Feasibility and safety of early mobilization in critically ill children: A prospective experimental study

Damien Moerman [a,b,d], Gregory Reychler [b,c,d], Pauline Bednarek [a], Stephan Clément de Cléty [a], Thierry Detaille [a], Laurent Houtekie [a]

[a] Pediatric Intensive Care Unit, Cliniques universitaires Saint-Luc, Université catholique de Louvain, Brussels, Belgium
[b] Institut de Recherche Expérimentale et Clinique (IREC), Pôle de Pneumologie, ORL & Dermatologie, Université catholique de Louvain, Brussels, Belgium
[c] Department of Pneumology, Cliniques universitaires Saint-Luc, Université catholique de Louvain, Brussels, Belgium.
[d] Secteur de Kinésithérapie et Ergothérapie, Cliniques universitaires Saint-Luc, Université catholique de Louvain, Brussels, Belgium

damien.moerman@saintluc.uclouvain.be

Keywords

Early mobilization ; feasibility ; pediatric intensive care unit ; pediatrics ; critically ill children ; safety.

Abstract

Objectives:

The study aims to evaluate the feasibility and the safety of early mobilization in critically ill children under 2 years old and its impact on comfort scores.

Methods:

Children were recruited in our tertiary care pediatric intensive care unit. One session of upper and lower limb mobilization was performed within 48 hours after admission. The heart rate (HR), respiratory rate (RR), systolic and diastolic blood pressures (SBP and DBP, respectively) and pulse oximetry oxygen saturation (SpO_2) were recorded before (T0) and at the end of the mobilization (T1). Parameters were also noted at 10 min (T2), 30 min (T3) and 1 hour after the end of the mobilization (T4). The EDIN score and the Comfort-B score were used to assess comfort.

Results:

Twenty patients were included and mobilized. HR, SBP and DPB showed no change at the end of the mobilization compared to baseline (138 bpm ± 20 vs 133 bpm ± 15; 101 mmHg ± 18 vs 94 mmHg ± 12; 54 mmHg ± 11 vs 49 mmHg ± 7, respectively). RR and SpO2 did not statistically change during the study. Four sessions of mobilization were interrupted because of discomfort associated with increased EDIN and Comfort-B scores. No technical adverse events were recorded.

Interpretation:

Early mobilization is feasible and safe in most stable critically ill children under 2 years old as long as the height and type of surgery allow for mobilization of the patient. Discomfort was observed in 20% of the children.

Introduction

Children admitted to the pediatric intensive care unit (PICU) can experience cognitive, psychologic, and functional sequelae as a consequence of critical illness. Immobility is associated with complications including muscle weakness, pressure ulcers, and venous thromboembolism that may impact the length of stay in the PICU (1). As a result, there is a great interest in early mobilization. The perceived benefits of early mobilization in critically ill children are a shorter duration of mechanical ventilation, improved wake – sleep rhythm and a shorter length of stay in the PICU (1). Nevertheless, the efficacy of early mobilization in the pediatric population remains unclear due to the low level of evidence (2). Moreover, the feasibility and safety remain poorly described in this population: the main barriers reported were hemodynamic instability, the risk of vascular catheters and endotracheal tubes dislocation, and the sedation level (1,3).

Early mobilization is defined as non-mobility interventions (passive range of motion) to prevent muscle atrophy and maintain range of motion (ROM) and mobility interventions (active ROM, in bed cycling, transfers) to enhance endurance, strength, and balance (3). Early mobilization should be started within 48 hours of PICU admission (4). In a Canadian survey, only 10% of children admitted to the PICUs were mobilized within 48 hours of admission (3). The chest physiotherapy sessions were favored over mobilization (4). Despite different working practices, the physical therapists are infrequently consulted for early mobilization in European PICUs (5). This low frequency of prescription could be explained by the lack of expertise of the medical team to recognize a patient who would require early rehabilitation and the absence of dedicated physiotherapists to the PICU (6). Nevertheless, the numbers of children who received physical therapy increased when a mobilization protocol was implemented in the PICU (7,8).

