

Feasibility and Safety of Early Mobilization in Critically Ill Children: A Prospective Observational Study

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Abstract

The study aims to evaluate the feasibility and the safety of early mobilization in critically ill children under 2 years and its impact on comfort scores. This prospective, monocenter clinical trial was conducted in a tertiary care pediatric intensive care unit in Belgium. Twenty children were recruited to the study. Early mobilization was done between 24 and 48 hours of admission. Mobilization of upper and lower limbs was performed according to practice protocol. The heart rate (HR), respiratory rate (RR), systolic and diastolic blood pressures (SBP and DBP, respectively) and pulsed oxygen saturation were recorded before mobilization, immediately after the treatment and after 10, 30 and 60 minutes. The EDIN score for the extubated children and the COMFORT-B score for the intubated children were used in order to evaluate comfort. The primary outcome was the feasibility and safety of early mobilization. The secondary outcome was to evaluate the impact of early mobilization on comfort. Sixteen sessions were completed and 4 sessions of mobilization were interrupted because of important agitation. HR, SBP and DPB showed no change immediately after the mobilization, compared with baseline. RR and SpO₂ were similar at the different times. Agitation had impact on the EDIN and COMFORT-B scores in children whose session was interrupted. No adverse events were reported.

Conclusions: Early mobilization is feasible and safe in the majority of critically ill children under 2 years even if the agitation is described as an adverse event. Early mobilization does not influence the cardio-respiratory parameters.

Clinical Trial Registration number and date of registration: Clinicaltrials.gov, NCT02958124, 10/09/2017

Contribution Of The Paper

What is Known

- The role of early mobilization in the pediatric population remains to be determined due to the low level of evidence.
- The feasibility and safety of early mobilization has been demonstrated in critically ill children over 3 years.
- Younger age was identified as a barrier to physical rehabilitation.

What is New

- Early mobilization is feasible and safe in most of critically ill children under 2 years.
- The cardio-respiratory parameters are not influenced by early mobilization.
- To our knowledge, agitation is first described as an adverse event in young child during an early mobilization session.

Introduction

Early mobilization in adult patients admitted to the intensive care has become a current practice since a few years. Indeed, many studies about early mobilization have reported improvement of patient's functional status [1], reduced mechanical ventilation duration [1] and hospital length of stay [2]. However, the efficacy of early mobilization in the pediatric population remains to be determined due to the low level of evidence [3].

Early mobilization has been defined as a mobility therapy started within 48 hours of the child's admission to intensive care [4]. In routine, less than 10% of unstable children are early mobilized [4]. The chest physiotherapy sessions are favored over mobilization [4]. Furthermore, the physical therapists are infrequently consulted for early mobilization in European pediatric intensive care units [5]. A Canadian survey explained this low frequency of prescription 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 pediatric intensive care unit (PICU) [6]. Nevertheless, the numbers of children who received physical therapy increased when a mobilization protocol was used at PICU [7, 8].

The feasibility and safety of early mobilization has been demonstrated in critically ill children over 3 years [9, 10]. Younger age was identified as a barrier to physical rehabilitation [4, 11] even if the early mobilization in children under 3 years has been already investigated [8, 12]. An inpatient rehabilitation program utilizing standardized care pathways showed to be safe for infants (median age: 1.1 years) after paracorporeal 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 the early mobilization were observed [8, 12].

From these statements, we hypothesized that an adapted early mobilization program can be safe on cardio-respiratory parameters and comfort scores in stable children in the PICU. The aim of this study was to evaluate the feasibility and the safety of early mobilization in critically ill children under 2 years and its impact on comfort scores.

Materials And Methods

Setting

A prospective, monocenter observational study was conducted in the PICU at Cliniques universitaires Saint-Luc from September 2016 to February 2017 following the STROBE statement. The PICU is a tertiary unit caring for various pathologies, including pediatric cardiac surgery and liver transplantation. The protocol study was approved by our institutional research ethics board (2016/11JUL/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 admitted to our study.

