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Effectiveness of a very early stepping verticalization protocol in severe acquired Brain injured Patients: A randomized pilot study in ICU

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**Background and Objective:** Verticalization was reported to improve the level of arousal and awareness in patients with severe acquired brain injury (ABI) and to be safe in ICU. We evaluated the effectiveness of a very early stepping verticalization protocol on their functional and neurological outcome

**Methods:** Consecutive patients with vegetative State or Minimally Conscious State were enrolled in ICU on the third day after an ABI. They were randomized to undergo conventional physiotherapy alone or associated to fifteen 30-minute sessions of verticalization, using a tilt table with robotic stepping device. Once stabilized, patients were transferred to our Neurorehabilitation unit for an individualized treatment. Outcome measures (Glasgow Coma Scale, Coma Recovery Scale revised -CRSr-, Disability Rating Scale –DRS- and Levels of Cognitive Functioning) were assessed on the third day from the injury (T0), at ICU discharge (T1) and at Rehab discharge (T2). Between- and within-group comparisons were performed by the Mann-Whitney U test and Wilcox on signed-rank test, respectively

**Results:** Of the 40 patients enrolled, 31 completed the study without adverse events (15 in the verticalization group and 16 in the conventional physiotherapy). Early verticalization started  $12.4\pm7.3$  (mean±SD) days after ABI. The length of stay in ICU was longer for the verticalization group ( $38.8 \pm 15.7 \text{ vs } 25.1 \pm 11.2 \text{ days}, p=0.01$ ), while the total length of stay (ICU + Neurorehabilitation) was not significantly different ( $153.2 \pm 59.6 \text{ vs } 134.0 \pm 61.0 \text{ days}, p=0.41$ ). All outcome measures significantly improved in both groups after the overall period (T2 vs T0, p<0.001 all), as well as after ICU stay (T1 vs T0, p<0.004 all) and after Neurorehabilitation (T2 vs T1, p<0.004 all). The improvement was significantly better in the experimental group for CRSr (T2-T0 p=0.033, T1-T0 p=0.006) and (borderline) for DRS (T2-T0 p=0.040, T1-T0 p=0.058)

**Conclusions:** A stepping verticalization protocol, started since the acute stages, improves the short-term and long-term functional and neurological outcome of ABI patients

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