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ORIGINAL ARTICLE

Safety and practicality study of using an exoskeleton in acute neurosurgery patients

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Abstract

Introduction Early mobilization is key in neurologically impaired persons, limiting complications and improving long-term recovery. Self-balanced exoskeletons are used in rehabilitation departments to help patients stand and walk. We report the first case series of exoskeleton use in acute neurosurgery and intensive care patients, evaluating safety, clinical feasibility and patients' satisfaction.

Methods We report a retrospective observational study including individuals hospitalized in the neurosurgical intensive care and neurosurgery departments. We included patients with a medical prescription for an exoskeleton session, and who met no contraindication. Patients benefited from standing sessions using a self-balanced exoskeleton (Atalante, Wandercraft, France). Patients and sessions data were collected. Safety, feasibility and adherence were evaluated.

Results Seventeen patients were scheduled for 70 standing sessions, of which 27 (39%) were completed. They were typically hospitalized for intracranial hemorrhage (74%) and presented with unilateral motor impairments, able to stand but with very insufficient weight shifting to the hemiplegic limb, requiring support (MRC 36.2 ± 3.70, SPB 2.0 ± 1.3, SPD 0.7 ± 0.5). The average duration of standing sessions was 16 ± 9 min. The only side effect was orthostatic hypotension (18.5%), which resolved with returning to seating position. The most frequent reason for not completing a session was understaffing (75%). All patients were satisfied and expressed a desire to repeat it.

Conclusions Physiotherapy using the exoskeleton is safe and feasible in the acute neurosurgery setting, although it requires adaptation from the staff to organize the sessions. An efficacy study is ongoing to evaluate the benefits for the patients.

Keywords Neurosurgery · Acute neuro care · Brain hemorrhage · Traumatic brain injury · Stroke · Gait-balanced exoskeleton · Early mobilization · Robot-assisted rehabilitation · Pulmonary embolism · Patient-centered rehabilitation.

Audrey El Kaim and Manon Serra contributed equally to this work.

Previous communication Preliminary results from this work have been presented at the congress for the "Société de Langue Française de Réanimation" in French in June 2023 by M. Serra.

Abbreviations

MRC	Medical Research Council
SPB	Seated postural balance
SPD	Standing postural balance

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Introduction

Early mobilization is a major concern for healthcare professionals and rehabilitation specialists caring for persons with a sudden loss of neurological motor function. In addition to preventing complications associated with immobility, this type of intervention aims to promote brain plasticity as quickly as possible, thereby maximizing their recovery potential. The guidelines for managing persons with acquired brain injuries recommend early rehabilitation interventions [5, 14]. However, the level of evidence remains low, and clinical trials are necessary to confirm the value of these therapies. In this context, the use of robotic assistive devices might be particularly suitable because it allows severe patients to train in functional situations they would not otherwise be exposed to. One meta-analysis found that patients with severe lower limbs impairment after a stroke have better outcomes in terms of walking movements and daily activities when they benefited from robotic assisted rather than conventional rehabilitation [6]. However, the benefit is only significatively higher during intervention, not on long-term outcome.. The benefit appears to be greater when the intervention occurs in the subacute phase rather than the chronic phase. However, some studies caution about the timing of initiating early mobilization in neurological rehabilitation, as it could have negative effects on middle-term patient outcomes [4]. Furthermore, early rehabilitation and the use of exoskeletons can sometimes be challenging to implement by healthcare providers [9, 13].

We used an exoskeleton for 8 months in our departments, as described previously [1], and we conducted a retrospective study based on the available data. The aim of this study was to evaluate the safety and feasibility of early rehabilitation assisted by an Atalante exoskeleton (Wandercraft, Paris, France) in neurosurgical intensive care and neurosurgery departments.

Methods

This is a retrospective cross-sectional observational study including individuals hospitalized in the neurosurgical intensive care and neurosurgery departments in one hospital. It is covered by a standard care protocol on the evaluation and prognosis of traumatic brain injuries and subarachnoid hemorrhages. The presentation of research results follows STROBE recommendations for cross-sectional studies [3].

Patients were recruited from the neurosurgery department (intensive care and post-rehabilitation) and were included from April to November 2022. Inclusion criteria were: any person hospitalized in the neurosurgery department, of legal age, with a prescription for an exoskeleton session, and who had at least one scheduled exoskeleton session during their hospitalization. Persons who met a contraindication for exoskeleton use defined by Wandercraft were excluded: extreme thigh and leg segment lengths; weight exceeding 90 kg; spasticity equal to or greater than 3 on the Ashworth scale for triceps surae, quadriceps, hamstring, adductors; joint ranges of motion below recommended values; osteoporosis secondary to treatment or osteoporotic fracture; presence of pressure sores at support points; pregnancy.