Participants

Critically ill children aged from 0 day to 2 years and admitted since 24 to 48 hours in our PICU were eligible for inclusion if children had no signs of discomfort, 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 ≤ 20 , PEEP between 4 and 8 cmH₂O, inspiratory pressure ≤ 30 cmH₂O, adequate breathing rhythm (twice maximum the target values), heart rhythm and systolic arterial blood pressure increased by maximum of 20% compared with basal status, arterial or venous pH ≥ 7.25 , no inotrope/vasoactive drugs (except for dobutamine ≤ 5 $\mu\text{g}/\text{kg}/\text{min}$ or milrinone ≤ 0.8 $\mu\text{g}/\text{kg}/\text{min}$), lactic acid ≤ 2.5 mmol/L.

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

Protocol study

One single session of mobilization was performed between 24 and 48 hours after admission. The same-trained physiotherapist performed all the mobilization sessions. 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 bilaterally done. Each movement was repeated for 10 times. During one hour after the session, no procedure or manipulation were carried out to ensure the validity of measurements.

At our PICU, continuous or discontinuous sedation or analgesia are administered to ensure safety and agitation control while keeping children awake. In case of minor agitation or crying during the session, some facilitators such as pacifier, glycerin, cuddly toy, music, massage were used to calm the child. No additional sedation was given during mobilization.

Criteria for interrupting mobilization session were as follows: persistent tachycardia, hypo- or hypertension for age, arrhythmia, desaturation (pulse oximetry $<$ target values for child), increased work of breathing, tachypnea, pain or discomfort that cannot be resolved with facilitators, catheter removal.

Outcome measures

The primary outcome was the feasibility and safety of early mobilization in children aged 0–2 years admitted in PICU. The feasibility was defined as the ability to mobilize ill critically children. The safety was assessed by the stability defined by change of respiratory and hemodynamic parameters. The variables heart rate (HR), respiratory rate (RR), systolic and diastolic blood pressures (SBP and DBP, respectively) and pulsed oxygen saturation were measured using a continuous monitor (Philips, Amsterdam, Pays-Bas). This data were recorded before (T0) and immediately after the mobilization (T1), after 10 min (T2), 30 min (T3) and 1 hour (T4). The rate of technical adverse events such as endotracheal tube removal or catheter loss was also recorded.

The secondary outcome was to evaluate the impact of early mobilization on comfort assessed by the EDIN scale and the Comfort-Behavior scale for extubated and intubated children, respectively. The EDIN

scale quantifies the pain and discomfort in spontaneously breathing young child [13]. Five criteria (face, body, sleep, relational and reassurance necessity) were rated from 0 to 3 points. The higher the score, the worst the comfort: a score above 5/15 evoked incomfort. The Comfort-Behavior scale was developed and validated to measure pain and discomfort as well as sedation in ventilated children from birth to adolescence in PICU [14]. Each item (awaking, calm or agitation, ventilation, movements, muscle tone and facial tension) was rated from 1 to 5. A total score was calculated by summing the score of each item: score from 6 to 10 (excessive sedation), from 11 to 17 (wellbeing, no excess of sedation), from 17 to 22 (potentially painful), from 23 to 30 (clearly uncomfortable, painful child). The comfort scores were calculated before mobilization (T0), immediately after the session (T1), and after 10 min (T2).

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

Statistical methods

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 \pm standard deviation (SD), when data are 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 was 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 this 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. Significance level was therefore set at .01.

Results

A total of 135 infants were eligible for inclusion. One hundred fifteen patients were excluded, of whom, 67 for cardiorespiratory instability. A total of 20 infants were recruited and mobilized (Fig. 1). The baseline characteristics of the infants are described in Table 1.

