ISSN 2434-0758
J.Asia.Reha.Sci.

Journal of Asian Rehabilitation Science

Vol.5 No.3 August 2022

Journal of Asian Rehabilitation Science

The Society of Asian Rehabilitation Science

The Journal of Asian Rehabilitation Science (ISSN 2434-0758) is published for the Society of Asian Rehabilitation Science. The journal is published quarterly.

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The Journal of Asian Rehabilitation Science
Vol.5 No.3, August
2022

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J. Asi. Reha. Sci.5(3): 29–36,2022

The Journal of Asian Rehabilitation Science

Original Article

Effect of Deep Local Core Muscles Activation Exercise on Low Back Pain During Pregnancy：A Randomized Controlled Trial

SU THIRI, PT, MS[1)], AYE AYE THANT, PT, Ph.D[1)], MYO THUZAR KHIN, MD, Ph.D[1)]

1) Department of Physiotherapy, University of Medical Technology, Yangon, Ministry of Health, Republic of the Union of Myanmar

(Lower Mingalardon Road, Aung San, Insein, Yangon, Myanmar)

Abstract: [Purpose] The present study aimed to determine the effect of activation of deep local core muscles on low back pain (LBP) during pregnancy. [Participants and Methods] 46 participants (gestational ages between 24 and 30 weeks) with LBP from Antenatal Clinic and Physiotherapy Department of Central Women's Hospital, Yangon were randomly assigned to the experimental group (EG) (n = 23) or the control group (CG) (n = 23). Participants in the EG received deep local core activation by using abdominal draw-in maneuver (ADIM) plus conventional physiotherapy (CE) while those in the CG received only CE. All participants carried out the respective exercise program twice daily for four weeks. Before and after four weeks of intervention, pain intensity and functional disability were assessed by using the Visual Analog Scale (VAS) and the Roland Morris Disability Questionnaire (RMDQ), respectively. [Results] After four weeks of intervention, participants in both EG and CG reduced mean VAS ($p < 0.001$) and the mean RMDQ ($p < 0.001$). However, there was no significant difference in reduction of pain intensity ($p = 0.959$) and functional disability ($p = 0.720$) of participants between 2 groups. [Conclusion] The deep local core activation exercise has no additional effects in terms of pain and disability of pregnant women with LBP.

Keywords: low back pain, pregnant women, abdominal draw-in maneuver, deep local core activation exercise

(This article was submitted March.13, 2022, and was accepted June.15, 2022)

I. INTRODUCTION

Low back pain (LBP) during pregnancy is one of the most common issues in the pregnant female body [1)]. The European Guidelines define LBP as the pain between the 12th rib and the gluteal fold [2)]. The global prevalence is reported to range from 24% to 90% with the most common onset in the 5th and 6th month of pregnancy [3, 4)]. Pain intensity is increased while pregnancy progress [4)] and generally worse in the evening [3, 5)]. About 80% of them have pain intensity high enough to stop their daily living activities which may lead to the functional limitations and lower quality of life [6)]. These functional limitations can affect pregnancy and labour outcomes [7)]. Although the back pain resolves within 12 weeks after delivery in most women, some women who have a high pain intensity during pregnancy can get persistent pain after delivery [8)] which can affect them physically and emotionally [9)]. Therefore, it is important to reduce the intensity of pain in women with LBP during the antenatal period.

The cause of pregnancy related LBP is considered multifactorial such as hormonal, mechanical, and others [2)]. During pregnancy, pelvic girdle ligaments, especially sacroiliac ligaments, become loose due to the increased hormone relaxin causing a decrease in stability and strain in the pelvic girdle and low back area [10)] by increasing shear forces on pelvic and lumbar spine [2, 3)]. The decreased joint stability may be

*Corresponding author: SU THIRI (suthiri.grace@gmail.com)

compensated for by enhancing deep local core muscles activity [11]. The enlarged uterus can result in postural changes which alter the load and biomechanics of the body [12] and stretches the abdominal muscles causing reduced strength and ability to maintain posture [10, 13].

As there is a correlation between core muscle strength and the intensity of pain and disability associated with LBP during pregnancy [14], exercises to maintain core muscle strength are important.

The local and global core muscles are responsible for stabilization of the spine and performance of movements, respectively [15]. Transversus abdominis (TrA) muscle, one of local core muscles, is responsible for lumbar stability and sacroiliac joint stability [16]. Local core muscles, TrA and lumbar multifidus (LM), can be activated by ADIM which can induce the co-contraction of LM and TrA muscle[17]. CE, the pelvic tilt exercise and Kegel exercise, include global core muscles (rectus abdominis, external oblique, erector spinae, latissimus dorsi and pelvic floor muscles) training exercises which are routinely recommended for LBP during pregnancy [18]. Although a meta-analysis demonstrated that core stability exercise is more effective in decreasing pain and improving physical function than general exercises in the non-pregnant population[19, 20], it still needs to be known for the pregnant population. Moreover, a systematic review states the need for further study for the lack of strong evidence in the treatment of LBP during pregnancy[4]. Therefore, the present study aimed to determine the effect of deep local core muscle activation exercise on reducing the pain intensity and disability associated with LBP during pregnancy

