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Impact of soft splints on upper limb spasticity in chronic patients with disorders of consciousness: A randomized, single-blind, controlled trial

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Abstract

Objective: To assess the effectiveness of soft splints on spasticity and hand opening in chronic patients with upper limb spasticity and disorders of consciousness (vegetative state/unresponsive wakefulness syndrome-VS/UWS and minimally conscious state-MCS).

Methods: In this prospective single-blind controlled trial, a blind evaluator assessed spasticity (Modified Ashworth Scale and Modified Tardieu Scale), range of motion (ROM) at the metacarpophalangeal, wrist and elbow joints and the patients’ hand opening before and after soft splinting, manual stretching and a control condition (i.e. no treatment), as well as 60 minutes later.

Subjects: Seventeen patients with chronic (>3 months) disorders of consciousness were included (five VS/UWS; seven women; mean age = 42 ± 12 years; time since insult = 35 ± 31 months). Patients received either passive splinting, manual stretching treatment or no treatment.

Results: Thirty minutes of soft splinting or 30 minutes of manual stretching both improved spasticity of the finger flexors. An increase of hand opening ability was observed after 30 minutes of soft splinting.

Conclusion: Thirty minutes of soft splint application reduces spasticity and improves hand opening of patients with chronic disorders of consciousness. Soft splinting is well tolerated and does not require supervision.

Keywords

Disorders of consciousness, manual stretching, spasticity, splint

Introduction

About one out of four patients with brain damage develop abnormal patterns of muscle activity within 2 weeks of their insult [1], with spasticity primarily affecting the flexors and pronators of the upper limbs. Nowadays, there is no consensus about the definition of spasticity. The most accurate definition of motor disorders arising after a brain injury is the ‘upper motor neuron syndrome’ which can be defined by positive and negative signs [2]. Spasticity is one of the positive signs between other motor symptoms which arise after lesions in the descending corticospinal system such as spastic dystonia (i.e. muscle’s constriction in the absence of any voluntary movement), spastic co-contraction (contraction of both the agonist and antagonist muscles resulting from an abnormal pattern of commands in the descending supraspinal pathway), extensor or flexor spasms, clonus, exaggerated deep tendon reflexes and associated reaction [3, 4]. On the other hand, negative signs are muscle weakness, loss of dexterity and fatigue. Spasticity is generally defined as a velocity-dependent increase in muscle tone and can be easily clinically assessed [5, 6]. The occurrence of spasticity is difficult to predict due to its high variability [7]. The prevalence of spasticity does not seem to differ between upper and lower limbs. However, higher degrees of spasticity (Modified Ashworth Scale; MAS>3) are more frequently (19% of patients) observed in the upper limb than in the lower limb muscles (6%), with the most frequently affected joints being the elbow (79%) and the wrist (66%) [8]. Moreover, spasticity is associated with muscle contracture, tendon retraction and pain [9, 10]. Muscle contracture is a pathological condition characterized by an increase of soft tissues’ stiffness and is usually associated with the loss of elasticity and fixed shortening of affected tissues which cause both loss of range of motion (ROM) and increased stiffness around the joint [11]. O’Dwyer et al. [12] showed that the resistance to passive stretch was associated with the presence of muscle contracture and this resistance could be due to the presence of muscle contracture. Moreover, contracture arises...
more easily if spasticity holds a joint in a shortened position [13]. Spasticity may contribute to contracture formation [11] and some studies confirm this association [14–17]. These symptoms increase muscular hyperactivity and may potentially worsen the functional recovery of patients with brain injury. For a complete review see (Thibaut et al., 2013) [18].

Treating spasticity is, therefore, of paramount importance, especially in patients who are not able to communicate, as is the case for many patients who recover from coma. Progress in acute neurocritical care has led to an increase in the number of patients surviving a severe brain injury. Whereas some recover quickly, others pass through various altered states of consciousness: coma (i.e. unconscious, no eye opening), vegetative state/unresponsive wakefulness syndrome (VS/UWS, i.e. eye opening, but still unconscious) [19, 20] and minimally conscious state (MCS; signs of consciousness, but no communication) [21]. Any possible sources of pain must be relieved, since patients with disorders of consciousness (DOC) are able to perceive pain, but cannot express their feelings [22–24]. It is even more important to treat spasticity, because the proportion of patients with DOC who suffer from this disorder reaches almost 90% and it seems to be correlated with pain during care [25].