Table 1
Clinical characteristics of the patients at baseline

Variables	Total (n = 20)
Age (days)	157 (126)
Weight (g)	6000 (2000)
Female gender – no. (%)	12 (60)
Diseases – no. (%)	14 (70)
Congenital heart disease	3 (15)
Neurologic disease	2 (10)
Lung disease	1 (5)
Digestive disease	15 (75)
Ventilation – no. (%)	5 (25)
Spontaneous breathing	
Invasive ventilation	
Values are expressed as mean (SD) or numbers (%).	

Primary outcome

Feasibility

Sixteen sessions were completed and 4 sessions of mobilization (3 cardiac patients and 1 patient with head trauma) were interrupted because of important agitation.

Safety

The HR changed at the different times ($p = .03$). The HR tended to decrease immediately after the treatment (T1) and 30 min after (T3) ($p = .01$ [after Bonferroni correction]). The SBP and DBP were influenced by time ($p = .02$ and $p = .04$, respectively). The SBP showed significant changes between immediately after the treatment (T1), 30 min after (T3) and 1 hour after (T4) ($p = .009$ and $p = .005$, respectively). Significant variation in DBP was observed between immediately after the treatment (T1) and 10 min after (T2) ($p = .006$). HR, SBP and DBP showed no change immediately after the mobilization (T1), compared with baseline. RR and SpO₂ were similar at the different times (Table 2).

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	.028 ^{a,*}
RR (cycles/min)	31 ± 13	33 ± 12	32 ± 12	30 ± 10	32 ± 13	.641 ^a
SBP (mmHg)	94 ± 12	101 ± 18	96 ± 14	93 ± 13	93 ± 13	.019 ^{a,*}
DBP (mmHg)	49 ± 7.0	54 ± 11	49 ± 8.0	48 ± 8.0	49 ± 7.0	.035 ^{a,*}
SpO ₂ (%)	99 [87; 100]	98 [81; 100]	98 [88; 100]	99 [89; 100]	98 [89; 100]	.443 ^b
EDIN scale (point)	2 [0.0; 5.0]	2 [0.0; 14.0]	2 [0.0; 6.0]			.017 ^{b,*}
HR, heart rate; RR, respiratory rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; SpO ₂ , pulsed oxygen saturation; T0, before mobilization; T1, immediately after the treatment; T2, after 10 min; T3, after 30 min; T4, after 1 hour.						
Values expressed by mean ± SD or median and min–max values in brackets.						
^a p-value (Within Subjects – Factor = Time); ^b p-value (Friedman test); * p < .05.						

No tube dislodgements and accidental extubations were observed during the mobilization sessions.

Secondary outcomes

EDIN scores were influenced by time ($p = .02$). EDIN scores showed no change between before mobilization (T0) and immediately after the mobilization (T1). However, EDIN scores tended to decrease immediately after the treatment (T1) and 10 min after (T2) ($p = .01$ [after Bonferroni correction]). Before mobilization, all the 15 extubated patients were non-painful with EDIN score ranging from 0/15 to 5/15. After mobilization, 3 children had a score higher than 5/15 and mobilization has been discontinued for 2 patients with EDIN score raised from 2/15 to 7/15 and from 5/15 to 14/15 (Fig. 2). Some patients showed a similar variation of their comfort score, which explains that the number of change is lower than 15 patients (Fig. 2). For the 5 intubated patients, COMFORT-B scores were modified for 2 patients (interrupted mobilization): the scores changed from 8/30 to 22/30 and from 10/30 to 19/30.

Four types of reactions were noticed during the mobilization session: calm ($n = 8$), agitation ($n = 6$), tears ($n = 4$) and grimaces ($n = 2$). At first, half of children needed facilitators like glycerin, cuddly toy or massage to calm down.

Discussion

The aim of this study was to consider feasibility and safety of early mobilization for children from 0 to 2 years at PICU. Practice recommendations for early mobilization in critically ill children are poorly described [15, 16].

