

The Influence of Combinations Air-splinting and Botulinum Toxin-A Therapy to Changes in Spasticity of the Hand

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ABSTRACT

Background: Spastic paresis of the hand causes problems in the grip and manipulative function of hand in activities of daily living, hygiene, nursing and rehabilitative care, deteriorations in quality of life and it also causes pain. Reduction or elimination of spasticity is one of the fundamental tasks of the rehabilitation of spastic paresis of the hand after cerebrovascular disease (stroke).

Aim: The aim is to describe the combined effect of botulinum toxin-A and air-splinting in patients after stroke with spastic paresis of hand.

Methods: This was a prospective observational cohort study describing an association between reduction of spasticity and splinting with air-splints (experimental cohort of 20 patients, 16 women, 14 men, mean age 59.5 ± 9.8 years) versus conventional rehabilitation with progressive stretching of spastic muscles (control cohort of 20 patients, 18 women, 12 men, mean age 60.0 ± 9.5 years). All patients had postictal spastic paresis of hand, therapy with botulinum toxin-A and six-week rehabilitation. The measured data were statistically evaluated at the significance level $p < 0.05$ using Student's t-test, Mann-Whitney U test, Chi square and logistic regression analysis.

Results: Forty patients (20 experimental and 20 control) completed the observational study. After six week of therapy was demonstrated very significant association of air-splint therapy and alleviation spasticity of hand – Odds Ratio: 4.0 (95% CI: 3.5 to 5.0) and significant association of conventional rehabilitation (progressive stretching) and alleviation spasticity of hand – Odds Ratio: 1.5 (95% CI: 1.1 to 2.0).

Conclusions: In our study has been described more significant relationship between the reduction in spasticity of the hand and therapy with use botulo toxin-A and air splint versus therapy with botulinum toxin-A and conventional rehabilitation with progressive stretching.

KEY WORDS

stroke, spasticity, splinting, air-splint, botulo toxinum-A, stretching

INTRODUCTION

Spasticity is a complex motor disorder in the event of a central motoneuron disorder. Spasticity was referred to as increased muscle activity, which was manifested by excessive excitability of stretching reflexes and muscle hypertonia. Generally, spasticity is also a so-called spastic dystonia, expressed as an abnormal postural possession (for example Wernicke-Mann Syndrome). Another manifestation of increased muscular activity in patients with central motoneuron lesion is flexor and extensor spasms, spastic co-contraction (poor coordination of active free movement manifested as “pseudodystonia”), and spastic synkine-

sis (associated distant motor reactions – movements accompanying free movement) (1, 2). Complication of the central motoneuron lesion is a shortening or contracture of the spastic muscle in which there is atrophy and the conversion of contractile proteins to the ligament. In motor disorders of the central motoneuron we are talking about spastic paresis in general. Spastic paresis is causing problems in mobility, in daily activities, hygiene, nursing and rehabilitation care, worsening the quality of life and causes pain (3, 4). After stroke (cerebrovascular accident – CVA), spastic paresis occurs in 20% – 40% of cases and its therapy is requiring a multidisciplinary approach (2). Botuli-

num toxin type A (BTX-A) together with rehabilitation is currently considered the first-line treatment for post-spasticity (3, 4, 5). Rehabilitation of spasticity is involving complex procedures of physiotherapy, ergotherapy, physical therapy, as well as new procedures such as robotic assisted rehabilitation, functional electrical stimulation and the use of virtual reality (4, 6). One of the requirements and objectives of treating spasticity is reducing muscle hyperactivity, stretching of shortened muscles, re-education of movement function and restoration of selective movement in the segment. The effectiveness of rehabilitation or individual rehabilitation approaches are currently being tested on the principles of evidence-based medicine (1, 6).

