient-days ventilated in a neonatal intensive care unit, in addition to identifying the occurrence of periodic events and newborn-related risk factors for AE.

Patients and methods

A prospective cohort study was conducted between September 2006 and July 2008 involving newborns with tracheal intubation admitted to the neonatal intensive care unit of a tertiary teaching hospital.

All newborns receiving AV for at least 12 hours were included, regardless of the route of intubation. Exclusion criterion was death before 24 hours of life.

AE was defined as every episode of unplanned tube removal or loss during intensive care, regardless of when or how it occurred, being identified by partial or total displacement of the endotracheal tube and/or impaired breathing on chest auscultation, whether or not these findings were confirmed by laryngoscopy. Episodes requiring tube replacement due to confirmed or suspected obstruction were not included.

The researcher in charge visited the unit daily, including weekends, to verify, in person, the number of newborns on AV and the route of intubation used. All newborns were followed up until AV was discontinued. Information on the occurrence of AE was obtained from reports by the physician and nursing staff and double checked on medical records.

Nasal intubation was the routine procedure in the unit, and the oral route was an alternative to technical difficulties during nasal insertion. Tube fixation was performed by the physician in charge of the procedure, and tube position was confirmed by radiography, being considered appropriate when the tip of the tube was placed at the level of T1.[16] The staff nurses in charge performed routine tube fixation, with no predetermined periodicity, based on necessity, due to loss of fixation (adherence) and/or presence of secretion. Tube aspiration was performed by the nursing staff or physical therapists whenever necessary.

Newborns on AV received analgesia with a continuous infusion of 0.5-2.0 µg/kg/h fentanyl, and, whenever necessary, sedation with midazolam.

Since 2004, this unit has assessed monthly AE rates and, for 9 months, monitored the characteristics of AE episodes through reports by the nursing staff of circumstances involving each event. The multiprofessional team underwent training and sensitization to the topic, the medical team was warned about the correct positioning of the tube, and an intubation-related care protocol was established.

In addition to intubation route, other variables were studied: birth weight, gender, gestational age (GA), use of sedation and analgesia during AV, and total ventilation time (and AV duration for each intubation route) per entire day, considering the first and last day on AV.

GA was determined according to the methods by Capurro[17] or New Ballard[18] or based on the estimates by early echography or amenorrhea.

In addition to absolute monthly AE numbers, AE density was calculated per each 100 patient-days ventilated. This rate was obtained by dividing the absolute number of accidental extubations occurred in a month by the total number of patient-days ventilated multiplied by 100. Each day on ventilation was considered as one patient-day.[19] This study was approved by the Research Ethics Committee of the institution, and the children's parents or guardians signed a written consent inform.

Sample size (n = 222) was calculated to establish the incidence of the main infectious and mechanical complications of AV; in the present study, we decided to describe only AE. The AE rate used in sample size calculation was 2.7 AE/100 patient-days,[12] with an alpha of 0.05 and sampling error of 2.5%. Weighted sampling error was obtained for each complication so that the lower confidence limit did not restrict incidence to values 50% greater than the reference values adopted.

Variables were compared between groups with and without AE using the chi-square test and the Mann-Whitney test. Values for overall AE density and each intubation route were calculated per month. To establish the presence of periodicity in monthly AE rates, we used Cosinor analysis[20] by means of nonlinear regression and estimated the values of mesor (M), amplitude (A), acrophase (Phi), and period (Tau). Cosinor analysis[20] was also used to compare the influence of variables on temporal series of AE density. The variables analyzed were: GA, birth weight, gender, use of analgesia/sedation, intubation route, and total number of patient-days ventilated/month. Analysis of the cross-correlation function was used to establish the correlation between the number of patient-days ventilated and AE frequency per month.[21] The Kruskal-Wallis test was used to compare weight, GA and AV duration according to intubation route. The Wilcoxon test for related samples was used in the analysis of AE density according to intubation route.