The feasibility and safety of early mobilization were evaluated within 20 sessions with patients from 1 day to 14 months admitted at PICU. Heart rate, systolic blood pressure and diastolic blood pressure showed no change immediately after the mobilization (T1), compared with baseline. Respiratory rate and SpO₂ were similar at the different times. No technical adverse events were recorded. Our results are similar to other paediatric studies. Choong and al. demonstrated no difference in cardio-respiratory and hemodynamic parameters after passive mobilization with cycloergometer or active mobilization with video game for children aged from 3 to 17 years [17]. Abdulsatar and al. also reported feasibility of a 25 minutes Wii session for 8 children aged from 3 to 18 years without change in heart rate, respiratory rate, blood pressure and pulse oximetry, compared with baseline [18]. Moreover, these studies showed no accidental tube dislodgements, extubations and cutaneous or physical injuries.

Sixteen sessions were feasible and mobilization sessions were discontinued in 4 cases (20%). Children were calm and stable before treatment but they twisted and turned during the mobilization. That agitation had impact on the EDIN and COMFORT-B scores in these children. The return to calm was possible without additional sedation. To our knowledge, our study is the first to describe agitation as an adverse event. The European PARK-PICU study reported 6% potential adverse events: the most commonly reported occurrences were decreased oxygen saturation, change in heart rate and in blood pressure [5]. Adverse events are also described in critically ill adults. Schweickert and al. met one severe adverse event in 498 mobilization sessions in ventilated patients (desaturation less than 80%) [1]. Hickmann et al. reported that adverse events occurred in 10 activities (0.8% of total sessions) such as hypotension, hypertension and tachycardia [19]. The incidence of adverse events of early mobilization in critically ill adults ranges from 1–6% including change in parameters, tube removals, skin injuries and falls [20–23].

Agitation can be defined as a behavioural symptom with multiple origins like hypoxia, hunger, excessive stimulations, neurological instability, tiredness or pain [24, 25]. Literature has revealed several causes: post-surgical agitation, delirium, benzodiazepine or opioid withdrawal symptoms and personal characteristics.

Studies showed that agitation was common for children after surgery. Some risks factors are known: young age, short time to awakening, use of anaesthesia drugs [26]. Most of patients in our study (17/20) were at PICU after a surgical procedure. All of them were affected by young age and contact with those drugs. However, time to awakening was longer because patients were transferred to PICU under sedation that was progressively decreased. Fear, pain and discomfort would also have impact on agitation. Pathology itself or invasive care could likewise cause agitation [27]. In addition, important anxiety from parents or child himself may lead to a predisposition to agitation [28].

Sedation and analgesia were used to ensure safety and control agitation during mechanical ventilation. Continuous use of benzodiazepine is known to be associated to delirium risk factor [29]. Delirium can be hypoactive with apathic behaviour or hyperactive with agitation and irritability or both. The delirium rate decreased to 11.9 % after the implementation of protocols about sedation and early mobilization [30]. It is still now difficult to detect and probably underdiagnosed. When a child hospitalized in PICU shows signs of agitation or confusion, it is not possible to determine whether this is due to delirium rather than the underlying disease or environment related anxiety. Delirium could explain some agitation episodes in our study although continuous infusions of midazolam are not used in our PICU.

Benzodiazepine or opioid withdrawal symptoms can also cause irritability, delirium, agitation and anxiety. However, it is less likely to be applicable in this study because of the time to apply mobilization was between 24 and 48 hours of admission while withdrawal symptoms are related to the cumulated dose of sedative/analgesics drugs [31].

Finally, children's own characteristics should not be excluded as an explanation. It is known that children more impulsive, less sociable and less flexible to environment changes are likely to be agitated after surgery [26, 28].

We used facilitators like pacifier, glycerin, cuddly toy, music or massage to relax the child during the mobilization. These facilitators could be considered as bias for evaluation of child behavior face with early mobilization. However, nursing staff regularly uses those techniques during the treatments and this is a non-pharmacologic option to avoid increasing sedation and antalgics. So, we considered this way as common during the physical therapy session with infants.