In addition, the feasibility and safety of early mobilization has been demonstrated in critically ill children older than 3 years (9,10). Younger age has been identified as a barrier to physical rehabilitation, despite reassuring studies on the safety of early mobilization in children younger than 3 years old (4,8,11,12). An inpatient rehabilitation program based on standardized care pathways was shown to be safe for infants (median age: 1.1 years) after extracorporeal ventricular assist device placement (12). Early mobilization after liver transplantation in children (median age: 1.1 years) was also well tolerated (8). No adverse events associated with early mobilization were observed (8,12).

Based on these statements, we hypothesized that an adapted early mobilization program can be performed safely without major changes in parameters. The aim of this study was to evaluate the feasibility and the safety of early mobilization in critically ill children under the age of 2 years by investigating the impact on cardiorespiratory parameters and comfort scores.

Materials and methods

Setting

A prospective experimental study was conducted in the PICU at Cliniques universitaires Saint-Luc from September 2016 to February 2017 following the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE statement). The PICU is a polyvalent tertiary unit caring for various pathologies, including pediatric cardiac surgery and liver transplantation. This study was performed in line with the principles of the Declaration of Helsinki. The protocol study was approved by our institutional research ethics board (2016/11JUI/316). The clinical trial was recorded in the National Library of Medicine registry (NCT02958124).

Written informed consent was obtained from parents or legal guardians for all patients included in the study.

Participants

All children younger than 2 years of age admitted for 24 to 48 hours in our PICU were eligible for inclusion. Children with cardiorespiratory instability were excluded. Cardiorespiratory stability was defined as no sweating, no signs of respiratory distress (nasal flaring, increased work of breathing, paradoxical breathing, stridor, grunting), adequate oxygenation [pulse oximetry within the target values of the child, oxygen index (OI) ≤ 20 (OI is a marker of the severity of hypoxic respiratory failure, combining FiO_2, PaO_2 and mean airway pressure (MAP): $OI = FiO_2 \times MAP \times PaO_2\text{-}1$. The higher the value, the more severe the oxygenation disorder), Positive End Expiratory Pressure (PEEP) between 4 and 8 cmH2O], inspiratory pressure ≤ 30 cmH_2O, adequate respiration (respiratory rate or RR twice maximum the target values), adequate heart rate (HR) and systolic arterial blood pressure (increased by maximum of 20% compared to basal state), arterial or venous pH ≥ 7.25, no inotrope/vasoactive drugs (except for dobutamine ≤ 5 µg/kg/min or milrinone ≤ 0.8 µg/kg/min, corresponding to a low severity of hemodynamic impairment allowing safe mobilization), lactic acid ≤ 2.5 mmol/L. The cardiorespiratory parameters were collected 30 min before the start of the mobilization session.

Children receiving high frequency oscillatory ventilation or extracorporeal membrane oxygenation or with delayed chest or abdomen closure were also excluded.

Protocol study

Monitoring data and scores were documented at the first mobilization session between 24 and 48 hours after admission. Only one mobilization session per patient was included in the study; further sessions were not recorded. Passive mobilization of the upper and lower limbs was performed by the same trained physiotherapist. Shoulder circumductions, elbow flexions and extensions, wrist and fingers flexions and extensions, pelvis movements, triple bilateral flexions (like pedaling) and feet flexions and extensions were performed bilaterally. All these movements were performed in all patients and each movement was repeated for 10 times. The range of motion was maximal. Mobilization was carried out 30 min after morning care. During one hour after the session, no procedure or manipulation was carried out to ensure the validity of measurements. Each child received continuous or discontinuous enteral feeding. At the time of the study, there were no institutional guidelines for early mobilization.

