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Case Report

Combined effects of botulinum toxin type A and repetitive transcranial magnetic stimulation with intensive motor training immediately after injection in a patient with chronic stroke: A case report

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ABSTRACT

Study Design: Single case report.
Introduction: A previous study clarified that spasticity and motor function were improved by combined treatment with botulinum toxin type A (BTX) injection and 1-Hz repetitive transcranial magnetic stimulation (rTMS) with intensive motor training at 4 weeks after injection. However, it is not clear whether 1-Hz rTMS with intensive motor training immediately after BTX injection also improves spasticity and motor function in stroke patients.
Purpose of the Case Report: The purpose of this case report is to test the short- and long-term effects of BTX injection and rTMS with intensive motor training on the spasticity, motor function, and usefulness of the paretic hand in a stroke patient.
Methods: A 64-year-old male, who suffered from a right cerebral hemorrhage 53 months previously, participated in the present study. BTX was injected into the spastic muscles of the affected upper limb. He then received the new protocol for a total of 24 sessions. The Modified Ashworth Scale (MAS), Fugl-Meyer Assessment (FMA), and Motor Activity Log, consisting of the amount of use and quality of movement scales, were assessed before and immediately after BTX injection, at discharge, and monthly for up to 5 months after discharge.
Results: For the short-term effects of the therapy, the MAS scores of the elbow and wrist, FMA score, and quality of movement score improved. For the long-term effects of the therapy, the MAS score of the fingers, FMA score, and amount of use score improved for up to 5 months after discharge.
Conclusions: The present case report showed the improvement of all assessments performed in the short and/or long term and suggest the possibility of shortening the intervention period of combined therapy of BTX and rTMS with intensive motor training.

Introduction

Spasticity is characterized by a velocity-dependent increase in resistance to passive movements in stroke patients.[1] The severity of spasticity is related to the improvement of upper limb motor function.[2] Botulinum toxin type A (BTX) has been used for the control of spasticity.[3] BTX acts on neuromuscular

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junctions within 24 hours after injection, and its effects are most prominent at 4-8 weeks after injection, with sustained beneficial effects observed for at least 12-16 weeks.[2,4-6] Bhakta et al reported that the score of the Modified Ashworth Scale (MAS) improved following BTX injection in stroke patients with spasticity.[3]

As a method for stroke rehabilitation, repetitive transcranial magnetic stimulation (rTMS) has been used to change the excitability of the human cortex. Low-frequency rTMS (ie, 1 Hz or less) suppresses cortical excitability.[7] In stroke patients, low-frequency rTMS applied to the contralesional primary motor cortex (M1) pathologically reduced transcallosal inhibition and improved the spasticity and motor function of the affected hand after mild stroke.[8] In more recent clinical studies, combination therapy of low-frequency rTMS and intensive motor training on the paretic hand has been proposed to improve the motor function of patients with mild to severe stroke.[9,10]

Subsequently, Kakuda et al proposed a protocol for combined treatment of BTX injection and 1-Hz rTMS with intensive motor training at 4 weeks after injection, when the effect of BTX becomes most prominent; they found that the motor function of the paretic hand was improved for up to 1 month.[11] However, it is not clear whether 1-Hz rTMS with intensive motor training immediately after BTX injection also improves the motor function of the paretic hand in stroke patients in the short and long term. In other words, the effect of combined therapy with both BTX and rTMS with intensive motor training without waiting to maximize the effect of BTX is not clear.

Purpose of the case report

The purpose of his paper is to report the short- and long-term effects of 1-Hz rTMS with intensive motor training immediately after BTX injection on the spasticity, motor function, and usefulness of the paretic hand in a stroke patient.

Materials and methods

Case

A 64-year-old male, who suffered from a right cerebral hemorrhage 53 months previously, participated in the present intervention. He was discharged after receiving 1-2 hours of standard rehabilitation every day for 6 months at an acute care and convalescent hospital. After discharge, 20- to 40-minute outpatient rehabilitation was performed twice weekly until the start of the present study for a total of 47 months. At the start of the intervention, at rest, his elbow, wrist, and fingers were flexed moderately (ie, approximate angles: elbow joint; 90°flexion, wrist joint; 15°palmar flexion, metacarpophalangeal joint; 40°flexion, proximal interphalangeal joint; 70°flexion, distal interphalangeal joint; 50°flexion, respectively). He was at a Brunnstrom stage II, and this was slightly more involved than the recommended stage (stage III to V) in a previous study.[9] In addition, he had mild sensory impairment in both the paretic upper and lower extremities, but no higher brain dysfunction was detected. He could walk using a cane and a double upright ankle foot orthosis; however, he needed assistance to perform other activities of daily living (ADLs) (eg, dressing and grooming activities) because of his upper limb paralysis. His goals for the ADL were to dry his face with a towel and to put his arm through a sleeve using both hands. He provided written informed consent to participate in this intervention, which was conducted after receiving approval from the ethical committee of our hospital.

