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Research paper

Implementation of a nurse-driven ventilation weaning protocol in critically ill children: Can it improve patient outcome?

Anita Duyndam, MSc^{a,*}Robert Jan Houmes, MD PhD^aJoost van Rosmalen, PhD^bDick Tibboel, MD PhD^aMonique van Dijk, PhD^aErwin Ista, RN PhD^a^a Intensive Care, Erasmus MC – Sophia Children's Hospital Rotterdam, the Netherlands^b Department of Biostatistics, Erasmus MC, Rotterdam, the Netherlands

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ABSTRACT

Background: Critically ill children treated with invasive mechanical ventilation in a paediatric intensive care unit (PICU) may suffer from complications leading to prolonged duration of ventilation and PICU stay.

Objective: The objective of this study is to find out if the use of a nurse-driven ventilation weaning protocol in a PICU can shorten the duration of mechanical ventilation.

Methods: In a prospective, pretest–posttest implementation study, we implemented a nurse-driven ventilation weaning protocol and compared its outcomes with those of the usual physician-driven weaning. In the posttest period, nurses weaned the patients until extubation as per this protocol. The primary outcome was duration of ventilation. The secondary outcomes were length of PICU stay, reintubation rate, and compliance with the protocol (measured by use of the prescribed support mode).

Results: In total, 424 patients aged from 0 to 18 years (212 pretest and 212 posttest) were included; in both groups, the median age was 3 months. The median duration of ventilation did not differ significantly between the pretest and posttest periods: 42.5 h. (interquartile range, IQR 14.3–121.3) vs. 44.5 h (IQR 12.3–107.0), respectively; $p = 0.589$. In the posttest period, the PICU stay was nonsignificantly shorter: 5.5 days (IQR 2–11) vs. 7 days (IQR 3–14) in the pretest period; $p = 0.432$. Compliance with the prescribed support mode was significantly higher in the posttest period: 69.9% vs. 55.7% in the pretest period; $p = 0.005$. The reintubation rate was not significantly different between the pretest and posttest periods (5% vs. 7%, respectively; $p = 0.418$). The extubation rate during nights was higher in the posttest period but not significantly different ($p = 0.097$).

Conclusions: Implementation of a nurse-driven weaning protocol did not result in a significantly shorter duration of invasive mechanical ventilation but was safe and successful. The reintubation rate did not significantly increase compared with usual care.

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1. Introduction

Critically ill children treated with invasive mechanical ventilation (iMV) in a paediatric intensive care unit (PICU) may suffer from complications such as atelectasis and ventilator-associated pneumonia and complications related to the administration of sedation.^{1–3} These complications may prolong the durations of iMV (DOV) and PICU stay, which in turn could lead to a cascade of

* Corresponding author at: Erasmus MC – Sophia Children's Hospital, Intensive Care Unit, P.O. Box 2060, 3000, CB, Rotterdam, the Netherlands. Tel.: +31 6 27126428.

E-mail address: a.duyndam@erasmusmc.nl (A. Duyndam).

extensive complications, especially if more sedation is needed, such as ventilator-induced diaphragmatic dysfunction and delirium.^{2,4–6} They may also have a negative psychological impact on both the child and parents.⁷ Nevertheless, premature extubation should be prevented, as it may necessitate reintubation, with increased risk of morbidity and mortality.⁸ There needs to be a balance between ensuring that iMV is not unnecessarily prolonged and also ensuring that children are not extubated before they are ready.⁹ Failure to wean is associated with haemodynamic dysfunction, neuromuscular insufficiency, malnutrition, metabolic disorders, and diaphragmatic muscle weakness.^{5,9}

A recent updated systematic review of 17 randomised control trials (RCTs) involving 2434 critically ill adult patients compared protocolised vs. nonprotocolised weaning. Protocolised weaning was associated with a mean 26% reduction of DOV in comparison with nonprotocolised weaning.¹⁰ In four studies, the weaning protocol was computer led. In the other 11 studies, it was professional led, mostly by registered nurses or respiration therapists. Considerable heterogeneity among studies was found, however, concerning the type of protocol and the achieved DOV, which limits generalisation of this finding.¹⁰ In a systematic review ($n = 3$ studies) in paediatrics,^{11–14} one RCT found that protocolised weaning reduced DOV by 32 h¹²; the other two studies did not show a significant effect on DOV.^{13,14}

Effective weaning of ventilation in critically ill children requires effective collaboration between physicians and nurses. From two previous studies, we know that key decisions concerning ventilation were mainly made collaboratively but that nurses were not always able to adjust ventilator settings independently, although they had the autonomy to do so.^{15,16} Reasons brought forward included not being allocated to a 'weanable' patient, high workload, perceived lack of support from medical staff, and lack of standardised competency programs and nurse-driven weaning protocol. Results of a survey among PICU nurses in 19 European countries showed variability in perceived nursing autonomy and involvement in weaning.¹⁷ The researchers speculated that the variability could be ascribed to differences in the level of general nursing education and provision of specialist intensive care unit (ICU) nursing education.

PICU nurses take care of ventilated patients night and day. Therefore, they are in an ideal position to determine if a patient is ready for weaning of iMV. The weaning protocols described by Blackwood et al¹⁰ were executed mainly by nurses and respiration therapists, probably because physicians are responsible for more patients, especially during evenings and nights. Our hypothesis was that the well-trained nurses in our PICU, in which the nurse-to-patient ratio is 1:1 or 1:2, should be able to reduce the weaning time and length of iMV with the use of a well-thought-out protocol. Before developing the new protocol, we sought the views of nursing and medical staff and took these into account as much as possible.^{18,19} Most of them, especially nurses, were excited to participate.

The primary objective of the study was to investigate if implementation of a nurse-driven ventilation weaning protocol could lead to a shorter DOV and shorter length of PICU stay.