Use of sedative and analgesic medications were based on local protocols according to international recommendations. The specific choice of drug and its administration interval depended on the personal evaluation of the physician in charge of the child, with the help of the bedside nurses and comfort scales. Continuous or discontinuous sedation or analgesia are administered to ensure safety and to control discomfort while keeping children awake. In case of minor agitation or crying during the session, some non-pharmacological facilitators such as pacifier, glucose, cuddly toys, music or massage were used to comfort the child. No additional sedation was given during the mobilization.

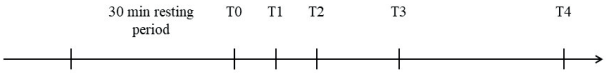
The mobilization was interrupted in case of important agitation, defined by reaching the discomfort threshold (Echelle Douleur Inconfort Nouveau-né (EDIN) and Comfort-Behavior (Comfort-B) scales) accompanied by one of the following criteria: increased work of breathing (nasal flaring, paradoxical breathing, stridor, grunting), increase in HR > 20% compared to basal state, increase in systolic or diastolic blood pressure (SBP or DBP) > 20% compared to basal state, occurrence of hypotension, increase in RR > 2 times the normal values, decrease in oxygen saturation (SpO_2) of > 4% below the target values of the child for > 60 sec, or accidental catheter removal (arterial, central venous, peripheral or urinary catheter).

Outcome measures

The primary outcome was the feasibility and safety of early mobilization in children aged 0 - 2 years old admitted in the PICU. The feasibility was defined as the ability to perform one full mobilization session of all upper and lower limbs through their full range of motion in critically ill children. The safety was assessed by the stability defined by change of respiratory and hemodynamic parameters. All the variables (HR, RR, SBP, DBP and SpO_2) were measured using a bedside monitor (Philips, Amsterdam, the Netherlands). These parameters were recorded continuously and noted before (T0), at the end (T1), 10 min (T2), 30 min (T3) and 1 hour after the mobilization (T4) (Figure 1). Adverse events such as endotracheal tube removal or catheter loss (arterial, central venous, peripheral or urinary catheter) were also recorded.

Figure 1: Experiment timeline.

T0, before the mobilization; T1, at the end of the mobilization; T2, 10 min after; T3, 30 min after and T4, 1 hour after the end of the mobilization.



The secondary outcome was to evaluate the impact of early mobilization on comfort assessed by the EDIN score for extubated children and the Comfort-B score for intubated children. The EDIN score is a score used to quantify the pain and discomfort in preterm and neonatal children (13). Nevertheless, this scale was chosen because it was already used in daily standard care to assess the comfort of children up to 9 months in our PICU. Five criteria (face, body, sleep, relational and reassurance necessity) are rated from 0 to 3 points. The higher the score, the worse the comfort: a cutoff score above 5 suggests discomfort. The Comfort-B score was developed and validated to measure pain and discomfort in mechanically ventilated children from birth to adolescence in PICU (14). When using the Comfort-B score, no other pain or sedation scale is necessary. We used the new version of Comfort-B score, without the physiological items: the arterial blood pressure and HR are difficult to assess. Each item (alertness, calmness or agitation, respiratory response, movements, muscle tone and facial tension) is rated from 1 to 5. The total score is calculated by adding up all individual scores: a score below 10 indicates excessive sedation, between 11 to 17 is the child comfortable, from 17 to 22 (potentially painful or discomfort) and a score > 23 indicates a clearly uncomfortable, painful child. We defined our discomfort threshold as a score greater than 5 on the EDIN score and above 17 on the Comfort-B score (13-14). Comfort assessments were performed before (T0) and at the end of the mobilization (T1), and 10 min after the session (T2).

During the mobilization, four patterns of behaviors were also recorded (calm, grimace, crying and agitation).

