뇌신경재활

게시일시 및 장소 : 10 월 18 일(금) 13:15-18:00 Room G(3F)

질의응답 일시 및 장소 : 10 월 18 일(금) 15:45-16:30 Room G(3F)

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The safety of cord blood therapy in stroke patients according to duration of immunosuppression

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Introduction

Stroke causes significant neurological sequelae, however, perfect treatment is not available yet. Previous studies reported umbilical cord blood (UCB) therapy showed positive functional recovery. UCB therapy is usually accompanied by immunosuppressive therapy, because side effects such as graft versus host failure can occur without the administration of immunosuppressants. However, when immunosuppressants are administered, adverse events (AEs) may occur or UCB therapy may be less effective. This study is to evaluate the safety and efficacy according to the duration of administration of immunosuppressants in the treatment of umbilical cord blood in subacute stroke patients.

Methods

Five patients with stroke with 1 month after the onset were included. A single intravenous infusion of allogenic UCB selected by criteria of immune compatibility and cell number was performed. Two patients received oral immunosuppressant for 1 week, and 3 others received immunosuppressant for 2 weeks. All adverse events are standardized into System Organ Class and Preferred Term by using the latest version of Medical Dictionary for Regulatory Activities. To measure the efficacy, National Institutes of Health Stroke Scale (NIHSS), motor and cognitive function were assessed at baseline, 3 months, and 6 months after UCB therapy.

Results

The demographic characteristics of the subjects are summarized in Table 1. As a safety issue, there were no serious AEs related to UCB and duration of immunosuppressant administration. Twenty AEs (14 types) were reported in 4 of 5 patients. The most common AEs were diarrhea, elevated liver enzyme, and headache (Table 2). As for the efficacy, NIHSS, motor function, and cognition tended to improve. In case of patient 2, the improvement by UCB treatment was slight due to the good initial function (Figure).

Conclusions

UCB treatment was safe regardless of the duration of immunosuppressant administration. There was no difference in the efficacy of UCB treatment depending on the duration of immunosuppressant administration. The results of this study may be a reference for UCB therapy protocols. Further studies with a larger number of patients are needed.

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Table 1. Patients characteristics

	Group	Age	Sex	Brain lesion	Type of stroke	From onset to treatment (months)	UCB cell count
Patient 1	1	42	M	Right basal ganglia	Hemorrhage	6	$15.1X10^8$
Patient 2	1	65	M	Right MCA territory	Infarction	13	$16.0X10^8$
Patient 3	2	36	M	Right basal ganglia	Hemorrhage	10	$15.7X10^8$
Patient 4	2	46	M	Right basal ganglia	Hemorrhage	15	$16.3X10^8$
Patient 5	2	52	M	Right thalamus	Hemorrhage	7	$16.3X10^8$