2. Materials and methods

2.1. Study design

We conducted a prospective, pretest–posttest study. Results of this study are reported using the Standards for Quality Improvement Reporting Excellence guideline.²⁰

2.2. Context

The study involved mechanically ventilated patients in a 28-bed ICU of a tertiary referral academic children's hospital in the Netherlands. This PICU had about 2200 admissions per year, including 700 ventilated patients. The nurse-to-patient ratio was 1:1 or 1:2 during both periods.

In accordance with the ventilation policy, all patients requiring iMV were ventilated with the Servo-i ventilator of Maquet (Solna, Sweden).²¹ Patients with lung disease, such as acute respiratory distress syndrome, pneumonia, or bronchiolitis, were ventilated with pressure control (PC). Patients with other conditions, such as epilepsy, postoperative care, or traumatic brain injury, were ventilated with the pressure-regulated volume control mode (PRVC).

2.3. Intervention

In the pretest period (December 2013 to September 2014), iMV was weaned off as usual at the time. This implies that a physician assessed a stable patient's iMV and instructed nurses to gradually wean off pressure, tidal volume, and positive end-expiratory pressure (PEEP) and change to a support mode. This assessment was made maximally three times daily. Nurses only weaned off oxygen on their own initiative and sometimes changed iMV to a support mode.

A nurse-driven weaning protocol then was implemented over the course of 3 months (September 2014 up to November 2014). In the posttest period (December 2014 until September 2015), nurses used the weaning protocol. Children up to the age of 18 years receiving iMV were eligible for inclusion in both periods. The exclusion criteria were as follows: airway obstruction, for example, epiglottitis, laryngitis, and paralysis of the vocal cord; receiving home ventilation for neuromuscular diseases or obstructive/central apnoeas; receiving chronic ventilation for longer than 1 month; traumatic brain injury established with intracranial pressure measurement; Glasgow Coma Scale score < 8; unable to swallow or cough; excessive work of breathing and too little physical growth (e.g. cardiac patients); and anticipated death during the study period. In both periods, distress and postoperative pain were treated as per our sedation and postoperative pain algorithms.²² Nurses are allowed to increase or decrease sedation and analgesic medication themselves, using these algorithms that are based on the COMFORT behaviour scores.²² An explicit cut-off level of depth of sedation where extubation is considered has not been set, but sedatives are tapered off or stopped during weaning of ventilation and before extubation, depending on the duration of sedation and the administration of opioids. In case of long-term sedation, intravenous sedatives and opioids are switched to an oral tapering off schedule with lorazepam, methadone, or clonidine.

2.3.1. Development and use of iMV weaning protocol

The nurse-led iMV weaning protocol was developed by five PICU nurses who had been trained as ventilation practitioners and a paediatric intensive care physician. The protocol includes a two-step algorithm: first, weaning off oxygen and PEEP and second, choosing a support mode (volume support in case of PRVC and pressure support in case of PC) and gradually weaning off pressure or volume (Fig. 1). The protocol did not include a spontaneous breathing trial (SBT) or extubation readiness test (ERT) because we could not find a validated method for children in literature. Therefore, we used extubation criteria derived from the paediatric literature and our clinical experience from a former project