For therapeutic principles, prolonged progressive stretching are being recommended as standard (6, 7). This therapy is sometimes supplemented by the application of thermoplastic orthosis in the so-called “functional position in the segment”. However, thermoplastic orthosis are having their limits and sometimes undesirable complications, such as decubitus, difficulty handling, adjusting the correct angles, high price of orthosis, etc. (7, 8, 9). Currently, one of the controversial questions is whether splinting are effective for treatment of spastic paresis (8, 9, 10, 11). A certain alternative of thermoplastic orthosis is an innovative modern concept that uses inflatable splints to affect spasticity, respectively spastic dystonia. It is a proactive neuro-rehabilitation method with Urias splints according to Margaret Johnstone (10, 12, 13). The inflatable splints (Figure 1) are specialized rehabilitation aids that maintain the limb in the physiological (neutral) position by pressure of splints and also positively affect microcirculation in affected tissues. At the same

time, they correct the muscular tension and plasticity of the participating tissues and dampen pathological manifestations of the central nervous system (hyperactivity of stretching reflexes, tremor, clonus, hyper-irritability) (10, 14). The inflatable splints are transparent and made of special soft PVC (polyvinyl chloride) material. They are inflated with a mouth at a maximum of 40 mmHg. The air in the splint helps to optimally adhere the splint along the entire circumference of the limb, while evenly circularly spreading the pressure on the limb. Permanent stretching of the spastic muscles causes the muscle spindle to adapt to reflex of stretching, thereby reducing the motoneuron discharge and thereby reducing muscle tension. The length of application of air-splint should not exceed sixty minutes to avoid circulatory changes leading to limb ischemia. Depending on the degree of disability and the intensity of the therapy, the air-splints can be used several times a day at any stage of the disease. These splints are used both in the hypotonic and spastic stages of the disease. Advantage is an possible to combine with other therapeutic procedures and aids, especially the possibility of application in the home environment (2, 10, 14, 15).

OBJECTIVE OF THE STUDY

The aim of the study was assessing the dependence of antispastic therapy using the Urias air splint, affecting the spasticity of the affected upper limb, using the modified Ashworth scale (MAS). Another goal was assessing the impact of antispastic therapy on hand functionality and self-sufficiency in activities of daily living (ADL) using the Score of visual evaluation of hand grip strength test (SVH) and Barthel Index (BI).



Figure 1
Two-chamber air splint
for hand and wrist
(own photo)

METHODOLOGY

The examined group was a total of 20 probands, men of 14 and females 6. All of probands had a stroke (CVA) with clinically expressed right or left central hemiparesis and various degrees of spasticity of the upper limb. The average age was 59.5 years. The control group had 20 probands, 12 males and 8 females, after CVA with spastic hemiparesis. The average age was 60.0 years. All patients were been in stabilized state for 3-22 months since CVA (Table 1). The inclusion criteria of study were patients with CVA with spastic upper limb paralysis, where BTX-A was applied to the forearm muscles on average 7 days before the start of antispastic rehabilitation (divided into 500 units of Dysport into flexor digitorum superficialis et profundus, flexor carpi ulnaris, flexor pollicis longus).

After application of BTX-A, a six-week comprehensive rehabilitation was done in the Center of Medical Rehabilitation of Prostějov Hospital. The Prostějov's antispastic rehabilitation included initially two weeks of intensive institutional rehabilitation with initial examination. The divide into the experimental and the control groups (cohort) was made at the beginning of the constitutional rehabilitation randomly according to the birth number.

The constitutional rehabilitation was done daily according to the rehabilitation plan five days a week (Monday-Friday), it was distributed to the morning (1.5 hours) and afternoon hours (1.5 hours) and both physiotherapists and ergotherapists participated in it. The standard daily rehabilitation program included twice a day individual physiotherapy (30 minutes) after which Urias air cavities (30 minutes) were applied to the experimental cohort or a progressive manual stretching (30 minutes) in the control cohort. At the end, all of them had targeted ergotherapy (30 minutes). Inflatable Urias air splints (Figure 1) were applied

to the affected limb immediately after physiotherapy in a physiologically neutral position in the wrist and with full extension of the fingers of the hand. The Urias air splints were inflated to 30 mmHg and applied for 30 minutes. Progressive stretching was performed in the wrists and fingers of the affected limb to the maximum possible stretching of the spastic muscles. The stretching increased progressively until full muscle extent. The stretching took place for 30 minutes. After the completion of the institutional rehabilitation, four weekly antispastic outpatient rehabilitation followed (two times a week, 1.5 hours), with the same therapeutic principle as in the case of institutional rehabilitation. The final outcome assessment was conducted after outpatient rehabilitation.