II. PARTICIPANTS AND METHODS

This hospital-based randomized controlled study was conducted at the Antenatal Clinic and Physiotherapy Department of Central Women's Hospital, Yangon from April, 2019 to August, 2020. Inclusion criteria were pregnant women between the ages of 20 years and 50 years, gestational period between 24 weeks and 30 weeks at first visit. In this study, participants having LBP with moderate pain intensity, VAS score of 4 to 7, were included because those having severe LBP (VAS score of greater than 7) need to take rest and other management [21, 22]. Pregnant women having delivery of more than twice were excluded because women having more than two births may have persistence or intermittent LBP due to severe LBP in previous pregnancies [8]. Participants were excluded if they had a history of LBP prior to pregnancy, had a history of premature labour, had persistent bleeding, had a seizure disorder, had an incompetent cervix, had pregnancy induced hypertension, had poorly controlled diabetes and had gestational diabetes. For ethical consideration, this study was approved by the Institutional Review Board of the University of Medical Technology, Yangon (IRB/UMTY/2-2019/010).

The sample size was calculated based on the difference in the mean changes of VAS [23] assuming 90% power by using the formula [24]. A sample size required was 22 for each group, this was increased by 5% because of drop out. Therefore, total sample size required for this study was 46.

Eligible participants were invited to participate in the study. They were explained the treatment procedures and asked to sign the written informed consent forms. The present study used VAS for pain intensity and RMDQ for functional disability which were assessed before and after four weeks of an exercise program. After that, participants were randomly assigned into 2 groups: EG (n = 23) and CG (n = 23). VAS is a validated, subjective measure which can be easily applied to evaluate pain intensity [25]. It is scored from 0 (no pain) to 10 (maximum pain). It has been widely used for evaluating pain intensity in a population of pregnant women. Test-retest reliability has been shown to be excellent and also has excellent internal consistency [26, 27]. RMDQ is 24 items self-reported measure that reflects limitations in different activities of daily living in a participant with LBP. Score 0 represents no disability whereas score 24 represents maximum disability. Psychometric properties of the RMDQ are excellent for all types of LBP [28] and also appropriate for use in pregnant women[4]. The principal investigator assessed all outcome measures and systematically trained the respective exercise program for one session at the study area. Figure 1 shows the flow diagram of the study.