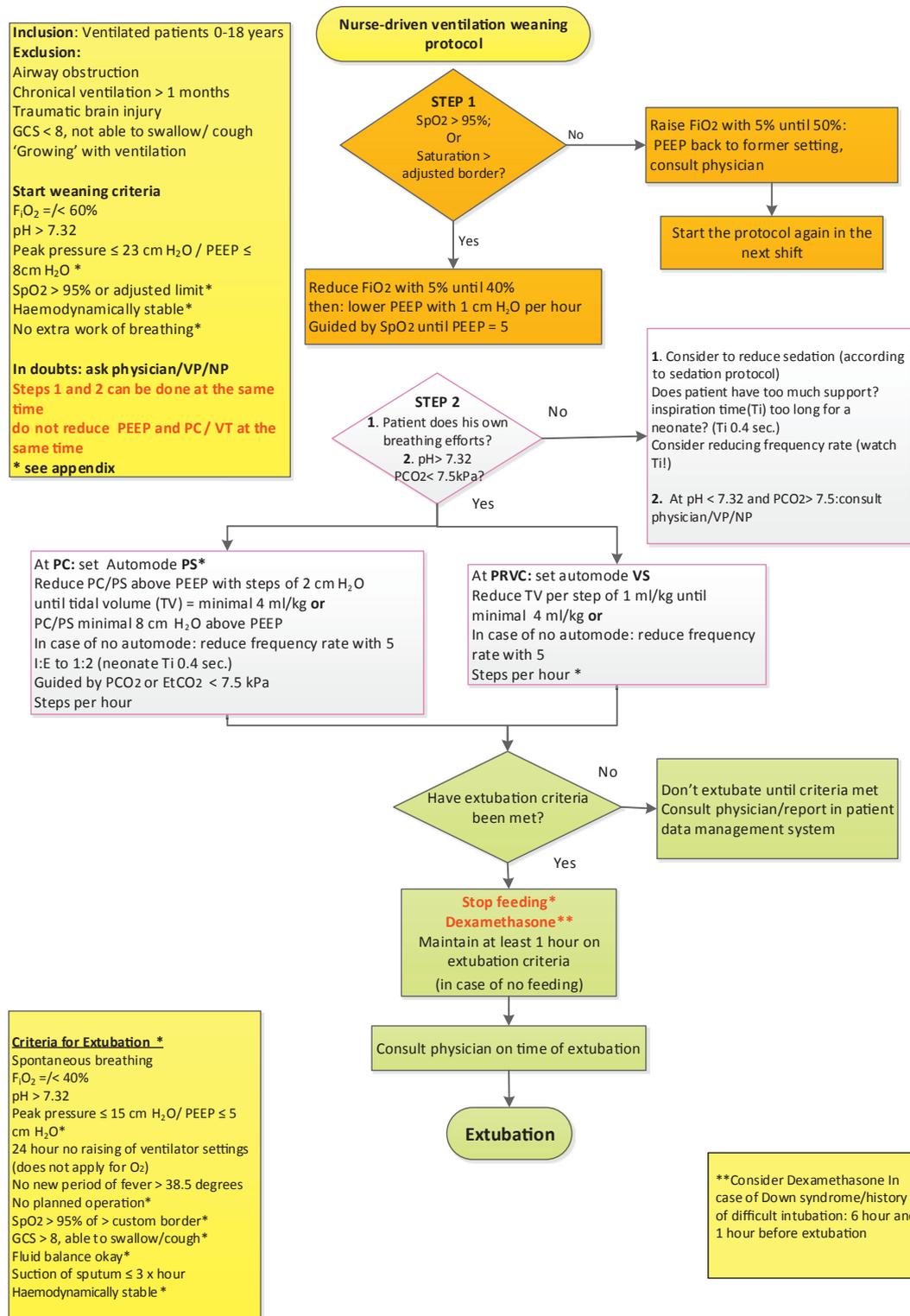


Fig. 1. Nurse-driven weaning protocol.* Start weaning: (1) at PC: peak pressure ≤ 23 cm H₂O/PEEP ≤ 8 cm H₂O (=15 cm H₂O above PEEP 8); (2) at PRVC: peak pressure is not higher than 23 cm H₂O with a set PEEP of 8 cm H₂O; (3) $SpO_2 \geq 95\%$ or in neonates: $\geq 92\%$ or adjusted limit: (a) cyanotic heart defect (>75%); (b) prematurely born with chronic lung disease (CLD) at $F_iO_2 \leq 40\%$ (88–96%); (4) haemodynamically stable without or with a low dose inotropics: dopamine ≤ 5 mcg/kg/min.; dobutamine ≤ 5 mcg/kg/min.; milrinone ≤ 0.5 mcg/kg/min; (5) no extra work of breathing: frequency < maximum frequency per age. * Extubation criteria: (1) at PC: peak pressure ≤ 15 cm H₂O/PEEP ≤ 5 cm H₂O (=10 cm H₂O above PEEP 5); (2) at PRVC: peak pressure is not higher than 15 cm H₂O with a set PEEP of 5 cm H₂O; (3) no planned operation within 12 h with need of ventilation or high sedation level; (4) $SpO_2 \geq 95\%$ or in neonates $\geq 92\%$ or adjusted limit: (a) cyanotic heart defect (>75%); (b) prematurely born with chronic lung disease (CLD) at $F_iO_2 \leq 40\%$ (88–96%); (5) Glasgow coma scale (GCS) > 8 with no or low dose sedation and capable to swallow and cough; (6) good fluid balance and no clinical signs of oedema; (7) haemodynamically stable without or with low dose inotropics; (8) in case of not severely ill neonates, strive for a short inspiration time (0.4 s) for own breathing drive. Automode: (1) in neonates, inspiration cycle off (ICO) 5–10% and trigger time out (TTO) 3–5 s; (2) in older children: ICO 30% and TTO 5–7 s; (3) stop feeding: 2 h before extubation at duodenal feeding and 4 h at gastric feeding. In case of no feeding, maintain low-ventilation settings for at least 1 h. Consult physician or ventilation practitioner or nurse practitioner in case of doubt

(unpublished).^{12,23–26} Extubation readiness was determined by these criteria. Nurses were empowered to make the ventilation decision steps without direct supervision of a physician, but approval from a paediatric intensive care physician was needed for the actual extubation. In usual care, the physician initiated the weaning but did not perform protocolised steps in stable patients.

2.3.2. Implementation

The implementation of the nurse-driven weaning protocol was based on the seven-step Implementation Model of Change of Grol et al.²⁷ At the end of the pretest period, we identified potential factors influencing its implementation (Table 1). We developed the implementation strategy, taking into account the barriers and facilitators identified.^{19,28} A full outline of the implementation is described in Supplement 1.

2.4. Study outcomes

The primary outcome was DOV, defined as the time elapsed from either intubation on the PICU or admission on the PICU with iMV (controlled and support modes) in place until the time of extubation.

The secondary outcomes were length of PICU stay (LOS-PICU), reintubation rate, and time of extubation (daytime, evening, or night). Further, the following implementation outcomes were determined: time elapsed between meeting the extubation criteria and the actual extubation during the posttest and protocol compliance. Successful implementation was defined as a compliance rate exceeding 80%.

2.5. Data collection

Five ventilation practitioners were available to screen patients for eligibility on a daily basis.

For both the pretest and the posttest, we collected the following parameters prospectively: patient characteristics, reason for admission, Pediatric Risk of Mortality Score III, DOV, and LOS-PICU. Ventilation characteristics were collected 1 h before extubation, including ventilation mode, PEEP, PC level above PEEP, tidal volume, FiO₂, dosage of continuous sedatives and opiates, COMFORT

behaviour scale scores, failure of extubation, and clinical signs of fluid overload. Failure of extubation was defined as reintubation within 48 h after extubation. Furthermore, times of intubation and extubation were collected (during daytime, evening, or night shift). Adverse events were defined as reintubation rate and need for noninvasive ventilation.

For the posttest alone, we collected the times of extubation readiness and reasons for delay of extubation after reaching the extubation criteria

The following subgroups were distinguished: those ventilated shorter and those ventilated longer than 48 h and patients belonging to the following admission groups: respiratory failure, postsurgical, and postsurgical cardiac patients. We hypothesised that for these groups the impact of the nurse-driven protocol would differ the most.

Furthermore, for both periods, we looked at the difference in outcome (DOV, LOS, reintubation, and need for noninvasive ventilation) between patients who were extubated from a controlled versus a support mode.

2.6. Analysis

On the basis of a median DOV of 4 days in 2012, the inclusion of at least 170 patients per period would give the study a power of 80% in detecting a decrease in DOV by 1.5 days with a significance level of 0.05.