As these patients are unable to actively participate in rehabilitation, passive techniques are mainly used to treat spasticity. The mainstay of physical treatment is muscle stretching, which should be started as early as possible to prevent muscle shortening. Physical therapy sessions commonly involve passive ROM exercises or short posturing sessions. However, to prevent contractures in the long-term, muscle stretching should be applied daily for several hours [26–28]. The disadvantage of manual stretching is the required participation of a physiotherapist, which limits the frequency at which it is applied. In addition, severe contractures necessitate prolonged stretching that can only be achieved through the use of postures, splints or casts [29]. Rigid splints are often used as orthopaedic devices in patients in VS/UWS and MCS, although, for this population of patients, their efficacy is still questionable [30, 31]. Moreover, they are poorly tolerated when used for long periods of time [32] and their effectiveness remains controversial, as they seem to be of little use if they are implemented when the patient with brain injury already presents severe contractures and significant spasticity [33–35]. Moreover, rigid splints can be harmful for patients with severe spasticity, because they may induce bedsores, oedema or circulatory troubles [32]. Soft splints are a potential alternative, but at present they are rarely used. They may avoid these negative effects due to their softness and still decrease spasticity and improve hand opening by relaxing the patient and maintaining their hands in an open position.

The aim of the present study was to compare the effectiveness of a hand rolled soft splint on the upper limb spasticity of patients with DOC, compared to conventional manual stretching. It was hypothesized that: (i) soft splints decrease spasticity of the finger flexor muscles, as assessed with the MAS and the Modified Tardieu Scale (MTS); (ii) soft splints increase hand opening of patients and (iii) manual stretching could have a higher impact on elbow spasticity than splints.
were always performed from distal to proximal, starting at the metacarpophalangeal joints and continuing up to the shoulder. All assessments were made while the patients were lying in bed.

Methods

Patients were seen at either the University Hospital of Liège or at their nursing homes. Those admitted to the University Hospital were subjects for a week-long behavioural, neuroimaging and electrophysiological assessment of their level of consciousness. Those who were in nursing homes were referred by their treating physicians.

The inclusion criteria were: (i) aged over 18 years, (ii) in a VS/UWS or a MCS after a severe acquired brain injury according to published diagnostic criteria [21, 44], (iii) in a VS/UWS or a MCS for at least 3 months, (iv) have stable vital signs and (v) have a spastic pattern in flexion bending both upper limbs (MAS ≥ 1). Exclusion criteria were: (i) have cutaneous or joint pathologic states in the upper limb (e.g. wound, bedsore or fracture), (ii) have a spasticity pattern in extension and (iii) demonstrate a hypersensitivity to polyurethane.

The experimental protocol was approved by the local ethics committee (University Hospital of Liège). The family of each patient signed a statement of informed consent.

Patients received a different treatment on each upper limb. Two treatments applied for 30 minutes (i.e., manual stretching, splint treatment or no treatment) were tested on each upper limb separated by 60-minutes of break. The order of the applied techniques was randomized (ratio: 1:1:1). In total, four techniques were tested in every patient, two for each upper limb to increase the number of applied techniques due to the small population of patients (17 patients and 34 measures). The protocol was divided in nine steps (Figure 2). The protocol was performed by two physiotherapists and lasted 4 hours and 30 minutes. The first physiotherapist, the assessor, handled pre- (T1), post- (T2) and 60 minutes post-treatment (T3) assessments alone in the patient’s room and left the room after the assessments. Then, the second physiotherapist, the experimenter, entered the room and applied the stretching or the splint or control condition to the patient (a different treatment on each upper limb) based on a list built by a classifier (ration: 1:1:1). The assessor physiotherapist stayed outside the room of the patient during the experimentation and was blinded to the treatment used prior to the assessments. Three groups were formed based on treatments received on one upper limb: (1) splint and manual stretching (n = 14), (2) splint and controlled condition (n = 12) and (3) manual stretching and controlled condition (n = 8).