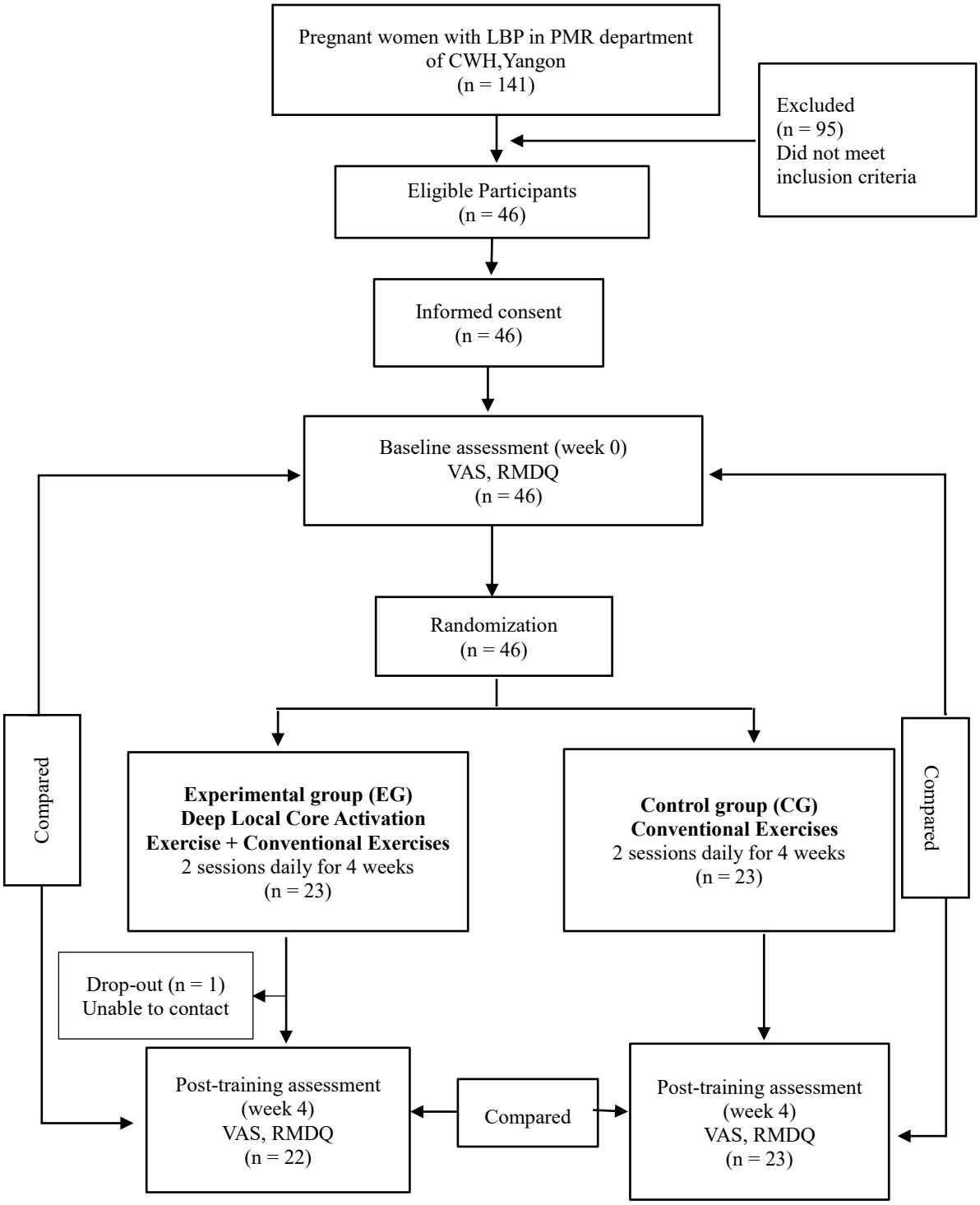

Figure 1 Study flow diagram

Participants in both groups were given warm up exercises for about 5 minutes and CE. Warm up exercises include breathing exercise, and upper limb and lower limb mobilization exercises. CE were pelvic tilt exercise and Kegel exercise. The pelvic tilt exercise was performed by positioning the participant in supine lying with knees 90° of flexion with feet flat on the floor. She was instructed to draw-up the lower abdominal muscles thereby flattening the lumbar spine and hold for 5 seconds followed by a relaxation period of 10 seconds. The Kegel exercise was performed with the starting position of sitting on the chair with the legs apart. The participant was instructed to tighten the pelvic floor as if attending to stop the urine flow, hold this for 5 seconds and relax for 10 seconds. She was instructed to perform pelvic tilt exercise 10 times and Kegel exercise 5 times each session for 2 sessions a day for up to four weeks.

Deep local core activation exercise, ADIM, was added for the participants in EG. ADIM was performed 10 times a session, 2 sessions a day for four weeks. The participant was positioned in supine lying with knees 90° of flexion. Inflatable cuff of standard sphygmomanometer was placed between lumbar lordosis and floor and then inflated to 40 mmHg. To know the contraction of the TrA muscle, the participant was asked to place her hand on the medial side of the superior anterior iliac spine. She was instructed to breathe in to elevate the abdomen and then slowly draw the lower abdomen toward the spine while breathing out. She held the contraction of her lower abdomen for 5 seconds with normal breathing while maintaining a pressure of 40 mmHg on the sphygmomanometer. After that, she relaxed for 10 seconds.

All participants carried out the exercise program as home exercise twice daily for four weeks. They were given a log sheet to record their home exercises and were requested to make a mark regularly after the exercises. At week-2 follow up, the investigator checked the home exercise performance. Advice on postural awareness was given to all participants.

Data analysis was carried out by using the statistical package for social science (SPSS) software version 16. For the categorical data, frequency and percentage were calculated. Chi square test or Fisher's exact test was used to compare the background categorical data. For the continuous data, a mean (SD) was calculated. A student's t-test was used to compare the significant difference in VAS and disability scores between 2 groups. A paired t-test was used to compare VAS and disability scores before and after treatment in each group. The two tailed $p < 0.05$ was considered statistically significant.

III. RESULTS

Although there were 46 eligible participants, one of the participants from EG was unable to be contact for after intervention assessments and was considered to be drop-out. Table 1 shows the demographic data of the participants. Before and 4 weeks after intervention, the pain intensity and functional disability were assessed by using VAS and RMDQ, respectively. When compared with before intervention, participants in both EG ($n = 22$) and CG ($n = 23$) showed a significant reduction in VAS ($p < 0.001$) and RMDQ ($p < 0.001$) after 4 weeks of intervention. Nonetheless, there was no significant difference in the mean VAS ($p = 0.959$) and the mean RMDQ ($p = 0.720$) of participants between EG and CG after 4 weeks of intervention. Tables 2 and 3 show the detailed results.

IV. DISCUSSION

The majority of participants in this study were aged between 20 and 35 years. Hicks (2005) stated that stabilization exercises for LBP with a non-pregnant population responded more effectively in those under 40 years of age [29]. The range of gestational age of the participants in this study was from 24 to 30 weeks. Although the pain intensity can increase as the pregnancy progress [4], the result of the present study showed the reduction of pain intensity occurred after 4 weeks of exercise intervention. Therefore, early intervention has a beneficial effect on the reduction of pain intensity in the later trimester. There was a positive correlation between pain intensity and disability in LBP during pregnancy [30]. As the intensity of pain reduced, the reduction of functional disability also occurred.

Table 1 Demographic characteristics of participants

Characteristics	EG (n = 22)	CG (n = 23)
Age (years)	30.27 ± 5.48	28.52 ± 6.15
Number of parity		
First parity	12 (54.5%)	14 (60.9%)
Second parity	10 (45.5%)	9 (39.1%)
Gestational age (weeks)	26.68 ± 1.91	25.95 ± 1.66
Nature of pain		
Intermittent	20 (90.9%)	17 (73.9%)
Continuous	2 (9.1%)	6 (26.1%)
Duration of low back pain (weeks)	7.91 ± 5.06	7.95 ± 4.92

Values are expressed as mean ± SD, and number (%), EG = Experimental group, CG = Control group

Table 2 Comparison of VAS and RMDQ of EG and CG

Outcomes	EG (n = 22)			CG (n = 23)		
	Week - 0	Week - 4	p-value	Week - 0	Week - 4	p-value
VAS	5.23 ± 1.11	0.36 ± 0.79	< 0.001*	5.09 ± 1.08	0.35 ± 0.88	< 0.001*
RMDQ	7.0 ± 3.69	0.32 ± 1.09	< 0.001*	6.0 ± 3.19	0.43 ± 1.08	< 0.001*

