뇌신경재활

발표일시 및 장소 : 10 월 18 일(금) 14:25-14:35 Room B(5F)

OP2-2-2

Randomized controlled trial of 1Hz rTMS over contralesional M1 for motor recovery in subacute stroke

Won-Seok Kim[1*], Bum Sun Kwon[2], Han Gil Seo[3], Jihong Park[1], Nam-Jong Paik[1†]

Seoul National University College of Medicine, Seoul National University Bundang Hospital, Department of Rehabilitation Medicine[1], Dongguk University College of Medicine, Department of Physical Medicine and Rehabilitation[2], Seoul National University Hospital, Seoul National University College of Medicine, Department of Rehabilitation Medicine[3]

Objective

We aimed to investigate whether 1Hz repetitive transcranial magnetic stimulation (rTMS) over the contralesional motor cortex (M1) versus sham rTMS could improve arm function in hemiplegic patients with subacute stroke when combined with motor training.

Methods

Subjects are enrolled from three university hospitals. Total 77 patients were enrolled and allocated to either real rTMS (n=40) or sham rTMS (n=37). We delivered 1 Hz 30-min active or sham repetitive transcranial magnetic stimulation to contralesional M1 before each of ten 30-minute occupational therapy sessions over a 2-week period, with outcomes measured at immediately and 1 month after the end of treatment (Fig. 1). The primary endpoint was the changes in the box and block test (BBT) score immediately after the end of treatment. Secondary analyses assessed changes on the upper extremity functional assessments immediately and 1 month after the end of treatment, including Fugl-Meyer assessment, finger tapping test (FTT), Brunnstrom stage, grip strengths, modified Ashworth scale and the Korean version of modified Barthel Index. Full analysis (FAS) (n=73) and per protocol (PP) analysis (n=69) were used for efficacy analysis. Intention to treat analysis (ITT) (n=76) was used for safety analysis.

Results

Changes in BBT immediately after the end of treatment was not statistically different between the two groups but in the PP analysis, BBT score 1 month after the end of treatment was higher in real rTMS group (16.9 in real and 11.9 in sham, p=0.038) and finger tapping score was also higher in real rTMS group (p=0.046) (Table 1). However, none reached statistical significance after Bonferroni correction. In the subgroup analysis according to the cortical involvements, real rTMS showed better improvements of BBT, FTT, Brunnstrom stage of hand and pinch grip strength only in the group with no cortical involvements (n=52 in FAS analysis, n=50 in PP analysis) (Fig. 2). Adverse outcomes were not statistically different between the two groups in ITT analysis.

Conclusion

There was no significant difference between the active and sham rTMS trial arms in our multicenter randomized controlled trial among patients within 3 months post-stroke. However, low-frequency rTMS over the contralesional M1 showed the tendency for the better long-term recovery of fine hand motor function and seems more effective in patients with no cortical involvements. The lesion location of stroke has to be considered in the clinical application or further clinical trials to use low-frequency rTMS for motor recovery.

Acknowledgment :This research was supported by a grant of the Korea Health Technology R&D Project through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea (grant number: HI15C0832).

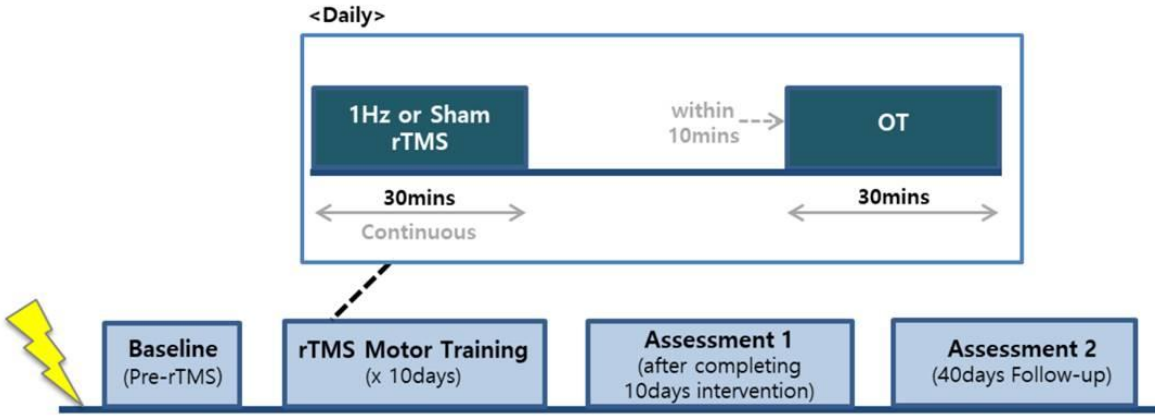

Figure 1. Experimental design.