2.7. Statistical methods

For children who were ventilated more than once during the current admission, only the first occasion was included for analysis. Data are presented as percentages, mean (standard deviation) for normally distributed data, and as median interquartile range (IQR) for non-normally distributed continuous data. Outcomes were compared between the pretest and posttest periods. Groups were compared using chi-square tests for categorical variables or the Fisher exact test to compare two groups on a dichotomous outcome with small sample sizes. Furthermore, the independent samples t-test (normally distributed data) or Mann–Whitney U test (non-normally distributed data) were applied for continuous variables

Table 1
Potential factors influencing implementation of a weaning protocol.

| Level | Barriers | Facilitators | Implementation strategy |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organisational level | <ul style="list-style-type: none"> - A large unit in which many people have to be educated. - Policy is that patients mainly are extubated after ward rounds in the morning/early afternoon. - Some patients will not be extubated during the night because more controlled situation with more physicians present is needed. | <ul style="list-style-type: none"> - Availability of ventilation practitioners who can have a stimulating role. - Good nursing leadership - Interdisciplinary collaboration and effective communication. | <ul style="list-style-type: none"> - Education to nurses. (45 min sessions) - Bedside training of nurses. - Medical staff meeting. |
| Professional level | <ul style="list-style-type: none"> - Nurses are not always familiar with the medical policy, the last X-ray, or the medical intention to reduce ventilator settings. - Resistance of doctors with nurses' autonomy or nurses' resistance with changes. - Nurses are concerned they do not get enough support from physicians. | <ul style="list-style-type: none"> - If physicians do not want to extubate during the night, the nurses will stop feeding anyway, as per the protocol. Extubation will then take place earlier than rounds. - Nurses wishing to have more influence on weaning. | <ul style="list-style-type: none"> - Medical staff meeting. - Ventilation practitioners supporting the nurses and providing bedside training. |
| Protocol intervention level | <ul style="list-style-type: none"> - Interpreting the algorithm takes time, and the layout of the protocol may be not attractive to use. - The moment when to apply the protocol is not clear, and patient categories are not well defined. | <ul style="list-style-type: none"> - Use of the PDMS. - Nurses eager to be taught about ventilation and the algorithm. | <ul style="list-style-type: none"> - Protocol developed by a physician and five ventilation practitioners - Educational sessions - Reminders: pocket manual, checklist in PDMS, laminated protocols on the ward - Bedside training/support by the ventilation practitioners |

PDMS, patient data management system; min, minutes.

(e.g. DOV, LOS, age). A p-value of 0.05 (two-sided) was considered statistically significant. Data were analysed using IBM SPSS Statistics for Windows®, version 21.0 (Armonk, NY: IBM Corp).

2.8. Ethical considerations

The Medical Ethics Review Board approved the study and, owing to its noninvasive nature, waived the need for informed parental consent. In this medical research, the participants were neither subjected to procedures nor required to follow rules of behaviour.

3. Results

3.1. Patient characteristics

In the pretest period, we screened eligibility of 297 patients. Eighty-five were not eligible, and thus 212 patients were included. In the posttest period, the corresponding figures were 319, 107, and 212. Exclusion reasons are shown in Fig. 2. Thus, in each of the predetermined time periods, we included more patients than the 170 calculated from the power analysis.

Demographic characteristics of the patient groups in both periods were not significantly different (Table 2).

3.1.1. Primary outcome: duration of ventilation

In the pretest period, the median DOV was 42.5 h (IQR 14.3–121.3 h) vs. 44.5 h. (IQR 12.3–107.1 h; $p = 0.589$) in the posttest period (Table 3). For the three selected subgroups of patients, the DOV was not significantly different between both periods (Table 3).

3.1.2. Secondary outcomes: LOS, compliance, reintubation

In the pretest period, the median LOS was 7.0 days (IQR 3–14) vs. 5.5 days (IQR 2–11); $p = 0.432$) in the posttest period (Supplement 3). The median LOS was not significantly different for the subgroups 'DOV \leq 48 h' and 'DOV $>$ 48 h'. This also held for the three selected patient groups (Table 3).

The compliance rate in the posttest period was significantly higher than that in the pretest period: 69.9% vs. 55.7% ($p = 0.005$).

The rates of adverse events in the pretest and posttest periods were comparable (Supplement 3). The reintubation rate did not significantly differ between both periods, respectively, 5% (11/212) vs. 7% (15/212); $p = 0.418$. The percentage of patients who needed noninvasive ventilation after extubation was low and not significantly different between groups, respectively, 3.3% (7/212 patients) pretest vs. 2.4% (5/212) posttest; $p = 0.771$. In the posttest period, 16.9% of extubations took place in the night, versus 9.4% in the pretest period ($p = 0.097$).

Patients in the posttest period were extubated within a median of 2 h (IQR 0–4) after meeting the extubation criteria. For those not extubated within 2 h, a median of 7 h (IQR 3–23) had elapsed before actual extubation. The most frequently reported reasons for later extubation were as follows: insufficient triggering, despite low ventilation settings ($n = 39$); too much mucus production according to the physician, but less than three times an hour, particularly in patients with viral airway infections ($n = 22$); need for a low-dose nitric oxide in case of pulmonary hypertension while set to sildenafil ($n = 9$) and developing arrhythmias ($n = 7$) (Supplement 4).

Sedation levels, COMFORT behaviour scores, clinical signs of oedema, ventilator settings, pH, and bicarbonate before extubation did not significantly differ between the two periods (Supplement 5).

Patients who were not changed to support mode were weaned to PC 15 cm H₂O (10 cm H₂O above PEEP 5 cm H₂O) or PRVC with pressures at 15 cm H₂O (with PEEP at 5 cm H₂O) at a frequency normal for age (or a lower frequency to provoke self-triggering) and an oxygen percentage of 40% or less. There were no significant differences in outcome for patients on a controlled or support mode before extubation in both periods. (see footnote in Table 3).