Balance between under-sedation and over-sedation is challenging. Children must be sedated to ensure their safety and comfort while keeping a level of alert during the day. Validated scales must be used to optimize analgesia and minimize sedation and, thus, prevent the delirium risk [29, 32].

Several limitations in our study should be noted. Firstly, we did not record the doses of drugs for each child. Nevertheless, this study was performed in an unit with a strong culture to optimize analgesia and minimize sedation while maintaining the safety and comfort of the infant. Use of sedative and analgesic medications were based on international recommendations [29]. The specific choice of drug and its administration interval depended on the personal feeling of the physician in charge of the child. Finally, our study did not evaluate the benefits of early mobilization. Muscular 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 the muscle evaluation at bedside of children [33–36].

Conclusions

Early mobilization is feasible and safe in the majority of critically ill children under 2 years even if the agitation is described as an adverse event. Early mobilization does not influence the cardio-respiratory

parameters.

Abbreviations

DBP, Diastolic blood pressure; HR, Heart rate; PARK-PICU, Prevalence of Acute Rehabilitation for Kids in the PICU; PEEP, Positive end-expiratory pressure; PICU, Pediatric intensive care unit; RR, Respiratory rate; SBP, Systolic blood pressure; SD, Standard deviation; SpO₂, Pulsed oxygen saturation.

Declarations

Acknowledgments

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Authors' contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Damien Moerman, Gregory Reychler and Pauline Bednarek. The first draft of the manuscript was written by Damien Moerman and Pauline Bednarek, and all authors commented on previous versions of the manuscript.

Gregory Reychler and Laurent Houtekie revised the final version.

All authors read and approved the final manuscript.

Conflicts of interest

Financial interests:

No funding was received for conducting this study.

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Non-financial interests:

The authors have no conflicts of interest to declare.

Availability of data and material

All data are available on request. All data sharing requests will require approval from Cliniques universitaires Saint-Luc prior to release.

Code availability

N/A

Authors' contributions

These contributions are listed at the title page.

Ethical approval

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).

Consent to participate

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

Consent for publication

The parents or legal guardians signed consent regarding publishing their child's data.