EG = Experimental group, CG = Control group, Values are expressed as mean ± SD,
VAS = Visual Analogue Scale, RMDQ = Roland Morris Disability Questionnaire

Table 3 Comparison of low back pain by Visual Analogue Scale and mean Roland Morris Disability Questionnaire between groups

Outcomes		EG (n = 22)	CG (n = 23)	p-value
VAS	Week - 0	5.23 ± 1.11	5.09 ± 1.08	0.670
	Week - 4	0.36 ± 0.79	0.35 ± 0.88	0.959
RMDQ	Week - 0	7.0 ± 3.69	6.0 ± 3.19	0.336
	Week - 4	0.32 ± 1.09	0.43 ± 1.08	0.720

EG = Experimental group, CG = Control group, Values are expressed as mean ± SD,
VAS = Visual Analogue Scale, RMDQ = Roland Morris Disability Questionnaire

When deep local core muscles are activated by using ADIM, the lumbopelvic stability is achieved by controlling intra-abdominal pressure [31, 32], transferring force to the lumbar spine through the thoracolumbar fascia [33], and increasing sacroiliac joint stability [34]. As the muscles are activated and strengthened, it provides compensation for the disturbed passive subsystem. In addition, the induced TrA contraction with LM can reduce the excessive lordosis and the pelvic tilt which is effective for treating LBP [35].

In the current study, the participants who received only CE also reported a significant reduction in pain and functional disability after 4 weeks of intervention. The pelvic tilt exercise is shown to reduce the intensity of pain from LBP during pregnancy [36]. Bi and coworkers stated that Kegel exercise can significantly reduce pain intensity of LBP in non-pregnant populations [37]. The result of the present study showed the reduction of pain intensity also in pregnant populations after 4 weeks of intervention. Exercises included in CE can strengthen the core muscles and provide the stabilization in the lumbopelvic region that cause the reduction of pain and disability [36, 38]. Pelvic tilt exercise recruits the global muscles [36] as well as strengthens or increases the flexibility of the muscles that need to compensate for the increased abdominal mass and maintain the normal posture [38]. This exercise also provides stabilization of the spine by stabilizing the pelvic against the anterior rotational forces and supporting the local muscles to stabilize the extension load on the spine or to control against external loads that cause backward bending and side bending of the spine [39]. Kegel exercise improves the pelvic floor muscles' strength to provide support to the uterus and other pelvic organs during pregnancy [18]. In response to perturbation, the pelvic floor muscles stabilize the trunk and control intra-abdominal pressure by using a feed-forward mechanism [37]. The results of present study revealed that the addition of ADIM to conventional exercises has no superior effect in terms of pain intensity and disability of pregnant women.

Some limitations in the present study are the relatively small sample size that makes it difficult to generalize the result, the use of only subjective outcome measures, cognitive and affective factors of pain were not assessed, did not include the group for ADIM only and the lack of differentiation between LBP and posterior pelvic pain.

ACKNOWLEDGMENTS

We sincerely thank all of the subjects and people concerned for their cooperation with our study.

FUNDING AND CONFLICT OF INTEREST

There are no conflict of interests to be disclosed in this study.

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Case Study

Effect of Using a Robotic Ankle-Foot Orthosis on Gait Function and Cerebral Blood Flow Dynamics in a Patient with Stroke Hemiplegia: A Single Case Study.

DAI KAWAKITA, RPT[1)], SHUHEI IIDA, RPT, PhD [1,2)], YUUDAI OKADA, RPT[1)], EMI SATO, RPT[1)]
YASUTOMO SAKAI, RPT, PhD[2)]

1) Department of Rehabilitation, Chiba Tokusyukai Hospital
(2-11-1Takanedai, Funabashi-shi, Chiba, Japan)
2) Department of Physical Therapy, Faculty of Medical Science for Health, Teikyo Heisei University

Abstract：[Purpose] To examine the gait function and cerebral blood flow dynamics after intervention using robotic ankle-foot-orthosis(R-AFO). [Subjects and Methods] The subject is a patient with stroke in the convalescent rehabilitation ward. Hemiplegia on the left side was observed and the lower extremity was with no ankle movement. Gait ability was watching level using a plastic AFO and a quad cane. The intervention consisted of 60-minutes standard-of-care physical therapy, followed by 20-minutes walking exercise using R-AFO, for a period of gait10 days. Gait function and Brunnstrom recovery stage evaluations were performed three times: preintervention, postintervention 1, and postintervention 2 (1 month later). Cerebral blood flow dynamics evaluation was performed after the intervention period. The functional near-infrared spectroscopy device was used for the measurement. [Results]The result of gait function evaluation showed that walking speed continuously improved after using R-AFO. Additionally, the left-right symmetry ratio of step lengths and one-leg support time also improved. Furthermore, cerebral blood flow dynamics of R-AFO walking improved significantly compared with those of ankle-foot orthosis walking. [Conclusion] Walking training using R-AFO was performed for one patient with stroke, and the walking function and cerebral blood flow dynamics on the lesion side improved.