4. Discussion

4.1. Summary

Mechanical ventilation is essential to overcome a period of respiratory insufficiency but its duration should be limited to avoid ventilator-induced lung injury, airway injuries, and high sedatives

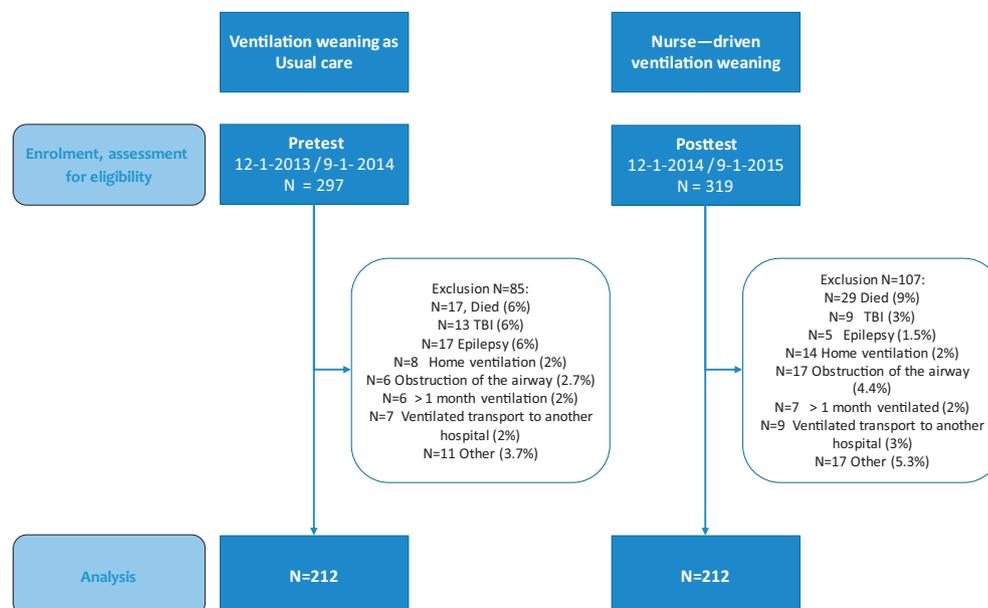


Fig. 2. Inclusion flowcharts.

Table 2
Demographic characteristics.

| Characteristics | Pretest (N = 212) | Posttest (N = 212) | p-value |
|----------------------------------------------|-----------------------------------|-----------------------------------|---------|
| Gender, n (%) | M = 121 (57.1%) F = 91 (42.9%) | M = 122 (57.5%) F = 90 (42.5%) | 0.90 |
| Age in months ^a | 3 (0–20) | 3 (0–32) | 0.533 |
| Age groups, n (%) | | | |
| Neonates (0–28 days) | 71 (33.5) | 66 (31.1%) | 0.610 |
| >28 days–1 year | 78 (36.8%) | 79 (37.3%) | |
| 1–3 year | 23 (11%) | 18 (8.5%) | |
| 3–12 year | 30 (14%) | 36 (17%) | |
| >12 year | 10 (4.7%) | 13 (6.1%) | |
| Reason for admission | | | 0.752 |
| Postoperative | | | |
| General | 71 (33.4%) | 53 (25.0%) | |
| Cardiac | 53 (25.0%) | 70 (33.0%) | |
| Respiratory failure | 54 (25.4%) | 51 (24.0%) | |
| Congenital abnormalities | 11 (5.2%) | 12 (5.7%) | |
| Cardiac | 7 (3.3%) | 4 (1.9%) | |
| Neurological | 1 (0.5%) | 3 (1.4%) | |
| Sepsis/infection | 5 (2.4%) | 11 (5.2%) | |
| Other | 10 (4.7%) | 8 (3.8%) | |
| Severity of illness (PRISM III) ^a | 23 (19–30.5) | 22.5 (18–28) | 0.190 |

PRISM, Pediatric Risk of Mortality score; IQR, interquartile range.

^a Median (IQR)**Table 3**
Primary outcome and subgroup analyses for DOV and LOS.

| LOS and DOV | Pretest (N = 212) | Posttest (N = 212) | p-value |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|------------------------------------------------|---------|
| DOV (hours) ^a | 42.5 (14.3–121.3) | 44.5 (12.3–107.0) | 0.589 |
| Subgroup 'DOV ≤ 48 h' | N = 110 | N = 113 | |
| DOV (hours) ^a | 15.5 (5.0–24.0) | 15.0 (6.0–25.0) | 0.796 |
| LOS (days) ^a | 3.0 (1.0–8.0) | 3.0 (1.0–5.0) | 0.224 |
| Subgroup 'DOV > 48 h' | N = 102 | N = 99 | |
| DOV (days) ^a | 5.0 (2.8–8.0) | 4.0 (3.0–7.0) | 0.428 |
| LOS (days) ^a | 12.0 (7.0–27.3) | 10.0 (7.0–19.0) | 0.455 |
| DOV and LOS for the largest admission groups | | | |
| Respiratory failure | N = 54 | N = 51 | |
| DOV (days) ^a | 4.0 days (2.0–7.0) | 3 days (2.0–6.0) | 0.210 |
| LOS PICU (days) ^a | 8.0 days (5.0–13.0) | 8 days (4.5–10.5) | 0.352 |
| Postsurgical cardiac | (N = 53) | (N = 70) | |
| DOV (hours) ^a | 17.5 (4.75–65.3) | 20.0 (7.0–72.0) | 0.615 |
| LOS PICU (days) ^a | 6.0 (1.75–13.3) | 5.0 (1.5–14.0) | 0.224 |
| Postsurgical | (N = 71) | (N = 53) | |
| DOV (hours) ^a | 21.5 (11.8–43.5) | 21.0 (11.0–40.5) | 0.600 |
| LOS PICU (days) ^a | 4.0 (2.0–11.3) | 3.0 days (1.8–6.0) | 0.673 |
| Footnote, only for posttest | Support N = 118 & Control N = 94 | Support N = 146 & Control N = 66 | |
| DOV in hours ^a for patients on a support mode before extubation vs. patients on a controlled mode before extubation | 48.5 (19–143.50) vs 33.50 (8.5–90.50) p = 0.202 | 48.5 (17–111) vs 22 (8–88) p = 0.522 | |
| LOS in days ^a for patients on a support mode vs. controlled mode | 7 (3–14) vs 6 (3–14) p = 0.547 | 6 (2.75–11) vs 5 (2–14.25) p = 0.132 | |
| Reintubation need | Controlled mode: N = 5 Support mode: N = 6 | Controlled mode: N = 5 Support mode: N = 10 | |
| Noninvasive support need | Controlled mode: N = 3 Support mode: N = 4 | Controlled mode: N = 1 Support mode: N = 4 | |

LOS, length of stay; DOV, duration of ventilation; PICU, paediatric intensive care unit.