Statistical methods

The sample size was estimated on HR variation. Preliminary data from 10 subjects were used. Considering a standard deviation (SD) value of 14 bpm, adopting a significance level of .05, a power of 80%, the sample size was estimated to be 19 participants. This change of 14 bpm is also described as a reference from a pediatric study (15). Statistical analyses were performed using SPSS Statistics 25.0 (IBM Company, Armonk, New York, USA). The analysis of all outcomes followed the intention-to-treat principle. All values were expressed as mean ± standard deviation,

when data were normally distributed, otherwise by median, minimum and maximum values. Parametric and nonparametric analyses were used in accordance with the results of the Kolmogorov-Smirnov test. Repeated measures analysis of variance were used to evaluate the effect of mobilization on hemodynamic and respiratory parameters (within factors: time). Mauchly's sphericity was verified. Friedman test was used in the absence of the distribution normality. This nonparametric test was also used to measure the comfort of the child. All these statistical tests used a significance level of 5%.

Wilcoxon rank-sum tests were applied for post hoc comparisons using the Bonferroni correction, comparing each time point to another to find the significant change. Significance level was therefore set at $p < .01$.

Results

A total of 135 infants were eligible for inclusion. Ninety-three patients were excluded, of whom 72 due to cardiorespiratory instability, 18 due to absence of parental consent and 3 due to delayed chest or abdomen closure. Forty-two children were recruited. Among them, 14 children discontinued the study for inapplicable protocol due to their height: their height did not allow triple bilateral flexion of the lower limbs (pedaling). Eight post-surgical patients had contraindications to the mobilization because the surgical site involved the spine or the esophagus (esophageal anastomosis). A total of 20 infants were included (Figure 2). The baseline characteristics of the patients are described in Table 1.

Primary outcomes

Feasibility and safety

Twenty patients were included and mobilized: 15 spontaneously breathing without respiratory support and 5 invasively mechanically ventilated children. Sixteen sessions were completed and 4 sessions (3 cardiac patients and 1 patient with head trauma) were discontinued because of important agitation.

Table 2 shows physiologic and safety outcomes. The HR varied during the study period ($p = .03$) and changed significantly between T1 and T3 ($p < .01$). The SBP and DBP were also influenced by mobilization during the study period ($p = .02$ and $p = .04$, respectively). The SBP significantly decreased between T1 and T3 and, T1 and T4 ($p = .009$ and $p = .005$, respectively). The DBP also significantly decreased between T1 and T2 ($p = .006$). HR, SBP and DBP showed no change at T1 compared to baseline. RR and SpO_2 did not statistically change during the study.

Four mobilization periods were early discontinued because of a 20% increase in HR (n=2), a 20% increase in SBP and DBP (n=3) or a 4% decrease in SpO_2 (n=3). All the parameters returned to baseline 10 minutes after early discontinuation.

Table 1: Clinical characteristics of the patients at baseline.

Variables	Total (n = 20)
Age (days)	162 [1; 434]
Weight (kg)	6 [3; 10]
Female gender	12 (60)
Reasons for admission	
Congenital heart disease	14 (70)
Neurologic disease	3 (15)
Lung disease	2 (10)
Digestive disease	1 (5)
Ventilation	
Spontaneous breathing without NIV	15 (75)
Invasive ventilation	5 (25)

NIV, non-invasive ventilation.

Values are expressed as median with min-max values in square brackets, or numbers with percentage in round brackets.

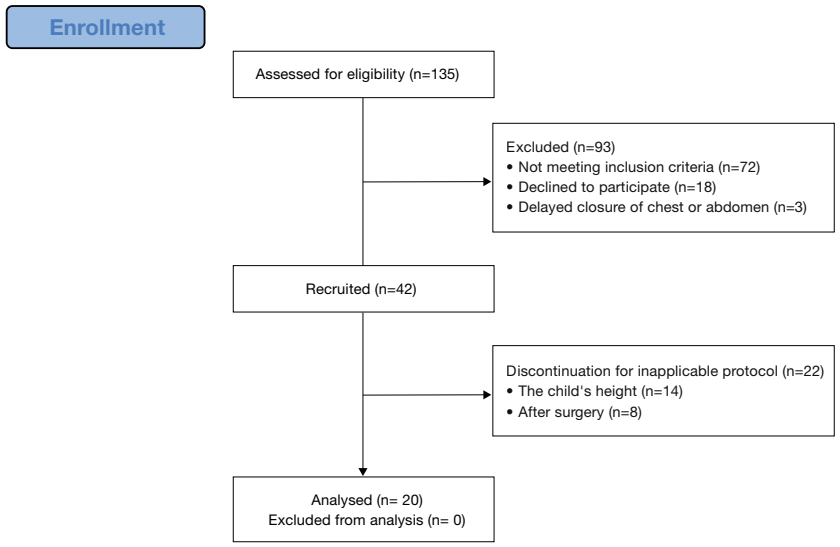
No adverse events were observed.