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Figures

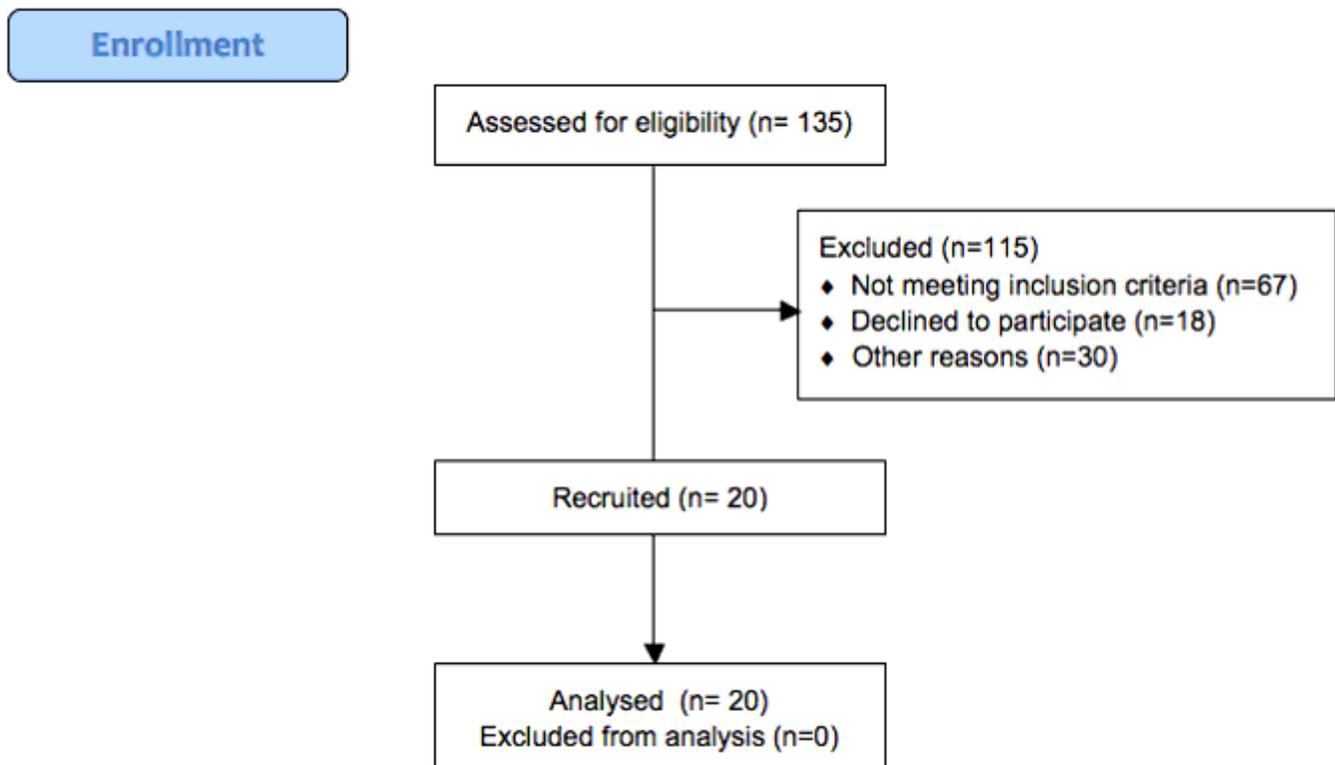


Figure 1

Consort flow diagram

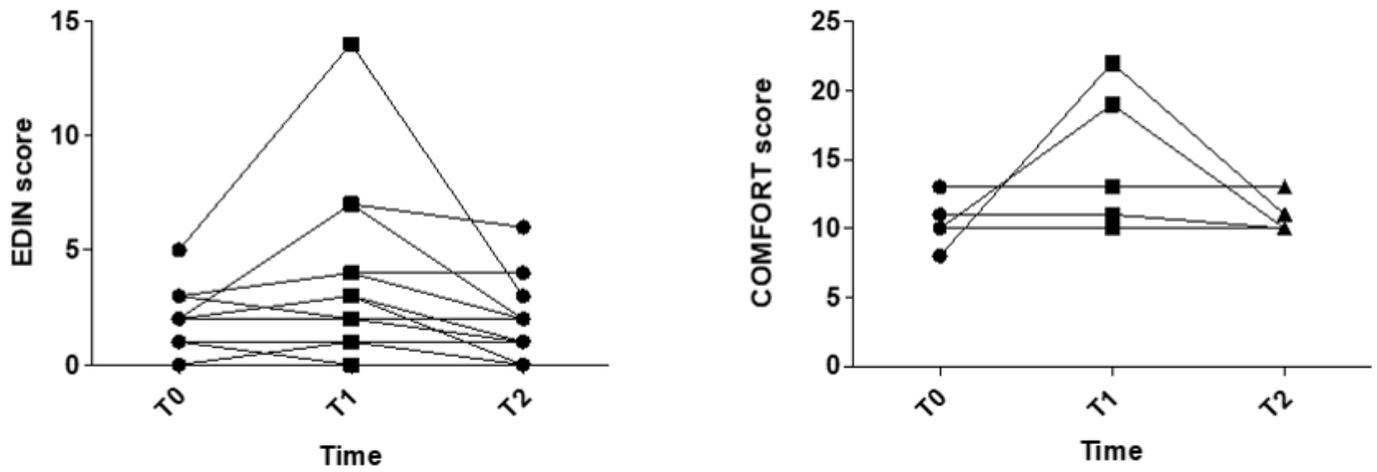


Figure 2

Evolution of EDIN scores and Comfort-Behavior scores T0, before mobilization; T1, immediately after the treatment, T2, after 10 min