^a Median (IQR)

consumption.^{1–3,7,8} Although, in this study, the use of the nurse-driven weaning protocol did not result in a significant shortening of the duration of ventilation, the application of this nurse-driven protocol was as safe and successful as physician-driven weaning, seeing that the reintubation rate had not significantly increased. However, the study design does not allow definitive conclusions.

4.2. Interpretation

Being 'as good as usual care' is valuable in itself, in this case, because the nurses have more autonomy and not every aspect of weaning needs to be authorised by a physician. In practice, during

evenings and nights—when fewer physicians are present—nurses can wean by themselves.

The increased use of a supportive ventilation mode in the posttest period indicates compliance with the protocol to some degree, but implementation success (compliance rate of greater or equal to 80%) was not reached, despite the multifaceted implementation strategy. Of all the strategies, reminders by the ventilation practitioners worked best to improve compliance. The low compliance rate might explain why we could not detect a significant difference in DOV. However, in rare cases, particularly in neonates, a support mode attempt failed because the ventilator was not triggered or the respiratory rate was too high, so that the child was extubated under controlled mode settings. In these cases,

compliance was nevertheless intended. It would be useful to ask the nurses how confident they feel, whether they see added value for the patient, and what problems, if any, they encounter with the nurse-driven protocol.²⁹

Various authors have recognised that implementation of an intervention is complex, explaining that many factors may influence its success. These include commitment of the management, culture in a ward, staff leadership skills, and staff characteristics such as educational level, attitude, autonomy, and degree of cooperation.^{10,15–17,28} The 3-months period for implementation of the protocol seemed long enough, but, in practice, its use may not yet have been ingrained in the nurses' work routines. This is why nurse managers and ventilation practitioners should keep reminding nurses of the protocol, stimulate them to use it, and also to educate them if they feel not confident to wean by themselves.

From interviews with physicians in our setting (not published), we know that some physicians are wary of nightly extubation because the staff-per-patient ratio in the night is lower than in the daytime. Although the extubation rate during nights had almost doubled in the posttest period, the number of adverse events had not increased. We thought that the higher nightly extubation rate in the night might explain a shorter stay, but we cannot demonstrate this with this insignificant result. An option for poorly resourced PICUs may be that the nurses wean and stop the feeding during the night shift, so that extubation can take place early in the morning, before the morning rounds.

There are many approaches to weaning, and not all use a change to support modes of ventilation. In our study, we found no significant difference in outcome for the patients weaned from a support mode and those who were extubated from a controlled mode with low settings. Some children may already have been ready for extubation when assessed for being weaning ready. The question is whether a shift to support modes could unnecessarily prolong iMV in these children.

Of all previous paediatric and neonatal studies on the effect of a weaning protocol on DOV, only the study of Foronda et al.¹² found a significant difference in DOV of 1.2 days (3.5 days vs. 4.7 days) compared with usual care without a weaning protocol. Four other studies found a significant earlier weaning time but no significant difference in DOV.^{13,14,26,30} However, only Foronda used an SBT as part of the weaning protocol. This was performed daily by protocol, until extubation. This protocol was not nurse driven. Fellows who were not involved in the decision to extubate patients assessed how patients in the intervention group performed the SBT and extubated these patients. The control group was weaned by physicians. The ventilator mode used before SBT is not clear in this research, but pressure support, synchronised intermittent mandatory ventilation, and pressure-controlled ventilation were applied. Before SBT, the patient had to be on an oxygen percentage equal or less than 50%, a positive end-expiratory pressure (PEEP) of equal or less than 8 cm H₂O, and a peak inspiratory pressure of equal or less than 25 cm H₂O. Because that protocol was not nurse-driven, the findings of Foronda et al. are hard to compare with ours, but it is important to realise that a daily evaluation and SBT can lead to a shorter DOV, even when settings of the ventilator are still high and the child is on a controlled mode.

The question remains if a nurse-driven ventilation weaning protocol actually can lead to a shorter DOV. Perhaps, DOV is determined to a larger degree by sedation depth, the underlying disease and severity of respiratory failure, waiting time for an operation or magnetic resonance imaging scan, or other reasons. As we showed, extubation can be delayed for many reasons after extubation criteria are reached. The most important reason in this study was a low-ventilation setting but not triggering the ventilator. The patients in question may have been too heavily sedated,

although nurses could have weaned sedation themselves, as a sedation protocol is in place. Incidentally, a recent study found no shorter DOV with a nurse-driven sedation protocol.³¹ Most of the named reasons for delaying extubation are subjective. An example is 'too much mucus production', as the presence of an endotracheal tube can stimulate mucus production. Fever and neutropenia also are relatively subjective contraindications. Good communication and documentation are needed here for good decision-making.