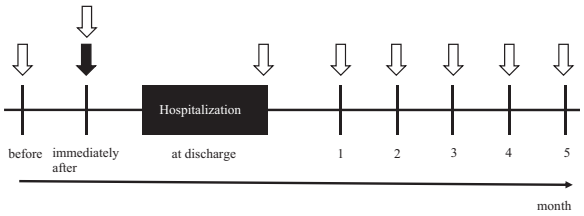

Fig. 1. Time schedule of this study. *Open arrows* indicate the timing of assessment. *Closed arrow* indicates BTX injection. BTX = botulinum toxin type A.

Procedure

Figure 1 shows the time schedule of this intervention. He received BTX injection into the spastic muscles of the affected upper limb at our hospital as an outpatient. Before and immediately after BTX injection, the spasticity and motor function of the affected upper limb were assessed to confirm the action of BTX. The next day, he was hospitalized to receive low-frequency rTMS with intensive motor training. For 2 consecutive weeks, excluding Sundays, a total 24 sessions (2 sessions per day) were conducted. At discharge, the spasticity and motor function of the affected upper limb were assessed again to evaluate the short-term effects of the intervention. After discharge, outpatient rehabilitation was performed on a twice-weekly basis. Daily self-exercise at home was encouraged. The same assessments were performed monthly for up to 5 months after discharge to evaluate the long-term effects of the intervention.

BTX injection

BTX (BOTOX; GlaxoSmithKline, Tokyo, Japan) was reconstituted with sterile normal saline (0.9%) to reach a total volume of 2.5 mL per vial. The physician assessed the patient with regard to the involved muscles by means of electromyography (EMG) needle electrode guidance, and the following muscles were selected for injection. The pectoralis major muscle was injected with 50 U BTX; the biceps brachii muscle was injected with 30 U; and the flexor carpi radialis muscle, flexor carpi ulnaris muscle, flexor digitorum superficialis muscle, flexor digitorum profundus muscles, flexor pollicis longus muscle, pronator teres muscle, and adductor pollicis muscle were each injected with 10 U. The maximum total dose of injected BTX was set to 150 U.

Repetitive transcranial magnetic stimulation

The patient was seated on a comfortable reclining wheelchair and asked to be as relaxed as possible. rTMS was performed using a transcranial magnetic stimulator (Magstim Super Rapid Magnetic Stimulator; Magstim Company, Dyfed, UK) with an air-cooled

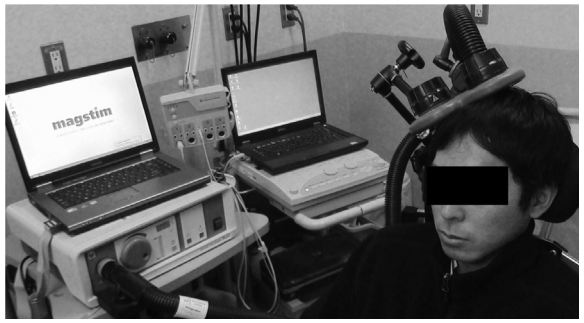

Fig. 2. Application of repetitive transcranial magnetic stimulation (rTMS). Coil is placed on the scalp to stimulate the hand area of the contralesional M1.

Table 1
Scores of the modified Ashworth scale

Variable	Before	Immediately after	At discharge	1 mo	2 mo	3 mo	4 mo	5 mo
Elbow	3	2	1	2	2	2	2	1
Wrist	4	3	2	3	3	3	3	3
Hand	3	3	3	2	1	1	1	1

Modified Ashworth Scale scores were assessed at the shoulder, elbow, wrist, and fingers with a 6-point ordinal scale ranging from 0 (no increase in muscle tone) to 5 (the affected part is rigid during flexion and extension).