Secondary outcomes

EDIN scores changed over time ($p = .02$). EDIN scores showed no significant difference between T0 and T1. However, EDIN scores changed significantly between T1 and T2 ($p < .01$). Before mobilization, all the 15 spontaneously breathing patients were non-painful with EDIN scores ranging from 0 to 5. After mobilization, 3 of these 15 children had a score above 5. Mobilization was discontinued in 2 of them due to an increase in EDIN score from 2 to 7 and from 5 to 14. In the 5 ventilated patients, mobilization was discontinued in 2 patients due to an increase in Comfort-B score from 8 to 22 and from 10 to 19 (Figure 3).

Four types of reactions were noticed during the mobilization session: calm (n=8), agitation (n=6), tears (n=4) and grimaces (n=2). Half of the children needed facilitators such as glucose, cuddly toys or massage to calm down.

Figure 2: STROBE flow diagram.



Discussion

The aim of this study was to examine the feasibility and safety of early mobilization for children from 0 to 2 years in the PICU. Practical recommendations for early mobilization in critically ill children are lacking (4,16).

The feasibility and safety of early mobilization were evaluated in 20 children aged 1 day to 14 months admitted to the PICU. HR, SBP and DBP showed no change at the end of the mobilization (T1) when compared to baseline. RR and SpO_2 did not change significantly during the study period. In some children some parameters changed after the mobilization session without clinical importance. No technical adverse events were recorded. Our results are similar to other pediatric studies. Choong et al. showed no difference in cardio-respiratory and hemodynamic parameters after

Table 2: Change in parameters at different times.

	T0	T1	T2	T3	T4	p-value
HR (bpm)	133 ± 15	138 ± 20	129 ± 15	128 ± 14	131 ± 14	.03 [a,*]
RR (cycles/min)	31 ± 13	33 ± 12	32 ± 12	30 ± 10	32 ± 13	.64 [a]
SBP (mmHg)	94 ± 12	101 ± 18	96 ± 14	93 ± 13	93 ± 13	.02 [a,*]
DBP (mmHg)	49 ± 7.0	54 ± 11	49 ± 8.0	48 ± 8.0	49 ± 7.0	.04 [a,*]
SpO_2 (%)	99 [87; 100]	98 [81; 100]	98 [88; 100]	99 [89; 100]	98 [89; 100]	.44 [b]
EDIN scale (point)	2 [0.0; 5.0]	2 [0.0; 14.0]	2 [0.0; 6.0]			.02 [b,*]

HR, heart rate; RR, respiratory rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; SpO_2, peripheral oxygen saturation.

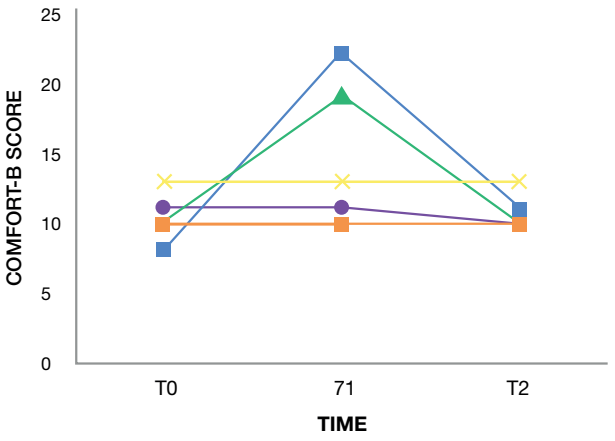
T0, before the mobilization; T1, at the end of the mobilization; T2, 10 min after; T3, 30 min after and T4, 1 hour after the end of the mobilization.