Keywords: robotic ankle -foot orthosis, hemiplegia, functional near-infrared spectroscopy

(This article was submitted May.2, 2022, and was accepted July.4, 2022)

I. INTRODUCTION

Recently, rehabilitation using robots has been attracting attention. Furthermore, it helps patients perform accurate, repetitive, and voluntary exercises. This has the advantage that motor learning is effectively performed [1)]. Walking support robots can be broadly classified into two types: double-legged type that covers both lower limbs from the pelvis and each part type that assists the movement of each joint such as the knee, foot, and waist. Hybrid Assistive Limb (HAL®) medical lower limb type (Cyberdyne, Ibaraki, Japan) and Lokomat® (Hocoma, Volketswil, Switzerland) are famous double-legged walking robots. These have been reported to have effects such as improvement in walking speed by intervention in patients with stroke and patients with spinal cord injuries [2-5)]. However, there are few reports of randomized controlled trials on exercise effects and brain activity in robotic orthotic devices of each part type. One of the typical robots of each part type is an ankle-foot orthosis (AFO) device with electric assist. This includes the Ankle Assist Device [6)] (Yaskawa Electric Corporation) and RE-Gait® [7)] (Space Bio Laboratories).

*Corresponding author: DAI KAWAKITA (xgmny681@yahoo.co.jp)

These devices have a load sensor on the sole of the brace. Based on the sensor information, they assist the ankle plantar flexion and dorsiflexion movements during walking. They have three elements: sensor, control, and drive. Therefore, they are also called robotic AFO (R-AFO).

In the literature, there are reports of kinematic effects and cerebral hemodynamics of individuals with stroke hemiplegia using R-AFO. In the report of kinematic effects, 12 patients with stroke hemiplegia in the maintenance phase performed a 15-minute walking exercise using R-AFO twice a week for 4 weeks. As a result, the walking speed improved after the intervention [8]. It was also reported in a conference [9] that the walking speed, the left-right symmetry of step length, and the left-right symmetry of one-leg support time improved in patients with stroke in the convalescent phase. In the report of cerebral blood flow dynamics while using R-AFO, ten patients with stroke hemiplegia in the maintenance phase were presented. It was reported that the medial primary motor cortex on the lesion side significantly improved in the cerebral blood flow dynamics when using R-AFO compared to when using AFO [10]. However, there are no reports of cerebral blood flow dynamics of patients with stroke hemiplegic in the convalescent phase. The recovery phase of stroke is the time when plasticity occurs due to new networks between the cerebral cortex [11]. Rehabilitation interventions during this period are important for both physical function and brain plasticity. Measuring cerebral blood flow dynamics of patients with stroke in recovery phase is one of the basic studies for examining the link between physical function and brain plasticity. In brain function research using the fNIRS device, the measurement result may be affected by the setting of the task or the measurement environment. Each subject has a different head size and different skull thickness. Therefore, the measurement site of each channel of the fNIRS device is not exactly same in all subjects. Therefore, it is necessary to carefully analyze data and set tasks [12]. If the subject of research are patients with stroke in the convalescent ward, there are various effects not only the name of the diagnosis, the degree of paralysis, walking ability, but also the recovery process of the disease and so on. On the other hand, it is difficult to efficiently recruit similar cases if the setting conditions of subject are clarified and limited.

Therefore, in this study, a 10-day walking training using R-AFO was performed for a single case with convalescent stroke hemiplegia. Then, the gait function and cerebral blood flow dynamics after the intervention were examined.

II. PARTICIPANTS AND METHODS

1. Participants

The subject is a male in his 80s in the convalescent rehabilitation ward. He was diagnosed with cerebral infarction, and hemiplegia on the left side was observed. Magnetic resonance imaging showed a low absorption area in the cerebral peduncle of the right side (Fig. 1). The subject started early rehabilitation in the acute care ward from the day after the onset day. On the 18th day of onset, he was transferred to the convalescent rehabilitation ward.

The physical therapy evaluation on the day of transfer is shown below. The subject had stable vital signs and had no problems in communication or cognition in daily life. The Brunnstrom recovery stage [13] (Br. stage) was used to assess motor paralysis.Br. stage has three evaluations: upper limbs, lower limbs, and fingers.Brunnstrom classified stages of recovery into six stages, stage 1 is flaccidity and stage 6 is that there are isolated joint movements. Br. stage of the left side was as follows: arm: V, finger: V, and leg: III. Hemiplegia was severe in the lower extremities with no ankle movement. However, it was possible to flex and extend the lower limbs by synkinesis. Sensory dysfunction was not observed. The basic movement ability was possible at the watching level. The characteristic of the movement was the excessive effort of the upper and lower limbs on the nonparalyzed side. Gait ability was watching level using a plastic AFO and a quad cane. It was possible to walk about 20 m continuously, but changing direction was a little unstable that it sometimes took some assistance.

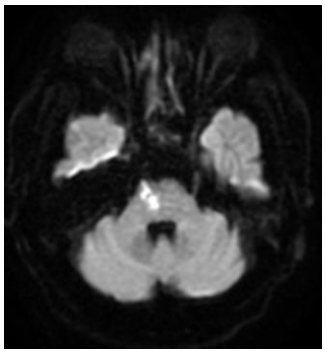

Figure 1 Study Flow Diagram

This study was approved by the Tokushukai Group Ethics Committee (Approval No. R01-029). The subject was informed of the research procedure in advance, and the measurements were conducted after obtaining written consent.