figure-8 coil (9 cm outer diameter). rTMS was applied over the hand area of the contralesional M1 (ie, left side). The coil was placed tangentially to the scalp and oriented at a 45° angle from the mid-sagittal line. Stimulation frequency and intensity of rTMS were set to 1 Hz and 90% of the resting motor threshold in the unaffected hemisphere over the hand area of M1, respectively (Fig. 2). To determine the stimulus point and intensity, motor evoked potentials were recorded using surface EMG (MEB-9404; Nihon Kohden, Tokyo, Japan). Electrodes (1 cm diameter) were arranged over the belly of the first dorsal interosseous muscle in the right metacarpophalangeal joint of the index finger with an interelectrode distance of 20 mm. The ground electrode was placed around the right wrist. The EMG signals were amplified 1000-fold with 10-2000 Hz bandpass filtering and digitized at a sampling rate of 5 kHz. The resting motor threshold was defined as the lowest stimulator output required to elicit motor evoked potentials with a peak-to-peak amplitude of 50 μV in the first dorsal interosseous muscle in 5 out of 10 trials.[12]

Intensive motor training

The individual program included static stretching exercises of the BTX injection muscles and repetitive bilateral and unilateral task training (eg, pushing a box on a table using both hands, putting the paretic hand on the top of a table and grasping the small ball and stick, and so forth), which was approached with progressively increasing difficulty to suit the motor function of the paretic hand. He used associated reactions with therapist assistance to perform these tasks because he could not flex and extend fingers actively. As part of the individual program, ADL training was also performed according to the patient's aims (eg, drying his face with a towel, putting his arm through a sleeve using both hands and holding a tooth-brush). After discharge, he continued to perform the self-training according to the individual program received in the hospital as much as possible at home (eg, wiping the table using both hands, stretching his fingers, and grasping the small ball and stick). Immediately after discharge, he used associated reactions with family assistance to perform these tasks. As motor recovery of paretic hand progressed, he increased proportion of active movement.

Assessment

The scores of the MAS and Fugl-Meyer Assessment (FMA) for the upper extremity were used as primary outcomes of spasticity and motor function, respectively. The Motor Activity Log (MAL) was used as a secondary outcome to evaluate the usefulness of the paretic hand. All assessments were performed by the same therapist throughout this experiment.

In the MAS evaluation, the shoulder, elbow, wrist, and fingers were assessed.[13] The degree of resistance to passive muscle stretch that was felt by the examiner was scored on a 6-point ordinal scale ranging from 0 (no increase in muscle tone) to 5 (the affected part is rigid during flexion and extension).

In the FMA,[14] 33 items were used to evaluate upper limb motor function. Since each item is rated on a 3-point ordinal scale (0 = cannot perform, 1 = can perform partially, and 2 = can perform fully), the maximum score for upper extremity motor performance was 66 points.

The MAL is a semi-structured interview used to assess real-world outcomes.[15] The MAL consists of the amount of use (AOU) and quality of movement (QOM) scales. AOU measures how often a patient uses an affected extremity in the ADL, which was scored on a 6-point ordinal scale ranging from 0 (never use the affected arm for this activity) to 5 (always use the affected arm for this activity). QOM measures how well a patient uses an affected extremity in the ADL, which was scored on a 6-point ordinal scale ranging from 0 (inability to use the affected arm for this activity) to 5 (ability to use the affected arm for this activity as well as before the stroke). Both AOU and QOM scales consist of 14 items. The present study used both the individual and mean scores of AOU and QOM.

Results

The MAS, FMA, and MAL (AOU and QOM) scores over time are shown in Tables 1-4. Before BTX injection, the patient had severe or moderate spasticity in the upper extremity (MAS scores: elbow flexor, 3; wrist flexor, 4; and finger flexor, 3), which affected upper limb function (FMA score: 14 points). As an example, he could not extend his paretic elbow or wrist and flex/extend fingers actively. The results of the MAL (AOU and QOM) indicated that he could not fully use the paretic hand for the ADL.

As a confirmation of the action of BTX, it decreased the spasticity of his paretic elbow, wrist, and fingers (MAS score from 3 to 2, 4 to 3, 3 to 2, respectively) and consequently improved motor function (FMA score from 14 to 16 points).

With regard to the short-term effects of the intervention (comparison between before treatment and at discharge), it was easier to move his paretic elbow and wrist to some extent during passive movement, whereas no change was observed for his fingers (MAS score from 3 to 1, 4 to 2, 3 to 3, respectively). The coordination of the paretic shoulder and elbow joint movements also improved (FMA score from 14 to 19 points). The results of MAL indicated that the QOM score increased gradually (from 4 to 6 points), whereas the AOU score did not improve (from 4 to 4 points).