To evaluate the influence of treatment and time since insult on patients enrolled in the present study, this study used the Mann-Whitney U-tests to investigate the difference of MAS scores according to medication (i.e. presence vs absence of pharmacological treatment). Correlations between MAS scores and time since insult was assessed with Kendall’s Tau tests. For parametric data (major-palm distances and ROM), differences between changes occurring after the treatment and 60 minutes later were analysed by ANOVA with repeated measures (pre, post and 60 minutes post). When a significant time effect was observed, a post-hoc analysis was performed using a t-test for paired sample. Non-parametric data (MAS and MTS) were analysed using Wilcoxon’s signed rank test. This study compared the difference between T1 and T2; and T1 and T3. Statistical analysis was performed using Statistica 10.0 with statistical significance set at the 5% level, Bonferroni-corrected for multiple comparisons (p < 0.025). This study further evaluated the possible impact of treatment, diagnosis and aetiology on major-palm distance and ROM using a repeated-measures analysis of variance with one independent variable. The independent variable represented whether patients were medicated or not, VS/UWS or MCS or if their injury had traumatic or non-traumatic origin. A Mann-Whitney U-test was used for the non-parametric measures (i.e. MAS or MTS).

Results

A total of 26 chronic patients with DOC were consecutively screened; seven patients suffered from a spasticity pattern in extension and two patients had no spasticity (MAS = 0). Seventeen patients who fulfilled the selection criteria were included in this randomized, single blind and controlled study (five VS/UWS, 12 MCS; mean age = 42 ± 12; time since insult = 35 ± 31 months; seven women, see Table I).

The soft splint was well tolerated by patients. The results showed significant changes at the level of the metacarpophalangean joints. No significant results were observed for the wrist and elbow. No differences were observed between patients in VS/UWS and MCS.

Splint-stretching group (n = 14)

Regarding the finger flexor muscles, the MAS score decreased significantly at T2 (post-technique) compared to T1 (pre-technique) after splint application (p = 0.014; median (IQR) from 3.5 (1.25) to 2.5 (2.25)) and after the manual stretching (p = 0.022; median (IQR) from 2.5 (3) to 2 (2)). At T3 (60 minutes post-treatment), however, no significant improvement was observed for either technique (p = 0.093; median (IQR) = 3 (1.25) and p = 1; median (IQR) = 2.5 (2.25), respectively; see Figure 3 and opening (i.e. major-palm distance) increased significantly at T2 for the splinting (p = 0.005; mean ± SD from 5.07 ± 4.32 to 7.46 ± 3.51), but
not for the manual stretching ($p = 0.249$; mean ± SD from $5.79 ± 4.49$ to $6.11 ± 4.58$). At T3, the values returned to baseline for the splint group (mean ± SD = $4.86 ± 3.79$). No significant changes were observed for the other variables (MTS, ROM). No difference in terms of treatment, diagnosis or aetiology was observed for MAS scores ($p > 0.05$), nor for major-palm distance ($p > 0.05$).

### Splint-no treatment group ($n = 12$)

When wearing the splint, the MAS score of finger flexor muscles decreased significantly between T1 and T2 ($p = 0.014$; median (IQR) from 2.5 (2) to 1.5 (2)) and this reduction was maintained at T3 ($p = 0.022$; median (IQR) = 2 (1.5)). Hand opening (i.e. major-palm distance) increased significantly in T2 ($p = 0.009$; mean ± SD from $3.54 ± 3.49$ to $6.17 ± 3.47$), but the effect was not maintained at T3 ($p = 0.486$; mean ± SD = $3.88 ± 3.29$). Other variables (MTS, ROM) did not change significantly. No significant changes were found when the patients were not treated. No difference in terms of treatment, diagnosis or aetiology was observed for MAS scores ($p > 0.05$), nor for major-palm distance in term of treatment or aetiology. This study, however, found an interaction effect for diagnosis ($p = 0.027$). Post-hoc Tukey’s test revealed a significant difference for patients in VS/UWS ($n = 4$), but not for patients in MCS ($n = 8$) at T2 compared to T1, but no difference was observed between T3 and T1.

### Stretching-no treatment group ($n = 8$)

This study did not find any significant changes for all the variables of all tested joints, neither after stretching nor after the absence of treatment.
All results and p values, median, mean, interquartile range, standard deviation and delta are summarized in supplementary material (Tables S1 and S2).

Discussion

The main results showed that the soft splint and manual stretching reduced spasticity of finger flexors muscles in patients with DOC.