Table 1. Changes in outcome scores from baseline after treatment (Per protocol analysis set (n=35 in real rTMS group and n=34 in sham rTMS group))

	Change (EOT-Baseline)	P-value	Change (1Mo – Baseline)	P-value
Box and block test				
Real rTMS	11.3 (8.0)	0.176	16.9 (9.7)	**0.038**
Sham rTMS	8.9 (6.7)		11.9 (9.7)	
Upper extremity FMA				
Real rTMS	10.4 (7.5)	0.549	15.1 (10.9)	0.518
Sham rTMS	9.2 (8.2)		13.3 (11.7)	
Finger tapping test				
Real rTMS	6.4 (6.9)	0.913	11.9 (8.7)	**0.046[a]**
Sham rTMS	6.6 (7.4)		8.6 (10.9)	
Hand grip strength (lbs)				
Real rTMS	10.0 (12.7)	0.313	9.5 (12.4)	0.229
Sham rTMS	7.2 (10.0)		13.5 (15.1)	
Pinch grip strength (lbs)				
Real rTMS	2.6 (3.0)	0.184	3.5 (3.6)	0.074
Sham rTMS	1.8 (2.2)		2.1 (2.7)	
Lateral prehension (lbs)				
Real rTMS	3.4 (3.4)	0.352	4.7 (4.6)	0.403
Sham rTMS	2.7 (2.9)		3.8 (4.2)	
Three jaw chuck (lbs)				
Real rTMS	2.9 (3.0)	0.347	3.6 (3.6)	0.519
Sham rTMS	2.2 (3.0)		3.1 (3.4)	
Brunnstrom stage, hand				
Real rTMS	0.5 (0.6)	0.196	0.9 (0.9)	0.656
Sham rTMS	0.4 (0.6)		0.8 (0.8)	
K-MBI				
Real rTMS	14.3 (10.2)	0.706	21.5 (12.6)	0.504
Sham rTMS	15.4 (13.1)		24.1 (18.4)	

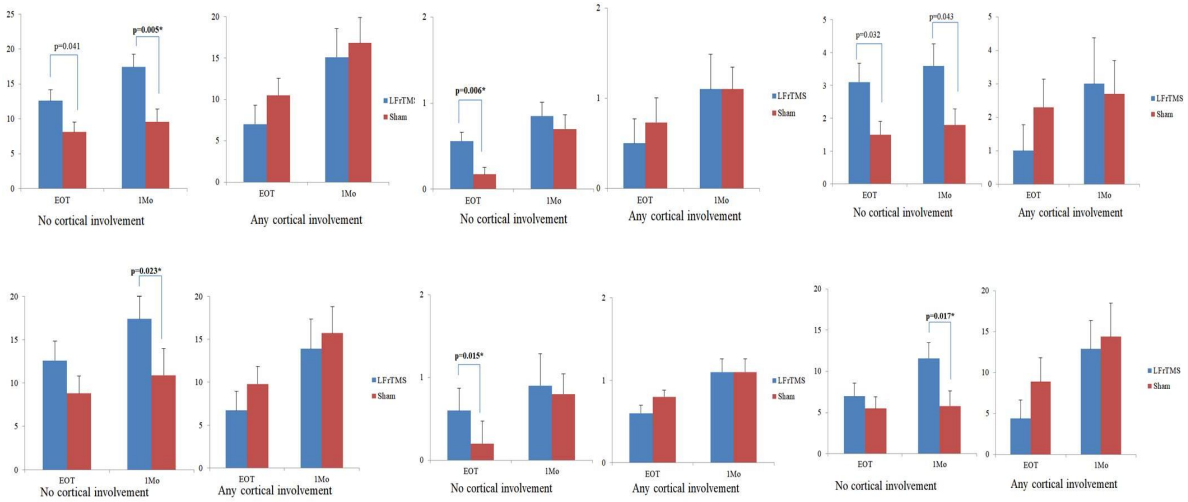

Figure 2. Changes in outcome scores from baseline after treatment. FAS: any cortical involvements (n=21, LFrTMS=9, sham=12), no cortical involvement (n=52, LFrTMS=27, sham=25). PP: any cortical involvements (n=19, LFrTMS=8, sham=11), no cortical involvement (n=50, LFrTMS=27, sham=23). *p<0.025 after Bonferroni correction.