Studies on extubation criteria vary widely in nature. Some studies describe extubation practices; others are prediction studies or weaning trials, such as an SBT or ERT.^{11,12,23,26,32} Although SBT and ERT have a different focus, they both assess whether a patient is ready for extubation or not. An SBT assesses the patient's ability to breathe while receiving minimal or no ventilator support. An ERT assesses if the weaning is completed and the patient is sufficiently awake with intact airway reflexes, is haemodynamically stable, and has manageable secretions.²³ There is little evidence for the use of an SBT and ERT in children, in contrast to adults.³³ It is not yet known which of these two methods, SBT or ERT, can best predict extubation success, and they are executed differently per study.^{24,32–36} A recent report of a European Paediatric Mechanical Ventilation Consensus Conference recommends a daily ERT in children.³⁵ A recent quality improvement study in PICU patients found that a protocol with a daily SBT decreased extubation failure, but DOV was not studied here.³⁷ Our algorithm already includes daily assessment of weaning readiness on the basis of our weaning criteria, but adding an SBT could shorten the weaning period, also considering that there is no proof that pre-extubation ventilator settings have an influence on weaning failure.^{12,38}

In our study, the reintubation rate and the use of noninvasive ventilation after extubation were low, and these suggest that the decision to extubate at a peak pressure of 15 cmH₂O and a PEEP of 5 cmH₂O was cautious.

4.3. Limitations

The design of the study was a single-centre pretest–posttest study and not a controlled trial. All nurses needed to be familiar with the protocol, and therefore, it was not possible to randomise the study on a patient or unit level. As we excluded the patients who died on the ventilator, we could not use the outcome of ventilator-free days (each day alive and free of mechanical ventilation). We did not assess the children's upper airway, although upper airway obstruction is the main cause of extubation failure. In the pretest, two of the 11 patients who needed reintubation had stridor versus seven of the 15 in the posttest. Upper airway obstruction is difficult to predict by an SBT or low ventilation parameters. Measuring compliance with the use of a support mode during weaning does not strictly represent compliance with the whole weaning algorithm. It would be more representative to establish in each case whether nurses were using the protocol and how they experienced it.

4.3.1. Directions for further research

In the posttest, patients ventilated longer than 48 h had a shorter LOS-PICU compared with the pretest, although the difference was not statistically significant. Nevertheless, in the future, we should focus on patients ventilated for more than 48 h, as in this group a larger reduction in LOS-PICU might be achieved with the use of a nurse-driven ventilation weaning protocol. This could be studied in a clinical trial. However, it would be difficult to randomise patients in a study on the effects of an intervention such as nurse-driven weaning which requires a change of practice of the whole team. Therefore, a stepped wedge cluster RCT would be an appropriate design to study both the effectiveness and implementation outcomes.

To increase the compliance, we should continue with our well-considered multifaceted implementation strategy, including training sessions, reminders, and input of local opinion leaders. Especially, the local opinion leaders should be present every day to support the nurses and to help them increase their autonomy. The compliance should be measured by the use of a support mode in combination with questionnaires and by having an independent observer monitoring the weaning process.

5. Conclusions

Implementation of a nurse-driven weaning protocol in our PICU did not result in a significantly shorter duration of invasive mechanical ventilation but was found safe and successful. The greater use of a support mode of ventilation in the posttest period indicates a moderate compliance to the protocol, but still the compliance was not satisfactory enough. Further research is needed with a focus on children ventilated for more than forty-eight hours and on increasing compliance with the protocol.

Ethical approval

The Medical Ethics Review Board approved the study, and owing to its noninvasive nature, it waived the need for informed parental consent. In this medical research, the participants were neither subjected to procedures nor required to follow rules of behaviour.

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Supplement 1

The implementation procedure

The implementation was based on the seven-step Implementation Model of Change of Grol et al.¹ First, we identified the problem and defined the aim of change. In the next five steps, a researcher (A.D.) and implementation expert (E.L.) identified the potential barriers and facilitators by asking three experienced paediatric intensive care physicians and ten nurses with more than five years of experience about their expectations of a nurse-driven weaning protocol on three levels: organisation, professionals, and the intervention itself. (see Table 1.). Furthermore, implementation strategies were developed taking into account these barriers and facilitators. Thereafter, we focused on executing and evaluating the implementation plan.^{2,3}

Implementation activities included 45-min nurse education sessions explaining the protocol and its purpose. Before the new protocol was actually implemented, we trained 15 groups of 5–10 nurses (75% of the whole staff); those who could not attend the group sessions were trained individually after implementation of the protocol, for 45 min. Medical staff was informed during a staff meeting and by emails. We added the weaning protocol to the ICU staff's pocket manual that contains all PICU protocols. Several laminated versions of the protocol were placed at each ICU unit. Furthermore, the five nurses who had been trained as ventilation practitioners disseminated the importance of the weaning protocol. They recruited the patients, supported the nurses with bedside teaching, and checked if nurses followed the protocol well. We further integrated the protocol in daily practice by means of red flags (reminders) raised in the patient data management system every shift and reading: 'start weaning' and 'ready for extubation' (Supplement 2).

Grol and Grimshaw found that education alone resulted in mixed effects when used in healthcare workers.⁴ Mixed effects were also found for several

Supplement 1 (continued)

commonly used strategies (such as feedback on performance), whereas supportive strategies such as reminders, decision support, use of information and communication technologies, and rewards were mostly effective. Furthermore, combined strategies were identified as more effective than were single strategies.^{4,5} Nurses are not a uniform target group, as van Achterberg states, but they are professionals with various educational levels, specialisations, patient populations to be served, and work settings. All these variations are potentially relevant to implementation. Numerous contextual factors influence successful implementation of evidence into practice. Factors identified in studies of implementation of evidence in nursing include nursing culture and leadership, hospital size, staffing support, organisational innovativeness, administration responsiveness, access to resources, organisational climate, provision of education, access to research findings, availability of knowledge and skills within organizations, integration of recommendations into organisational structures and processes, interorganisational collaboration, money, workload, resistance to change, and time. Multiple factors can cause noncompliance and indicates the need for selecting multiple strategies for improving compliance. For this research, we identified potential influencing factors, for example, barriers and facilitators on our ward to improve adherence to our new protocol (Table 2). We focused on extrinsic motivation (work setting, barriers, a few peer reviews) and intrinsic motivation (competence, attitude, training, feedback, consultation, and reminding). After we knew that most nurses were capable and willing to use the protocol, we started the implementation.⁵

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Supplement 2

Reminder items in patient data management system with respect to weaning and extubation criteria.