Our study began on 3/2015 and ended in 12/2016. The study was initially contain 44 patients. The study was eventually completed by 40 probands (20 in the exposed group and 20 in the control group). All patients were acquainted with the course and reason for testing and agreed to participate in the study by signing informed consent. For the pre- and post-therapy evaluation, a clinical scale of spasticity was used – the modified Ashworth scale (MAS), questionnaires evaluating the ability of the patient to perform normal daily activities – Barthel Index (BI), and a test evaluating the handling functions of hand (the Score of visual evaluation of hand grip strength test SVH).

Measured data were statistically analyzed and was evaluated ($p < 0.05$) by the Student t-test for age, time of initiation of therapy, Mann-Whitney U test for MAS, BI, SVH and Chi-square test for nominal data (sex, type of CVA, disability lateralization). The relationship between spasticity and different (cohort) therapies was evaluated logistic regression analysis using the Odds Ratio (OR). The statistical analysis was performed using the NCSS11 program.

Table 1 Characteristic of the experimental cohort (with splint) and the control cohort (without splint)

Charakteristic	Patients with splint	Patients without splint	p
Analyzed patients N	20	20	NS
Age, years – mean (SD)	59.5 (± 9.8)	60.0 (± 9.5)	NS
Women / Men, N (%)	6 (30%) / 14 (70%)	8 (40%) / 12 (60%)	NS
CVA ischemia / haemorrhage, N (%)	18 (90%) / 2 (10%)	17 (85%) / 3 (15%)	NS
Hemiparesis right / left N (%)	12 (60%) / 8 (40%)	10 (50%) / 10 (50%)	NS
Time (months) of start of therapy since onset CVA, mean (SD)	13.5 (± 9.0)	12.9 (±10.1)	NS

Legend: CVA – stroke, SD – standard deviation, N – number, Min. – minimum, Max. – maximum, p – statistical significance, NS – non-significant value at significance level $p < 0.05$

RESULTS

Complex antispastic therapy with BTX-A and six-week rehabilitation has been leading to clinical and significant mitigation of spasticity (MAS), improvement of the manipulative function of the spastic upper limb (SVH-assessed) and overall self-sufficiency (BI assessed). This improvement has been observed in both cohorts (Table 2). The difference in the resulting has been stated between the two cohorts (group with air-splint vs. group without air-splint) was minimal, the BI parameter was non-significant, with MAS and SVH were nearly statistically significant at the significance level $p < 0.05$ (Table 2).

Based on the results of the regression logistic analysis, a significant dependence between the reduction of spasticity according to the MAS and Urias air splint therapy was being proven after six weeks of therapy – OR 4.0 (95% CI: 2.5-5.0) and conventional rehabilitation with progressive stretching – OR 1.5 (95% CI: 1.2-2.0) (Table 3).

Our study showed that patients, that were treated with BTX-A complex therapy and six-week standard rehabilitation with Urias splint, have a four times better chance of achieving a one degree decrease in spasticity of the fingers. Patients with BTX-A complex therapy and six weeks of standard rehabilitation with a progressive stretching have a 1.5 chance to reduce finger spasticity by one degree according to MAS.

DISCUSSION

The results of our study confirmed a significant dependence between air-splints therapy and reduction of hand spasticity in CVA patients. The study also