2. Methods

(1) Protocol

Figure 2 shows the study protocol. The study started on the 31st day after the onset. The intervention consisted of 60-minute standard-of-care physical therapy, followed by a 20-minute walking exercise using R-AFO (R-AFO exercise) for a period of ten days. Standard-of-care physical therapy exercises targeted range of motion, neurovascular function, balance, basic movements, and activities of daily living. R-AFO exercise consisted of 5 minutes for wearing and assist settings and 15 minutes for walking exercise. The walking exercise was 15 minutes including the break time, and the subject walked in the rehabilitation room about 50 m per lap. Breaks were set at 13 "slightly tight" levels on the Borg scale. The walking practice was restarted when the pulse rate became stable until the resting pulse. Quad cane was used as in standard physiotherapy. The only verbal instruction during walking was "raise your face". The subjects' walking exercises were performed at the watching level and were assisted only when danger was expected.

After the intervention, only 60-minute physical therapy was usually performed. Gait function and Br. stage (leg) evaluations were performed three times: preintervention, postintervention 1, and postintervention 2 (1 month later). Cerebral blood flow dynamics evaluation was performed after the intervention period.

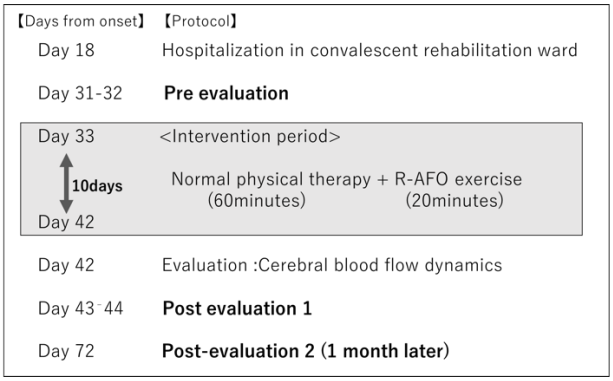

Figure 2 Protocol

(2) R-AFO

R-AFO used in this study was the Ankle Assist Device (CoCoroe AAD, Yaskawa Electric Corporation). CoCoroe AAD is a training device that assists the ankle joint movement during walking. This device is indicated for patients with ankle dorsiflexion dysfunction, such as stroke hemiplegia and fibular nerve palsy. It guides the heel contact at the initial contact and promotes the forward movement of the center of gravity from the loading response to the mid stance. It assists ankle dorsiflexion during the swing phase and promotes smooth lower limb movement. This subject had left hemiplegia, including ankle dorsiflexion dysfunction, and circumduction gait was observed in barefoot. Therefore, the intervention of R-AFO exercise was decided. It takes about 1 minute to wear the device and set it up. The AFO weight is 1.5 kg, and the controller part weight is 1.4 kg. This device has the following four assist settings: "sole sensor threshold," "walking speed," "angle of ankle joint," and "assist force." According to the subject's function or ability level, there are no rules or reports on assist settings. Therefore, each setting was adjusted based on the subject's gait in this study. This device is also for training in the rehabilitation room. Therefore, patients do not purchase this device and do not use it at home.

(3) Gait function evaluation

The gait function evaluation was performed three times: preintervention, postintervention 1, and postintervention 2 (1 month later). The main evaluation item was the 10 m walking test (seconds). It was measured once in each evaluation. To evaluate the distance factor, the stride length (m), the nonparalyzed step length (m), the paralyzed side step length (m), and the left-right symmetry ratio of the step lengths were used. To evaluate the temporal factor, the one walking cycle time (sec), the both-leg support time (sec), the one-leg support time of the nonparalyzed side (sec), the one-leg support time of the paralyzed side (sec), and the left-right symmetry ratio of the one-leg support time were used. The left-right symmetry ratio of the step length was the absolute value of [1 - step length of the paralyzed side / step length of the nonparalyzed side][14]. The left-right symmetry ratio of one-leg support time was also set to the absolute value of [1 - the one-leg support time of paralyzed side / the one-leg support time of the nonparalyzed side][15]. The subject's walking with a quad cane and a plastic AFO was watching level in the preintervention evaluation and the postintervention evaluation 1. The subject's walking with T-cane and without AFO was watching level in postintervention evaluation 2. A video camera (HC-WXF990M, Panasonic, Japan), which had a frame rate of 60 FPs, was used to record the gait. It was fixed to a tripod at the height of 50 cm and set 5 m from the walking line. The distance and the temporal factors were analyzed from the video images, using Dartfish Software (Dartfish Japan Co., Ltd.).

(4) Cerebral blood flow dynamics evaluation

The cerebral blood flow dynamics evaluation was performed after the intervention period. The functional near-infrared spectroscopy (fNIRS) device was used for the measurement. The fNIRS device emits near-infrared light from above the scalp into the skull and measures near-infrared light that has passed through the brain and exited from the skull. Using this method, fNIRS measures the concentration of total hemoglobin (Hb), oxygenated hemoglobin (oxy-Hb), and deoxygenated hemoglobin (deoxy-Hb) in the capillaries of the cerebral cortex. The data are not the absolute value of Hb but the relative value of the concentration change.