Risk factors for AE were determined by univariate and multivariate (stepwise) logistic regression analysis. In the regression analysis, the number of patient-days ventilated was determined using mean values from the months in which the newborn remained on AV.

Receiver operating characteristic (ROC) curves were constructed for AV duration and overall AE occurrence and for each intubation route. The significance level was set at $p < 0.05$. The statistical software Statistical Analysis System for Windows, version 9.1.3 (SAS Institute Inc, 2002-2003, Cary, NC, USA) was used for data analysis.

Results

During the 23-month study period, 222 newborns required AV, totaling 2,563 patient-days ventilated. Fifteen subjects did not meet the inclusion criteria: AV duration was less than 12 hours (n = 1), and parents or guardians were not found to sign the written consent form (n = 14). Six newborns were excluded due to death before 24 hours of life.

Of the total study subjects, 119 were included in AE rates in more than one month, because AV duration was greater than 30 days, totaling 341 assessments. Newborns' distribution according to study year was 42 (18.9%) in 2006, 112 (50.5%) in 2007, and 68 (30.6%) in 2008. A total of 62 subjects had AE episodes (27.9%). Of these 62 subjects, 36 (58%) had a single AE episode. Recurrence of extubation occurred in 26 subjects, 13 had two episodes and the remaining 13 were extubated in three or more occasions. Seventeen subjects (27.4%) did not require reintubation within 48 hours after the AE episode.

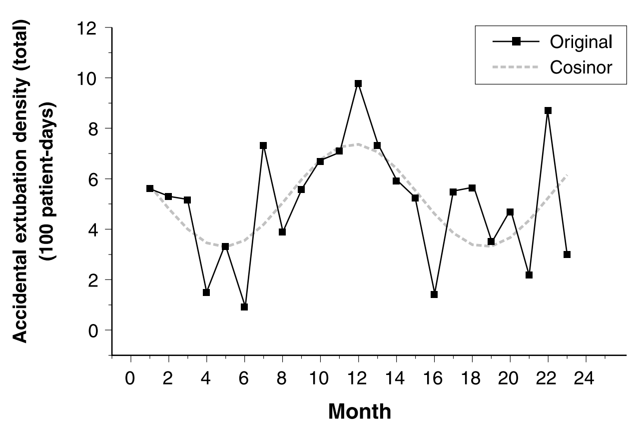
The frequency of subjects using only one intubation route, either the nasal or oral route, was: 45.4 and 21.8%; 58.7 and 23.0%; 63.8 and 27.5%, respectively for weight < 1,000 g, 1,000-2,500 g, and > 2,500 g. Forty-three subjects were intubated using both the nasal and oral routes and at any sequence.

Subjects with and without AE were significantly different in all variables, except for distribution according to gender and presence of analgesia/sedation (Table 1). Subjects using both routes showed lower birth weight ($p = 0.004$), lower GA ($p = 0.003$), and longer AV duration ($p < 0.001$) when compared to those using a single route.

Monthly AE rate ranged from 0.92 to 9.77/100 patient-days, with a mean of 5.34 (Figure 1). Mean extubation rates per year were 4.38±1.94, 5.36±2.59 and 4.73±2.16 in 2006, 2007 and 2008, respectively. AE rates according to the variables analyzed are described in Table 2.

The occurrence of significant periodicity was verified in overall AE density of the period (Figure 1) and also for oral route ($p = 0.009$), nasal route ($p = 0.031$), and both routes ($p = 0.037$). Significant periodicity was identified in AE density according to the number of patient-days ventilated ($p = 0.014$). No cyclical pattern was observed in overall AE rates when the other variables were analyzed.