The primary objective was to evaluate the safety and practicality of using an exoskeleton for standing sessions in neurosurgical intensive care and post-neurosurgical rehabilitation, practicality exploring the extent to which the intervention can be delivered when resources, time, commitment are constrained in some way[2]. The secondary objective was to assess patients acceptability.

The safety of using the exoskeleton in neurosurgical intensive care and post-neurosurgical rehabilitation was assessed by the percentage of minor (reversible during the session) and major (any event causing consequences after the session, including a longer stay in hospital, need for a new treatment, death) adverse events occurring during exoskeleton sessions. The practicality of its use was assessed by the percentage of completed sessions compared to the number of scheduled sessions, and the reason for non-completion of the session was recorded. Finally, patients' acceptability to this device was established through the following two questions, asked at the end of the session: "Are you satisfied with the session?" and "Would you like to do it again next time?". Anthropometric data of persons were collected (age, gender, weight, height), as well as length of hospital stay, etiology, number of exoskeleton sessions performed, session and standing duration, number of steps taken, seated postural balance (SPB), standing postural balance (SPD), the score on the MRC (Medical Research Council) scale out of 60 points. MRC scale evaluates strength from 0 (no movement) to 5 (normal power) in 6 muscles bilaterally. The analyses were performed using RStudio software version 2021.09.2. Variables underwent univariate analysis to describe the recruited population. Only descriptive statistics were used.

Results

Four therapists were trained in the use of the exoskeleton in the neurosurgery department. The final analysis focused on 27 standing sessions (17 patients with an average of 1.6 sessions per person, ranging from 1 to 4) in persons with an average age of 58 ± 12 years (23—84) from the

Fig. 1 Patients standing upright with the exoskeleton assistance. In this context, the sessions required two therapists. The patients benefited from the sessions even when they needed medical equipment such as urinary catheter, intravenous drip, nasogastric tube. Those patients presented with unilateral motor impairment secondary to intracranial hemorrhage impeding standing without support. Orthostatic hypotension was the only side effect. All patients expressed the wish to repeat the sessions

neurosurgical intensive care and post-rehabilitation departments (Fig. 1). The majority (74%) of persons were hospitalized for intracranial hemorrhage (including intracerebral hematoma: 6, chronic subdural hematoma: 4, subarachnoid hemorrhage: 4, trauma: 2 and else: spine corporectomy 1, spine ependymoma 1, intracranial meningioma 1); 14 (86%) patients showed some degree of cognitive impairment, that was not systematically evaluated. The mean time between the injury and the first session was 37 ± 22 days [1—87]. Patients were hospitalized for a total 58 ± 29 days [13—125], including 21 ± 21 days [0—99] in intensive care and 39 ± 27 days [6—80] in the neurosurgical ward. All patients were then transferred to a rehabilitation department.

The MRC score averaged 36.2 ± 3.70 out of 60, SPB was 2.0 ± 1.3 out of 4, and SPD was 0.7 ± 0.5 out of 5, indicating that the typical profile of the subjects corresponded to unilateral motor impairments (hemiplegia, hemiparesis), with maintained sitting postural balance without posterior support but unsteady for any directional push, and with the ability to stand with very insufficient weight shifting to the hemiplegic limb, requiring support.

No major side effect occurred, including vascular, respiratory, or painful complications. Five episodes (18.5%) of orthostatic hypotension occurred during standing sessions and were controlled by returning the person to a seated position, considered as minor side effects.

Out of 70 scheduled sessions, 27 (38.6%) were completed; 43 sessions could not be completed, either due to service priorities (39.5%), insufficient rehabilitation staff in the departments (34.9%), ineligibility based on study criteria or intrinsic properties of the exoskeleton (20.9%), mostly inadequate leg segment lengths that were measured after the patient's inclusion, or excessive fatigue on the day of the session (4.7%). Most sessions were completed in the neurosurgical department (74%) and 26% in intensive care. The average duration of standing sessions was 16 ± 9 min. The average ratio of standing time to session time, with session time referring to the effective time spent in the exoskeleton was 66 ± 21%. The average time for verticalization was 16 ± 9 min and for walking was 2 ± 2 min. Patients walked 148 ± 125 steps.

A hundred percent of patients who had exoskeleton sessions answered the two satisfaction questions: they were all satisfied and expressed a desire to repeat it.

Discussion

The use of exoskeleton is safe in acute neurosurgery patients

The objective of this study was to assess the practical feasibility and safety of using an exoskeleton for early rehabilitation in neurosurgical intensive care and neurosurgery units, with potential benefits described previously. We already reported in two pre-study patients that cognitive impairment is not a limitation to exoskeleton use, and confirmed in the present group that cognitive troubles are not a contraindication for exoskeleton rehabilitation, as long as cooperation and basic understanding are not impaired [1].