Values expressed as mean ± *SD* or median with min–max values in square brackets.

[a] *p*-value (Within Subjects – Factor = Time); [b] *p*-value (Friedman test); * $p < .05$.

Figure 3: Evolution of Comfort-B scores.

T0, before the mobilization; T1, at the end of the mobilization, T2, 10 min after the end of the mobilization.



passive mobilization with a cyclo-ergometer or active mobilization with a video-game in children aged 3 to 17 years (17). Abdulsatar et al. also reported feasibility of a 25 minutes Wii™ session for 8 children aged 3 to 18 years without changes in HR, RR, blood pressure and SpO_2, compared baseline (18). Additionally, these studies, like ours, showed no accidental tube displacements or extubations.

Sessions were feasible in 16 cases (80%) and discontinued in 4 cases (20%). All the children were calm and stable before treatment but they wiggled and turned during the mobilization.

Discomfort in these children was shown by changes in EDIN and Comfort-B scores, as well as hemodynamic and respiratory parameters. They all calmed down without need for sedative drug administration. Few studies focus on discomfort expressed by agitation as an adverse event (19). In the pediatric population, study data suggest that rates of potential safety events range from 1% to 6% (5,11,19). The European PARK-PICU study reported 6% potential adverse events: the most frequently reported events were a decrease in SpO_2, a change in HR and blood pressure (5). Adverse events are also described in critically ill adults. Schweickert et al. encountered one severe adverse event in 498 mobilization sessions in ventilated patients (desaturation less than 80%) (20). Hickmann et al. reported that adverse events, such as hypotension, hypertension and tachycardia, occurred in 10 activities (0.8% of total sessions) (21). The incidence of early mobilization adverse events in critically ill adults ranges from 1% to 6% including parameters changes, tube removals, skin injuries and falls (22–25).

We used facilitators such as a pacifier, glucose, cuddly toys, music or massage to relax the child during the mobilization. These facilitators can be considered as bias for evaluation of the child's behavior in the face of early mobilization. However, our nursing staff regularly uses these non-pharmacological techniques during treatments to avoid increasing sedation and analgesics. We therefore considered this technique to be common during the physiotherapy session with infants.

Several limitations to our study should be noted. First, our cohort was small due to strict inclusion criteria and surgical contraindications, the main limiting factor regarding external validity. Second, we did not include sedative and analgesic drug doses which could have had an impact on our results. Nevertheless, our unit has a strong culture of optimizing analgesia and minimizing sedation while maintaining infant safety and comfort. In addition, the comfort scales do not allow good discrimination of agitation and pain. Finally, our study did not assess the benefits of early mobilization. Muscle strength in young children is difficult to evaluate in clinical settings due to lack of non-invasive and reliable assessment tools. Peripheral muscle ultrasound could be a promising tool for bedside muscle assessment in children, as demonstrated in adults (26–29).

Conclusion

Early mobilization is feasible and safe in most stable critically ill children under 2 years old as long as the height and type of surgery allow for mobilization of the patient. Discomfort expressed by agitation is described as an adverse event. Future large-scale studies are still needed to assess the effect of early mobilization in children under 2 years old.

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Conflict of interest

GR has received research support from the Institut de Recherche Expérimentale et Clinique (Université catholique de Louvain, Brussels, Belgium).

Ethical considerations

This study was performed in line with the principles of the Declaration of Helsinki. Ethical approval was granted by the regional Ethic Committee in Cliniques universitaires Saint-Luc and Université catholique de Louvain in Brussels (2016/11JUI/316).

Written informed consent was obtained from parents or legal guardians for all patients included in the study.

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