There was a significant positive correlation (correlation coefficient = 0.723; $p < 0.05$) between the number of patient-days ventilated per month and absolute AE numbers. Univariate logistic regression analysis identified the following risk factors for AE: total AV time, AV duration per each intubation route, naso and orotracheal intubation routes, and number of patient-days ventilated (Table 3). Multivariate analysis showed that AV duration was the only independent predictor of AE. Every day on ventilation increased AE risk in 3% [relative risk (RR) = 1.03; 95% confidence interval (95%CI) 1.02-1.04; $p < 0.01$] in the non-adjusted model and 2% (RR = 1.02; 95%CI 1.01-1.03; $p < 0.001$) in the model adjusted for weight and GA covariables.



Cosinor for AE density: M = 5.34; A = 2.04; Phi = 7.20; Tau = 13.78. Periodicity is significant (p = 0.037). Mean density (M) = 5.34, with mean range (A) = 2.04 AE, plus or minus. Approximate total period (Tau) = 13.8 months. First peak or first valley at 7.2 months.
A = amplitude; AE = accidental extubation; M = mesor; Phi = acrophase; Tau = period.

Figure 1 - Individual values and Cosinor curve for accidental extubation density per 100 patient-days ventilated during a 23-month study period

Table 1 - Characteristics of the study sample according to the presence of accidental extubation (n = 222)

	Without AE (n = 160)	With AE (n = 62)	p
Birth weight (g)	1,881.3±947.0	1,615.3±1,007.9	0.014*
Median	1,740.0	1,082.5	
Minimum-maximum	540-4,670	545-4,500	
< 1,000	31	24	0.009†
1,000-2,500	86	23	
> 2,500	43	15	
GA (weeks)	32.8±4.3	31.2±4.6	0.011*
Median	32.5	30.0	
Minimum-maximum	25-41	24-39	
≤ 28	27	21	0.022†
29-36	90	28	
≥ 37	43	13	
Gender (male/female)‡	87/72	41/21	0.123†
AV duration (days)	6.7±6.5	25.6±25.3	< 0.001*
Median	5	16	
Minimum-maximum	1-46	1-110	
Use of analgesia/sedation§	141	54	0.833†
Intubation route			
Nasal	93	33	< 0.001†
Oral	47	6	
Nasal and oral	20	23	

AE = accidental extubation; AV = assisted ventilation; GA = gestational age.
* Mann-Whitney test.
† Chi-square test.
‡ One case with undetermined gender.
§ 27 cases did not use sedation/analgesia.
Values expressed as mean ± standard deviation and absolute numbers.

Table 2 - Mean values ± standard deviation of accidental extubation density according to neonatal variables and intubation route

	Extubation density/100 patient-days	p
Birth weight (g)		
< 1,000	5.2±3.8	0.542*
1,000-2,500	4.3±4.2	0.273*
> 2,500 (reference)	6.2±8.0	
GA (weeks)		
≤ 28	5.3±4.0	0.559*
29-36	5.5±4.4	0.476*
≥ 37 (reference)	4.3±7.1	
Gender†		
Female	4.8±3.5	0.958*
Male (reference)	4.9±3.1	
Analgesia/sedation		
Yes	4.8±2.6	0.187*
No (reference)	13.1±28.9	
Intubation route		
Orotracheal	3.9±5.2	0.053‡
Nasotracheal	5.8±2.9	

GA = gestational age.
* Cosinor analysis.
† One case with undetermined gender.
‡ Wilcoxon test for related samples.

Table 3 - Univariate logistic regression analysis for accidental extubation (n = 222)

Variable	RR	95%CI	p
Birth weight (g)		0.26-2.33	0.648
> 2,500 (reference)	1.00		
2,000-2,500	0.77		
1,501-2,000	0.34	0.10-1.18	0.089
1,001-1,500	1.07	0.53-2.20	0.845
500-1,000	1.73	0.91-3.27	0.095
GA (weeks)			
≥ 37 (reference)	1.00		
29-36	1.02	0.53-1.97	0.948
≤ 28	1.89	0.94-3.76	0.073
Gender			
Female (reference)	1.00		
Male	1.42	0.84-2.40	0.193
AV duration (per day)	1.03	1.02-1.04	< 0.001
Oral route	1.04	1.01-1.06	0.011
Nasal route	1.03	1.02-1.04	< 0.001
Analgesia/sedation		0.51-2.25	0.858
Yes (reference)	1.00		
No	1.07		
Intubation route		0.97-5.52	0.059
Oral (reference)	1.00		
Nasal	2.31		
Nasal and oral	4.73	1.92-11.60	< 0.001
Patient-days ventilated (per unit)	1.01	1.01-1.02	0.004