Similar to other comparable studies [11, 12], we found no adverse events with post-session consequences associated with the use of the exoskeleton. However, the rate of in-session adverse events is high compared to that generally found for early mobilization in intensive care. Indeed, a meta-analysis found a rate of minor adverse events at 2.6% [10]. But their patients are mostly non-neurological, and the interventions include very low-risk techniques, such as

in-bed mobilization, making comparison irrelevant. In contrast, the use of the exoskeleton specifically allows for standing in persons for whom it would not be possible without significant technical assistance. Another study focused on the use of an exoskeleton in individuals within one month of a stroke, and found results more similar to ours, with a rate of adverse events at 11.6% in the intervention group [8]. However, the adverse events in this study also included sessions not completed for various reasons, such as staff shortages.

To reach practicality, exoskeleton rehabilitation requires a radical reorganization of physiotherapy in acute care, with dedicated staff

We also encountered an unexpectedly high rate of uncompleted sessions (61.4%), mainly due to understaffing or a lack of personnel trained in exoskeleton use. Indeed, this study was conducted with only 4 therapists trained in exoskeleton use, and the exoskeleton could only be operated by these therapists, always in pairs. Other care givers could have been be trained if long-term use of the exoskeleton was organized, and if they had enough time to participate in rehabilitation in addition to their usual tasks. In this context, the completion of the sessions depended on the department's workload and the availability of these 4 therapists, resulting in a low session rate. These results confirm the difficulty of using such a significant device in healthcare, which can sometimes be tedious for therapists[7]. Globally, the number of sessions completed of the sessions planned calls for a low practicality in the use of an exoskeleton in an acute care setting unless trained staff is dedicated.

However, we observed that, as the staff became more experienced, some practical issues were solved more efficiently, making the organization of the sessions more fluid. In addition, despite minor adverse events and the difficulty in conducting sessions effectively, patients' satisfaction rates following the sessions are very high, showing that these practical difficulties did not discourage the patients.

Study limitations

This study is a case series without a control group and without blinding, with a low level of evidence (level 4). Cognitive impairment was not evaluated thoroughly, with a heterogeneous group of patients. The analyses were retrospective, on a small number of persons, because the rental period of the exoskeleton and the organization of the department did not allow for more inclusions. We tested only one type of exoskeleton, which is a robotic self-balanced exoskeleton that supplies gait motor activity to the patients. Our results must be extrapolated cautiously to other types of exoskeletons, with individual evaluations. In addition, intrinsic properties of Atalante exoskeleton, particularly weight and leg-length limitations, only allow rehabilitation for a selected population of patients. Although these characteristics evolve quickly as exoskeletons grow more widely available, the results only apply to this population. Finally, the outcome measures focus on the safety and practicality of exoskeleton use and do not provide any information on the intervention's effectiveness or its cost–benefit ratio.

The use of a self-supported exoskeleton offers significant rehabilitation opportunities for persons with severely impaired locomotor function. Given the absence of major adverse events and high patient satisfaction, the next step is to improve implementation of this technique in daily care, and assess the effectiveness of this device on patient-centered outcomes in the short, medium, and long term. Due to the substantial cost of the device and the complexity of its use, cost–benefit analyses should be conducted, and comparisons with simpler interventions should be considered to establish recommendations for using an exoskeleton in the acute and subacute phases of cerebrovascular patients.

Conclusions

This study has demonstrated that it is safe and feasible to use an exoskeleton in neurosurgical intensive care and post-neurosurgical rehabilitation. It also reveals a very high level of patient satisfaction with the device. Given the small sample size analyzed, further studies will be necessary to include a larger number of persons and to investigate the economic aspect of such a device. An efficacy studies will be conducted in our department to assess the impact of using an exoskeleton on the motor and functional recovery of acute-phase neurosurgical patients.

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Authors' contributions CA developed the original idea. MS, VD, AC and CA coordinated the funding of the exoskeleton. VD, AC, MR and CA organized the access to the exoskeleton, selected and informed the patients. AEK, MS, AL, CG, HN and MR performed the exoskeleton sessions and collected the clinical data. AEK, MS, AL and CA performed the data analyses. AEK and MS drafted the manuscript. CA critically revised the manuscript. All authors approved the final version of the manuscript.

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Data availability Data are available on demand for academic purpose.

Code availability Not applicable.

Declarations

Ethics approval The procedures used in this study adhere to the tenets of the Declaration of Helsinki and comply with the French law Jarde 2012–300. Approval was granted to the intensive care department for the use of innovative therapy to improve the standard of care.

Consent to participate Informed consent was obtained from all individual participants included in the study or their legal guardian.

Consent for publication The authors affirm that participants provided informed consent for publication of the images in Fig. 1 and for their data analysis and publication.

Conflicts of interest/Competing interests The authors declare no conflict of interest.

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