confirmed the dependence between standard rehabilitation therapy supplemented by progressive muscle stretching and reduction of hand spasticity. The Urias air splint therapy is a relatively new innovative method and is constantly extended by up-to-date scientific informations from the field of neuroscience. One of the few traceable air splints efficacy studies was a randomized study by Cambier (8) assessing the efficacy of intermittent pneumatic compression in the treatment of impaired hemiplegic upper limb in CVA patients. A randomized trial comprised 23 patients after CVA and compared the application of intermittent pneumatic compression treatment. In the experimental group of patients was done standard physiotherapy combined with intermittent pneumatic compression (10 cycles of 3 minutes with a maximum of 40 mmHg), on their hemiplegic upper limb. In the control group, in addition to conventional physiotherapy, placebo treatment was used, using fake short-wave therapy for 30 minutes on the hemiplegic arm. Somatosensory disorder was clinically evaluated three times in four weeks according to the Nottingham Sensory Assessment scale. The result was improvement of sensitization over time in both groups, with the experimental group improved by 81%, in the control group by only 31%. Cambier concluded that the use of intermittent pneumatic compression in rehabilitation of patients after a stroke may be clinically important for the recovery of somatosensory function. Similarly, reduction of spasticity and improvement of limb function (SVH) and self-sufficiency (BI) in complex therapy with air splints application can be observed in our observational study.

Table 2 Input and output data of spasticity and functional tests

Characteristic	Patients with splint (N = 20)	Patients without splint (N = 20)	p
MAS input, median, Min. – Max.	2 (3–1)	2 (3–1)	NS
MAS output, median, Min. – Max.	1 (2–1)	1+ (3–1)	0.049
BI input, Median, Min. – Max.	67 (40–85)	65 (35–90)	NS
BI Output, Median, Min. – Max.	75 (50–90)	74 (40–95)	NS
SVH input, Median, Min. – Max.	11 (7–16)	10 (6–17)	NS
SVH output, median, Min. – Max.	14 (9–18)	12 (7–18)	0.051

Legend: N – number of probands, Min. – minimum, Max. – maximum, MAS – the value of the modified Ashworth scale, BI – the value of the Barthel index, SVH – the value of the score of visual evaluation of hand grip strength test, p – the statistical significance, NS – non significant value at the significance level $p < 0.05$

Table 3 Logistic regression analysis of the effect of the monitored indicators on 1 degree improvement of spasticity according to MAS

Variable	OR (95% CI)
Air splint	4.0 (2.5–5.0)
Progressive stretching	1.5 (1.2–2.0)

Legend: OR – The odds ratio for a favorable result assessed in a 1 degree MAS change and its 95% confidence interval (CI)

Another study by Amini et al. (16) was comparing the therapeutic effect of combined upper limb splinting therapy and BTX-A versus only therapy with BTX-A or only splinting treatment. Within three months intensive therapy, the authors found no significant differences in the function of the upper spastic parietal limb. Significant reduction of spasticity in the wrist was observed and the change in the improvement of motor function of the upper limb in combination therapy with BTX-A and splinting against other groups, after three months of therapy. In our study, we observed similarly the greatest therapeutic effect in the combination of BTX-A and splint. Compared to the study of Amini et al. (with a volar/dorsal wrist fixed ortesis), we used the Urias air-splints for fixations in the neutral position of hand and we observed the effect of spasticity reduction already after six weeks treatment. A study by Pizzi et al. (17) was describing the positive effects of three-month wrist fixation therapy in alleviating spasticity of the elbow and wrist, improving the range of momentum and alleviating wrist pain in patients four months after CMP with spastic hemiparesis. Similarly, in a case study by Denham (18), a good antispastic and functional outcome following BTX-A combined therapy, ergotherapy and applying splints (fixed brace) is observed. Our study also shows good results after combined therapy. Better results, however, are observed after a comprehensive Urias air splint therapy. These effects are being caused by the complex action of the air splint not only by mechanical pressure, but also by an anti-oedematic effect, by the influence of microcirculation and by positive thermal action (the heated air created by inflating the splint).

LIMITS

The study limit was a relatively small number of probands, so the study was conceived as an observational cohort describing the occurrence of a dependence.

CONCLUSION

Combined antispastic therapy has a positive effect on the reduction of spasticity of the affected upper limbs in stroke patients. In our work, a significant dependence of BTX-A combined therapy with the Urias air splint has been demonstrated with the reduction of spasticity of the upper limb fingers. This relationship (by reducing spasticity and combined BTX-A therapy with air splint) is more significant than BTX-A combined therapy and standard rehabilitation with progressive stretching.

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