In this study, LIGHTNIRS (Shimadzu Corporation, Kyoto, Japan) was used. It is a portable device. Therefore, it was possible to measure brain activity during walking in a wireless environment without using a treadmill. Holders placed at 3-cm intervals in front, back, left, and right were placed from the forehead to the top of the subject's head. The analysis target regions were the left and right primary motor areas, the supplementary motor areas, and the left and right premotor areas. A total of 16 probes, 8 light transmitting probes (T1 to T8) and 8 light receiving probes (R1 to R8), were arranged in two sets of four columns and two rows. The measurement channels were 20. The Cz point in the international 10–20 method of electroencephalography (EEG) (the point where the bisecting point of the line connecting the nose root and the occipital nodule and the bisecting point of the line connecting the right and left preauricular points) is used for the measurement. The position of channel 2, which is the midpoint between T3 and R5, was set to Cz. Before the measurement, it was confirmed that light transmission and reception were performed normally in the setting of the fNIRS device. After stabilizing cerebral hemodynamics in all channels, a zero reset was performed, and the measurement was started. Brain functional localization was set as follows (Fig. 3): the right medial primary motor cortex was ch1 and 5; the right lateral primary

motor cortex was ch4; the left medial primary motor cortex was ch3 and 6; the left lateral primary motor cortex was ch7; the supplementary motor cortex was ch5, 6, 9, 12, 15, 16, and 19; the right premotor cortex was ch8, 11, 14, and18; the left premotor cortex was ch10, 13, 17, and 20.

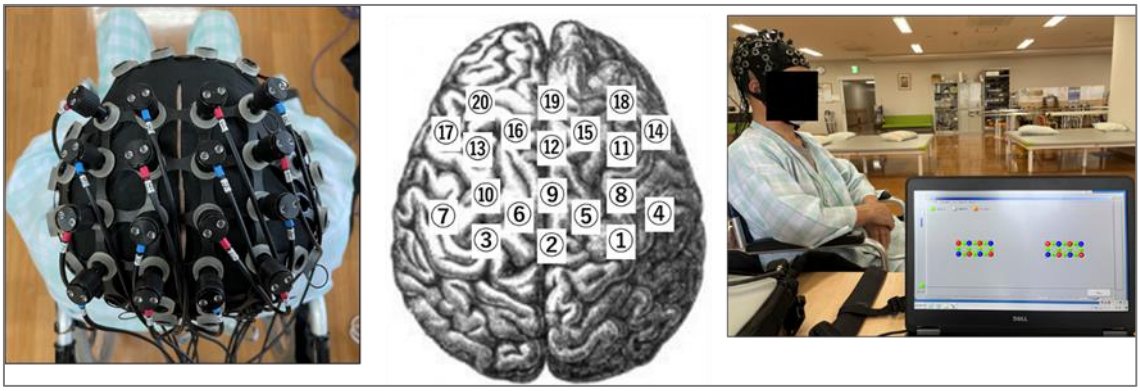

Figure 3 measurement area of fNIRS

The cerebral blood flow dynamics measurement was performed on a flat straight line for 20 seconds while walking (Figure 4). Task 1 was AFO walking, and Task 2 was R-AFO walking. Both tasks were performed after the rest standing position of 20 seconds and at the watching level using a quad cane to prevent falls. Additionally, the therapist had the fNIRS device and R-AFO controller.

Figure 4 Measurement scene of surface cerebral blood flow dynamics during walking while using R-AFO

(5) Analysis method

Regarding the gait function and Br. stage (leg) evaluation, a simple numerical analysis was performed on the values of each item of the preintervention evaluation, postintervention evaluation (1), and postintervention evaluation (2) (1 month later).

In this study, oxy-Hb was used as a local brain cortical activity index in assessing the surface cerebral blood flow dynamics because oxy-Hb best reflects brain activity associated with the task[12]. In previous research[16], there are statistically significant correlation between total-Hb and oxy-Hb signal and functional MRI signal, but deoxy-Hb signal did not show any correlation with functional MRI signal. An increase of total-Hb or oxy-Hb may reflect an increase of capillary beds. A decrease of deoxy-Hb may reflect an increase of blood flow velocity at capillary level. Therefore, this study used oxy-Hb as an index of local brain cortical activity. Based on the obtained results, the baseline correction was performed between resting standing (20 seconds) before and after the task. Sampling was 13 times/sec. First, The oxy-Hb average value in the resting standing before tasks (20 seconds. number of data in each channel: 2600) was set to baseline. Second, the oxy-Hb average value for the tasks (20 seconds. number of data in each channel: 2600) was calculated for each channel. Then, the amount of change in oxy-Hb value was calculated for each channel. Finally, the amount of change in the oxy-Hb value of each channel between Task 1 and Task 2 (number of data in each task and each channel: 2600) was compared. Statistical analyses were performed using SPSS version 22 (IBM, Armonk, NY, USA). Furthermore, a normal distribution test, Shapiro–Wilk's test, was performed to confirm that both results were normal distribution. After confirmation, a paired t-test was performed. The significance level was less than 5%.

III. RESULTS

Table 1 shows the evaluation results of gait function and Br. stage (leg).