A decrease in spasticity was observed after 30 minutes of soft splinting and after 30 minutes of manual stretching. A long-lasting effect of the soft splint was only observed in the group ‘splint-no treatment’. The results of manual stretching are in line with previous studies that report the transient effect of manual stretching in children with DOC [45]. Other studies also showed the direct effect of manual stretching in reducing spasticity for post-stroke patients [46], children with cerebral palsy [47] and traumatic brain injury [48], but its effect fades after ~ 30 minutes. Gracies et al. [49] tested the effectiveness of wearing a soft splint (a glove in Lycra) for 3 hours in 16 acute patients with stroke. They showed that this glove provided comfort to patients by reducing spasticity (MAS) in flexion of the wrist and fingers and improving wrist posture. The lasting effect of the soft splint in the ‘splint-no treatment’ group may be interpreted by the comfortable aspect of the splint, which could be relaxing. Unlike manual stretching, where the upper limb is mobilized, putting on a soft splint is less likely to cause pain, which could induce a spastic reaction [50]. Thus, when the splint is removed, the patient is relaxed and this relaxing effect can last longer. The advantage of splinting as compared to manual stretching is the duration of its application.

The results are consistent with those of Gracies et al. [49]. The advantages of soft splints are that they are easy to place, comfortable and flexible and allow patient contraction (e.g. grasping reflex or muscles contraction) without resistance. Thus, they can be worn for hours without pain and without inducing a grasping reflex or muscle cramps. In addition, compared to rigid splints, the risk of injury and bedsores are reduced. Indeed, rigid splints are often difficult to place, especially in patients with severe spasticity and tendon retraction, for whom hand opening and access to the palm is frequently difficult. Furthermore, a study conducted by Lannin et al. [34] showed that the rigid splints were not effective against spasticity. In patients with DOC, using a soft and comfortable splint should be recommended, since they are not able to communicate their pain feelings. Moreover, in cases of abrupt muscle contraction, soft splints can adapt themselves to the increase of patient over-activity. Thanks to this adaptation, spasticity is not increased.

The soft splint failed to show an improvement on spasticity and ROM of the wrist and elbow. This is logical as the splint extended the fingers, but had no direct action on the wrist or elbow. Nevertheless, manual stretching also failed to decrease the spasticity of the wrist and elbow joints, even if all the joints have been maximally elongated. This could be due to the order of joint assessment, since the physiotherapist who performed the evaluations always started by assessing the fingers, then the wrist then the elbow. This order could increase the chance to observe an effect on the fingers flexor muscles. Moreover, manual stretching can generate pain and increase spasticity. Indeed, in this study, the physiotherapists often had to decrease the stretching due to pain signs (e.g., grimaces, crying, restlessness).

In both groups ‘splint-stretching’ and ‘splint-no treatment’, the soft splinting improved hand opening (major-palm distance). The thickness of the splint allowed metacarpophalangeal and interphalangeal joints to be positioned near their maximum stretching position. In patients with DOC, it is important to maintain a good hand opening, first from a hygienic standpoint, to avoid problems of maceration, pressure sores or injury caused by driving nails into the palm and also to facilitate nursing. In addition, if patients recover cognitively, it is important that they are able to mobilize their fingers to grasp objects, in order to maximize their autonomy.

For the group ‘splint-no treatment’, better improvement of hand opening (i.e. major-palm distance) was observed after 30 minutes of splinting for patients in VS/UWS than for patients in MCS. At the individual level, this study found that two patients in VS/UWS improved substantially compared to the 10 others, VS/UWS (n = 2) and MCS (n = 8) (hand opening increased by 5 and 10 cm respectively), which may have had an influence on the results. None of them were taking anti-spastic medication at the time of assessment and none showed tendon retraction in the upper limbs. This could explain why they reacted well to the splint. Nevertheless, as the sample size is very small (four VS/UWS compared to eight MCS), the results must be interpreted carefully.

One of the limitations of this study is the small number of patients and the results must interpreted with caution. Further studies should assess the effect of soft splints in a larger group of patients with DOC, as well as in both the acute and chronic stages.

Conclusion

This is the first study that compares soft splints and manual stretching in patients with chronic DOC. Soft splints and manual stretching both transiently reduced spasticity of the flexor finger muscles. The soft splint, however, was the only treatment able to improve hand opening. Thanks to its comfort and simple application, soft splints could be easily applied in patient’s daily cares. Further studies of the long-term effects of wearing these splints are required prior to their introduction in daily clinical practice, but they have shown promise in this study of upper limb spasticity.

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Declaration of interest

The study was supported, in part, by Vigo Group, Belgium. The company put soft splint at our disposal but provided no financial support, had no control over the data analysis and
interpretation, the decision to publish or the content of this article. The authors report no conflicts of interest.

**Supplemental material**

Supplemental data for this article can be accessed on the publisher’s website.

**References**