With regard to the long-term effects of the intervention (comparison between monthly results for up to 5 months after discharge), it was easier to move his fingers to some extent during passive movement (MAS score from 3 to 1). Conversely, his paretic

Table 2
Scores of the upper limb Fugl-Meyer Assessment

Variable	Before	Immediately after	At discharge	1 mo	2 mo	3 mo	4 mo	5 mo
Shoulder/elbow/forearm	14	16	18	20	21	20	21	22
Wrist	0	0	0	0	0	0	0	0
Hand	0	0	0	1	1	4	4	4
Coordination/speed	0	0	1	0	0	0	0	0
Total	14	16	19	21	22	24	25	26

Scores for the upper extremity component of the Fugl-Meyer Assessment can range from 0 to 66 points. Each item (33 in total) is rated on a 3-point ordinal scale (0 = cannot perform, 1 = can perform partially, and 2 = can perform fully).

Table 3
Scores of the amount of use (AOU) scale

Variable	Before	Immediately after	At discharge	1 mo	2 mo	3 mo	4 mo	5 mo
1. Hold a book, journal, or magazine/turn pages for reading	0	0	0	1	1	2	2	2
2. Use a towel to dry face or other part of the body	1	1	1	1	1	2	2	3
3. Pick up a glass	0	0	0	0	0	0	0	0
4. Pick up a toothbrush and brush teeth	/	/	/	/	/	/	/	/
5. Shaving/make-up	/	/	/	/	/	/	/	/
6. Use a key to open a door	/	/	/	/	/	/	/	/
7. Letter writing/typing	/	/	/	/	/	/	/	/
8. Steady oneself while standing	3	3	3	3	3	3	3	3
9. Put an arm through a sleeve of clothing	0	0	0	1	2	2	2	3
10. Carry an object in one hand from place to place	0	0	0	0	0	0	0	0
11. Pick up a fork or spoon and use for eating	/	/	/	/	/	/	/	/
12. Comb hair	/	/	/	/	/	/	/	/
13. Pick up a cup by its handle	0	0	0	0	0	0	0	0
14. Button clothes	0	0	0	0	0	0	0	0

AOU measures how frequently the patient uses an affected extremity in the ADL. AOU was scored on a 6-point ordinal scale ranging from 0 (never use the affected arm for this activity) to 5 (always use the affected arm for this activity). The mean score is calculated by adding the rating scores for each scale and dividing the total by the number of items assessed. If the patient did not perform the task in the ADL, the rater used a diagonal line (/) in the table to indicate its absence.

elbow and wrist did not change and were at almost the same level at the end of the intervention as at the beginning. The coordination of the paretic shoulder and elbow joint movements improved gradually (FMA score from 19 to 26 points). The AOU score increased gradually (from 4 to 11 points), whereas the QOM score was almost at the same level (from 6 to 7 points).

Discussion

The aim of this case report was to test the short- and long-term effects of 1-Hz rTMS with intensive motor training immediately after BTX injection on the spasticity, motor function, and usefulness of the paretic hand in a stroke patient. The results indicated the improvement of all assessments in the short- and/or long-term and suggest the possibility of shortening the intervention period of combined therapy of BTX and rTMS with intensive motor training because the waiting period to maximize the effects of BTX injection has not been defined.

Regarding the short-term effects of the intervention, the MAS score in elbow and wrist flexion, FMA scores, and QOM score in MAL improved to almost the same level as observed in a previous study that used rTMS with intensive motor training at 4 weeks after BTX injection.[11] A previous biochemistry study showed that BTX inhibits acetylcholine release, which requires 24-72 hours to take effect, reflecting the time necessary to disrupt synaptosomal processes. The effect of BTX is prominent for 4-8 weeks, and sustained beneficial effects of BTX are observed for 12-16 weeks.[4,6] These results suggest that it is not necessary to have a waiting period to maximize the effects of BTX to improve spasticity by combined therapy of BTX and rTMS with intensive motor training. However, the MAS score in finger flexion did not improve, which was different from the results of a previous study.[2] Although it is not fully clear why the MAS score did not improve only in finger flexion, shortening of the intrinsic and extrinsic muscles might be one of the limiting factors for improving spasticity. In the present case, his paretic fingers were not able to move actively and were always flexed, thereby shortening the intrinsic and extrinsic muscles. A previous study suggested that a reduced range of joint motion due to contractures might also limit the reliability of the MAS.[16] For the improvement in the FMA, many previous studies suggested a positive relationship between decreased spasticity and functional improvement in the upper extremities. Mizrahi et al suggested that upper extremity spasticity interferes with voluntary motor function and the ADL.[17] Wei et al showed a fair to moderate correlation between the MAS and motor function in patients with chronic stroke.[18] In addition, rTMS with intensive motor training might also contribute to increase the FMA score. Previous studies showed that motor function was improved by combination therapy of low-frequency rTMS over the contralesional hemisphere and intensive motor training on the paretic hand. For example, Kakuda et al used low-frequency rTMS with 120-minute intensive motor training every day during 15-day hospitalization in patients with mild to