95%CI = 95% confidence interval; AV = assisted ventilation; GA = gestational age; RR = relative risk.

AV duration with the best accuracy for total AE occurrence and for nasal and oral routes was achieved, respectively, at 10.5 days, 7.5 days, and 5.5 days. The respective areas under the curve and 95%CI were: 0.79, 0.71-0.87, p < 0.001; 0.74, 0.62-0.87, p < 0.001; 0.69, 0.42-0.96, p = 0.12.

Discussion

In a cohort of 222 newborns, we obtained a mean AE rate of 5.34/100 patient-days ventilated in a neonatal intensive care unit of a tertiary teaching public hospital. AV duration was the independent predictor of these events, and AV time of 10.5 days showed the best accuracy for the occurrence of AE. A significant periodicity of AE incidence rate was observed. A cyclical pattern was also observed in the number of patient-days ventilated with a positive correlation between this variable and AE numbers.

AE has been the object of several studies in adult and pediatric intensive care units.[3,5,12,13,22-25] However, we identified only a few publications analyzing, in the neonatal age group, incidence and circumstances accompanying AE,[2,8-10] total AV time,[2] length of hospital stay and mortality in extubated patients,[2] association between types of fixation and AE,[10] and one intervention study to reduce AE.[11]

The extubation density obtained in this study is higher than that reported in previous studies,[2,8-11] and, in some months, unacceptably high rates were observed, revealing the need for the implementation of an effective intervention.

In 2004, an intervention program to reduce the occurrence of AE was implemented, including a written routine on intubation procedures and checking of tube position, standardization of care concerning tube fixation and aspiration, as well as the use of analgesia and sedation. In addition, a training course was offered to the multiprofessional team. After the implementation of this program, mean AE rate was 4.4 AE/100 patient-days in 2006 against 6.5 AE/100 patient-days in 2005 (data not published).

In addition to the factors analyzed to explain the high AE rate in this unit, we should also consider characteristics inherent in a teaching public hospital, which provides training to multiprofessional teams and care to high-risk newborns (3-4% of very low birth weight newborns). Furthermore, as suggested by some authors,[2] the clinical staff does not routinely perform laryngoscopy for suspected AE, which could reduce some occurrences of tube replacement associated with false extubation episodes. Other factors, previously described, such as length of hospital stay,[13,26] patient restlessness or agitation,[26] insufficient sedation and restraint,[8,22] orotracheal intubation route,[22] inaccurate tube fixation,[2,22] and AV duration,[13,25] may contribute to AE. Regarding the last aspect mentioned, this study showed that a longer AV duration was the most significant predictor alone of AE in the study sample. Every day on ventilation increased AE risk in 2-3%. Other studies have also suggested that a longer AV duration may have an effect on AE, but they have not quantified the risk.[2,9,10,13,25]

This study determined that AV time of 10.5 days has 79.6% of accuracy in identifying the occurrence of AE in this unit. This information may be very useful in reducing AE, since it indicates a suitable moment for extubation.

In pediatric units, a factor associated with AE is the child's age.[13] Based on similarity, one could assume that newborns with lower weight and GA are more likely to have AE episodes, since they have a smaller body surface area available to tube fixation and receive AV for longer periods of time. It is well known that newborns < 1,500 g and < 28 weeks are more affected by all types of adverse effects in neonatal units.[4] However, in the present study, weight and GA were different between groups with and without AE, but did not remain significant in the multiple analysis, although there is a trend toward risk ($p = 0.095$ and 0.073) for newborns less than 1,000 g and 28 weeks, respectively. On the other hand, we observed that AE rates by weight were higher among newborns > 2,500 g, indicating a possibility of inadequate sedation/analgesia or the need for a higher level of care in this group of children.