Red flag every 8 h, in each shift.

Start weaning:

No fever > 38.5

Haemodynamically stable without high dosage of inotropics

Low-dose sedation (midazolam ≤200 mcg and morphine ≤10mcg)

pH ≥ 7.32

SpO₂ ≥ 95% or ≥ 75% in case of cyanotic heart defect or ≥ 88% in case of premature birth

No increased breathing efforts, no use of accessory muscles, no use of nostrils, breathing frequency ≤ maximum limit for the age

Red flag in PDMS every 8 h

Extubation criteria

• Spontaneous breathing efforts.

• F_iO₂ ≤ 0.4.

• pH ≥ 7.32

• Peak pressure ≤ 15 cm H₂O. Positive End-Expiratory Pressure (PEEP) ≤ 5 cm H₂O.

• During past 24 h, no raise in ventilation settings.

• No planned surgery in which sedation is needed in the next 12 h.

• SpO₂ saturation ≥ 95% before extubation or ≥ SpO₂ saturation ≥ 75% dependent on cyanotic heart defect or chronic lung disease in prematurely born neonates

• Glasgow coma scale > 8, capable of swallowing or cough

• Stable fluid balance

• Mucus production normal (≤3 x suctioning per hour)

• Haemodynamically stable

Supplement 3

Secondary outcomes

| Characteristics | Pretest N = 212 | Posttest N = 212 | P value |
|------------------------------------------|-----------------|------------------|---------|
| Length of stay in days ^a | 7.0 (3.0–14.0) | 5.5 (2.0–11.0) | 0.432 |
| Compliance by use of support mode | N = 118 (55.7%) | N = 146 (69.9%) | 0.005 |
| Reintubation rate | N = 11 (5%) | N = 15 (7%) | 0.418 |
| Noninvasive ventilation after extubation | N = 7 (3.3%) | N = 5 (2.4%) | 0.771 |
| Extubation rate during day/evening/night | | | 0.097 |
| 0–8 a.m. | | | |
| Reintubation rate | N = 20 (9.4%) | N = 36 (16.9%) | |
| Noninvasive support after extubation | 0 | 0 | |
| 8–12 a.m. | | | |
| Reintubation rate | N = 68 (32.1%) | N = 56 (26.4%) | |
| Noninvasive support after extubation | 1 | 0 | |
| 12–18 p.m. | | | |
| Reintubation rate | N = 86 (40.6%) | N = 78 (36.9%) | |
| Noninvasive support after extubation | 2 | 2 | |
| 18–24 p.m. | | | |
| Reintubation rate | N = 38 (17.9%) | N = 42 (19.8%) | |
| Noninvasive support after extubation | 4 | 2 | |
| | 7 | 10 | |
| | 1 | 3 | |
| | 2 | 3 | |
| | 1 | 0 | |

Supplement 4

Reasons for delay of extubation > 2 h from extubation readiness

| Reason | N = 141 |
|----------------------------------------------------------------------------------------------------------------|------------|
| Low ventilation setting but not triggering | 39 (27.7%) |
| Other (e.g. no clear reason found) | 35 (24.8%) |
| Too much sputum according to the physician (but less than 3 times an hour) | 22 (15.6%) |
| Need for a low-dose nitric oxide (pulmonary hypertension) while set to sildenafil | 9 (6.4%) |
| Arrhythmias | 7 (5.0%) |
| Waiting for ward round | 5 (3.5%) |
| Need for additional support, for example, blood transfusion, MRI planned after surgery, need for dexamethasone | 6 (4.3%) |
| Too much fluid overload according to the physician | 4 (2.8%) |
| Fever | 3 (2.1%) |
| The physicians doubted if the child was ready for extubation | 2 (1.4%) |
| Neutropenia | 2 (1.4%) |
| Muscular disease | 2 (1.4%) |
| Sepsis | 2 (1.4%) |
| Low venous saturation | 1 (0.7%) |
| High lactate | 1 (0.7%) |
| Busy on the ward | 1 (0.7%) |

MRI, magnetic resonance imaging.

Supplement 5

Sedation and parameters before extubation

| Clinical parameters | Pretest N = 212 | Posttest N = 212 | P value |
|--------------------------------------------|---------------------------------------|---------------------------------------|---------|
| Sedation before extubation | | | |
| Morphine | 83 (39%) | 98 (46%) | 0.447 |
| Number of patients | 12 mcg/kg/hr (10–20) | 10 mcg/kg/hr (6–17) | |
| Continuous infusion ^a | | | |
| Midazolam ^a | 90 (42%) | 86 (40%) | 0.541 |
| Number of patients | 100 mcg/kg/hr (57–151) | 100 mcg/kg/hr (50–150) | |
| Continuous infusion ^a | | | |
| COMFORT behaviour scale score ^a | 12 (11–13) | 12 (11–13) | 0.128 |
| Parameters before extubation | | | |
| Clinical signs of oedema ^a | 16 (8%) | 17 (8%) | 0.856 |
| PEEP ^a | 5 cm H ₂ O (5–5) | 5 cm H ₂ O (5–5) | 0.218 |
| FiO ₂ ^a | 25% (21%–30%) | 25% (21%–30%) | 0.635 |
| PO ₂ ^a | 74 Torr (61–103) [9.8 (8.1–13.7) kPa] | 78 Torr (59–93) [10.4 (7.8–12.4) kPa] | 0.358 |
| CO ₂ ^a | 42 Torr (38–48) [5.6 (5.0–6.35) kPa] | 41 Torr (37–46) [5.5 (4.9–6.1) kPa] | 0.215 |
| pH ^a | 7.40 (7.35–7.44) | 7.41 (7.37–7.45) | 0.441 |
| Bicarbonate ^a | 25 (22.0–28.8) mEq/L | 25 (22.8–28.2) mEq/L | 0.622 |

PEEP, positive end-expiratory pressure.

^a Median (IQR).

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