Table 4
Scores of the Quality of Movement (QOM) scale

Variable	Before	Immediately after	At discharge	1 month	2 months	3 months	4 months	5 months
1. Hold a book, journal, or magazine/turn pages for reading	0	0	1	1	1	1	1	1
2. Use a towel to dry face or other part of the body	1	1	1	1	1	1	1	1
3. Pick up a glass	0	0	0	0	0	0	0	0
4. Pick up a toothbrush and brush teeth	/	/	/	/	/	/	/	/
5. Shaving/make-up	/	/	/	/	/	/	/	/
6. Use a key to open a door	/	/	/	/	/	/	/	/
7. Letter writing/typing	/	/	/	/	/	/	/	/
8. Steady oneself while standing	3	3	3	3	3	3	3	3
9. Put an arm through a sleeve of clothing	0	0	1	1	1	1	1	2
10. Carry an object in one hand from place to place	0	0	0	0	0	0	0	0
11. Pick up a fork or spoon and use for eating	/	/	/	/	/	/	/	/
12. Comb hair	/	/	/	/	/	/	/	/
13. Pick up a cup by its handle	0	0	0	0	0	0	0	0
14. Button clothes	0	0	0	0	0	0	0	0

QOM measures how well a patient uses an affected extremity in the ADL. QOM was scored on a 6-point ordinal scale ranging from 0 (inability to use the affected arm for this activity) to 5 (ability to use the affected arm for this activity as well as before the stroke). The mean score is calculated by adding the rating scores for each scale and dividing the total by the number of items assessed. If the patient did not perform the task in the ADL, the rater used a diagonal line (/) in the table to indicate its absence.

moderate hemiplegia and reported the improvement of upper limb motor function.[9] Conversely, the AOU score did not change in the present case. This result agrees with that of the previous study by Kakuda et al, which suggested that the real-world usefulness of the affected upper limb was augmented in the usual ADL but not in the clinical setting.[11]

Regarding the long-term effects of the intervention, the MAS score of his paretic fingers, FMA score, and AOU score improved. The improvement of the MAS score of his paretic fingers and FMA score might be caused by maximization of the effect of BTX and constant outpatient rehabilitation with self-training. Sun et al reported that constraint-induced movement therapy after BTX injection improves motor function and spasticity in stroke patients from baseline to after 6 months.[19] The improvement of the FMA score in our case might have contributed to the improvement of the AOU score because the AOU score is highly correlated with motor function.[20] Although it is not fully clear why the QOM score did not change, one of the underlying factors might be the patient's self-disciplined personality, that is, he had a tendency to give a lower QOM score, which is a qualitative and subjective evaluation.

Conclusion

This case report showed the short- and/or long-term effects of 1-Hz rTMS with intensive motor training immediately after BTX injection on the spasticity, motor function, and usefulness of the paretic hand in a patient with severe hemiplegia after stroke. As the waiting period to maximize the effects of BTX injection has not defined previously, the results of this case suggest the possibility of shortening the intervention period of combined therapy of BTX and rTMS with intensive motor training. However, the present work was a single case study and did not include a control group. To confirm the generalizability of these results, a future study should increase the number of cases and include a control group to test the effects of the present intervention.

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1. The intervention included
   a. intensive motor training
   b. BTX injection
   c. rTMS
   d. all of the above
2. The study design was
   a. RCTs
   b. qualitative
   c. a case report
   d. a case series
3. Outcomes were measured with the following
   a. QOM, AOU, FMA, and MAS
   b. ABC, CDE, FGH, IJK
   c. DASH
   d. Mayo Stroke Assessment Index
4. The patient was initially evaluated as being a stage _____ on the Brunnstrom hand assessment
   a. I
   b. II
   c. III
   d. IV
5. While not conclusive, the authors expressed enthusiasm for the combined protocol
   a. false
   b. true

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