Adequate sedation has been related to a better management of AE.[3,23] In our study, AE rates were higher in newborns without sedation/analgesia, but this variable was not associated with AE, probably due to the limited number of subjects without sedation/analgesia (12.2%). However, we cannot confidently state the level of sedation/analgesia in these subjects, since this variable was not assessed.

There is no strong evidence showing that a choice of either of the intubation routes could reduce AE.[27] Similarly, this study did not identify intubation route as a risk factor for AE. We observed, however, that newborns using both routes during AV had the highest risk (4.73 times) for AE. Analyzing this group in more detail, we observed that these are the newborns with significantly lower weight and GA and longer AV duration, which justifies the risk associated with this group.

Access route as a preventive measure for AE remains an open question, which might be satisfactorily answered by multicenter clinical trials with a large number of subjects.[27]

A finding of this study, not previously mentioned, is the number of patient-days ventilated as a risk factor for AE, which might correspond to a greater need for nursing care. Once the nurse-to-patient ratio in this unit was established, about 1.5:1, a higher number of patient-days ventilated could exceed the capacity of nursing care delivery, compromising its quality. The recommended nurse-to-patient ratio in pediatric units is 1:1, and it has been observed that pediatric patients are 4.24 times more likely to experience AE when being cared in a nurse-to-patient ratio of 1:2.[28] On the other hand, it has been suggested that AE episodes occur most frequently in the care of nurses with less experience, with no significant difference in nurse-to-patient ratio.[29] Time spent at ventilated patients' bedside may also be associated with AE, since 79.1% of the episodes occurred when patients were not being closely controlled,[29] such as during meal breaks or shift changes. On the other hand, some reports state that in 75% of the events occurred with children, there was a professional at the patient's bedside.[9]

We investigated the presence of AE periodicity to confirm a clinical suspicion, but we did not find references in the literature with a similar finding. The cyclical pattern is rather a peculiarity of this unit, related directly to the periodicity of the number of patient-days ventilated, than an inherent characteristic of AE events, since the neonatal diseases most commonly associated with the need for AV are not seasonal. The assessment of AE periodicity in this unit may contribute to a more accurate identification of the time for monitoring intervention effects, which, in the case of this unit, should be of at least 13.7 months.

This study has some limitations, such as the absence of an analysis of variables that could better define the focus of intervention measures. Thus, the shift in which AE occurred,[29] as well as nurse-to-patient ratio, or even caregivers' technical education and experience in intensive care[29] are variables that could more clearly define the focus for action. Moreover, for some of the studied variables, as well as for lower weight and GA ranges and number of subjects using the oral route, sample size may yield inadequate results.

The occurrence of AE can be considered as acceptable, since the attempt to keep AE rates close to zero may increase the use of sedation and prolong AV duration, in addition to causing stronger fixation of the tracheal tube, with a risk of soft tissue necrosis.[2] Nevertheless, the results of the present study suggest that there is a need to adopt measures intended to reduce the incidence of AE focusing on a more appropriate nurse-to-patient ratio, in addition to offering continual education programs to the multiprofessional team. Likewise, early extubation intended to reduce AV duration should be another strategy to reduce AE, as well as the use of noninvasive ventilation techniques, which seems to be a promising alternative in the attempt to minimize adverse effects related to traditional ventilation approaches.[30]

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Correspondence:
Fabiana L. Carvalho
Rua Salvador Penteado, 105/62 - Bonfim
CEP 13070-270 - Campinas, SP - Brazil
Tel.: +55 (19) 3243.3805, +55 (19) 9118.0629
E-mail: flcquintana@ig.com.br