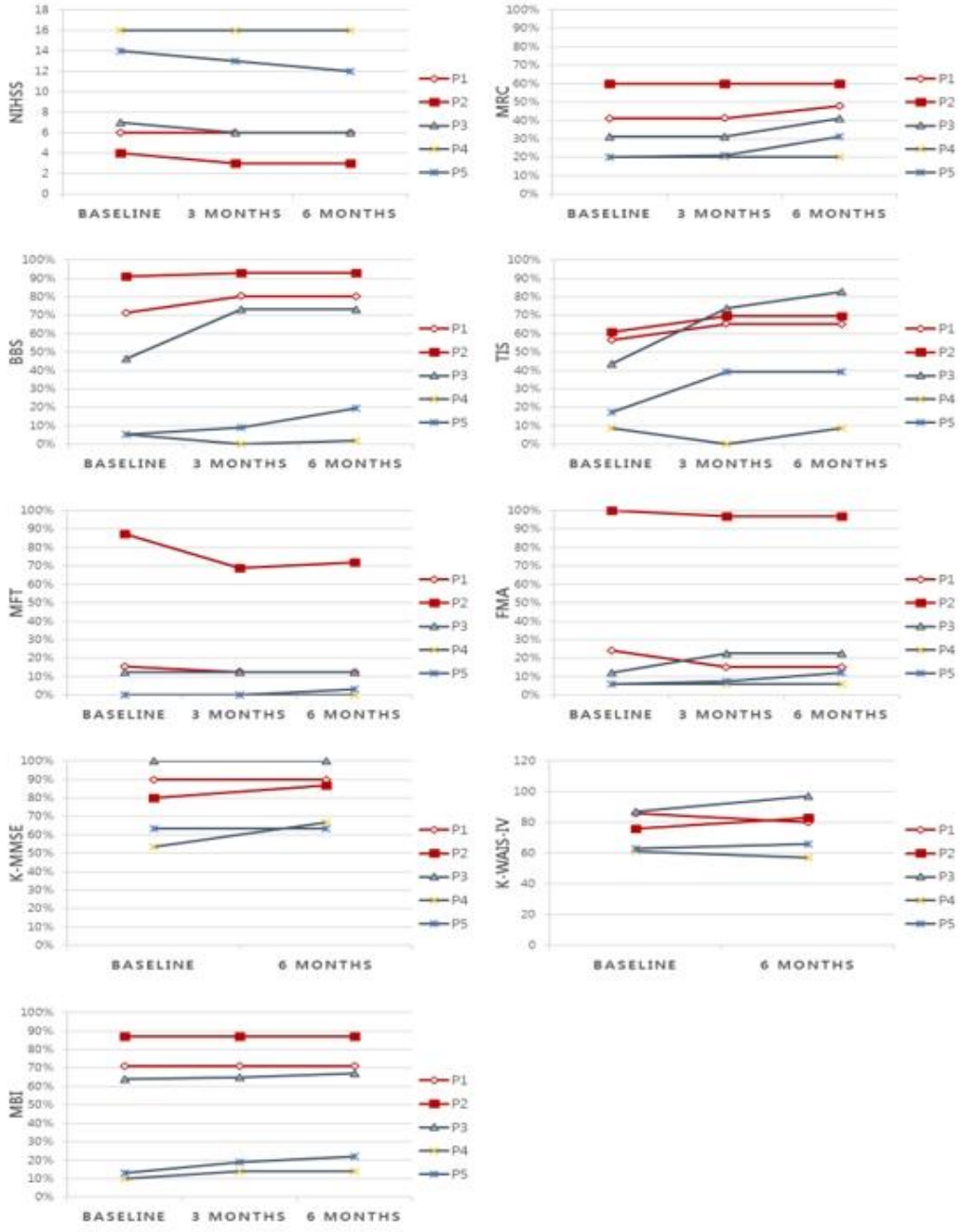
Group 1 was administrated immunosuppressants for one week. Group 2 was administrated immunosuppressants for two weeks. MCA, Middle Cerebral Artery

Table 2. Adverse events

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Gastrointestinal disorders					
Aphthous ulcer				+	
Abdominal pain				+	
Constipation					+
Diarrhea			+	+	+
Dyspepsia			+		
Vomiting				+	
Infections and infestations					
Folliculitis				+	
Investigations					
Aspartate aminotransferase increased				+	+
Alanine aminotransferase increased				+	+
Musculoskeletal and connective tissue disorders					
Back pain				+	
Shoulder pain	+			+	
Neck pain				+	
Nervous system disorders					
Headache	+		+		
Skin and subcutaneous tissue disorders					
Pruritus			+		

The source of terminology was Medical Dictionary for Regulatory Activities (MedDRA) 21.1.

Figure. Changes in functional evaluation after umbilical cord blood administration



Red line is group 1 administrated immunosuppressants for one week. Blue line is group 2 administrated immunosuppressants for two weeks. NIHSS, National Institutes of Health Stroke Scale; MRC, Medical Research Council; BBS, Berg Balance Scale; TIS, Trunk Imbalance Scale; MFT, Manual Function Test; FMA, Fugl-Meyer Assessment; K-MMSE, Korean Mini Mental State Exam; K-WAIS-IV, Korean Wechsler Adult Intelligence Scale-IV; MBI, Modified Barthel Index