Evaluation items (unit)	Pre	Post①	Post②
10m walking test (sec)	19.6	11.9	8.7
<distance factor>			
the stride length (m)	0.98	1.16	1.08
the non-paralyzed step length (m)	0.42	0.51	0.52
the paralyzed side step length (m)	0.56	0.65	0.56
the left-right symmetry ratio of the step lengths (value)	0.25	0.22	0.08
<temporal factor>			
the time of one walking cycle time (sec)	1.57	1.53	1.31
the time of both leg support (sec)	0.60	0.47	0.37
the one leg support time of non-paralyzed side (sec)	0.53	0.57	0.48
the one leg support time of paralyzed side (sec)	0.43	0.50	0.46
the left-right symmetry ratio of the one leg support time (value)	0.23	0.13	0.05
Br. stage (Leg stage)	V	V	V

In the 10 m walking test, a significant improvement was seen in post evaluation 1, and a continuous slight improvement was observed in post evaluation 2 (1 month later). In terms of distance factor, stride length continuously improved in post evaluation 1 and post evaluation 2 (1 month later). The left-right symmetry ratio of the step lengths continuously improved in post evaluation 1 and post evaluation 2 (1 month later). Furthermore, no clear left-right difference was observed in post evaluation 2 (1 month later). In terms of temporal factor, the time of one walking cycle continuously improved in post evaluation 1 and post evaluation 2 (1 month later). The left-right symmetry ratio of the one-leg support time continuously improved in post evaluation 1 and post evaluation 2 (1 month later). Furthermore, no clear left-right difference was observed in post evaluation 2 (1 month later). In each evaluation, Br. stage was all V level.

Regarding the result of cerebral blood flow dynamics, the amount of changes in oxy-Hb is shown in Table 2. In all ch except ch2 and ch10, R-AFO walking improved significantly compared to AFO walking.

Table 2 The amount of changes in oxy-Hb

ch	AFO Walking			R-AFO Walking			
1	0.015	±	0.005	0.021	±	0.015	*
2	0.030	±	0.02	0.030	±	0.02	
3	0.006	±	0.003	0.023	±	0.015	*
4	0.015	±	0.004	0.020	±	0.013	*
5	0.012	±	0.005	0.017	±	0.014	*
6	0.005	±	0.003	0.016	±	0.011	*
7	0.026	±	0.014	0.030	±	0.018	*
8	0.013	±	0.005	0.017	±	0.01	*
9	0.013	±	0.01	0.017	±	0.011	*
10	0.022	±	0.012	0.023	±	0.013	
11	0.013	±	0.004	0.018	±	0.011	*
12	0.007	±	0.004	0.013	±	0.009	*
13	0.009	±	0.004	0.012	±	0.01	*
14	0.015	±	0.004	0.019	±	0.013	*
15	0.011	±	0.005	0.015	±	0.008	*
16	0.014	±	0.01	0.016	±	0.008	*
17	0.067	±	0.018	0.204	±	0.124	*
18	0.013	±	0.009	0.018	±	0.012	*
19	0.017	±	0.011	0.030	±	0.018	*
20	0.010	±	0.005	0.008	±	0.011	*

NOTE. Values are represented as mean ± standard deviation

The unit of oxy-Hb are represented as mM・cm.

＊: $p < 0.05$

IV. DISCUSSION

In this study, a 10-day walking training using R-AFO was performed for a single case with convalescent stroke hemiplegia. Additionally, the gait function and cerebral blood flow dynamics after the intervention were examined. This study is a single case study, but there is a novelty. To the best of our knowledge, this is the first report of the improvement in gait function and the observation of cerebral blood flow dynamics in patients with convalescent stroke using R-AFO.

The result of gait function evaluation showed that the walking speed continuously improved after using R-AFO. Additionally, the left-right symmetry ratio of step lengths and one-leg support time also improved. In stroke rehabilitation, the effectiveness of orthotic therapy from an early stage has already been proposed [17]. AFO is the most commonly used lower limb brace for stroke with hemiplegia. It has been confirmed that it is effective in improving standing stability and walking speed and reducing walking energy costs [18-20]. In addition to the normal AFO functions such as fixing and braking, R-AFO has an assist function. In motor learning, the amount of exercise and its repetition are important factors [21]. In this study, it is considered that repeated exercise using R-AFO for 10 days improved walking efficiency. As a result, the 10 m walking test and the left-right symmetry ratio of the step length and the one-leg support time improved. Furthermore, regarding the continuous improvement in post evaluation 2 (1 month later), it is possible that the 10-day repetitive practice was carried over after the intervention period. In other words, the ankle movements learned using R-AFO may have been maintained during normal walking practice after the intervention.

In the result of cerebral blood flow dynamics evaluation, R-AFO walking improved significantly compared to AFO walking. There are the primary motor area, the premotor area and the supplementary motor area in the motor-related areas of the frontal lobe of the measurement area in this study. The primary motor area is involved in the representation of voluntary movement. The primary motor area is orderly arranged (in an inverted fashion) from the toe (at the top of the cerebral hemisphere) to mouth (at the bottom) along a fold in the cortex called the central sulcus [22]. The primary motor area integrates inputs from the higher motor cortex [23] (premotor area, supplementary motor area, and cingulate motor area) and parietal cortex [24] that are involved in voluntary motor programming, resulting in a final motor command. And it output this to the lower centers (brain stem and spinal cord). Supplementary motor areas are cortical motor areas that occupy medial area of 6 area in the Brodmann brain map in the frontal lobe of the cerebral cortex[22]. The representative role of supplementary motor area is "the start of spontaneous exercise [25] ", "choice of exercise sequence [26]" and so on. The premotor area is located anterior to the primary motor area, lateral to the supplemental motor area, and posterior to the prefrontal area [27]. The representative role of the premotor area is to perform a motion associated with visual information and to Control coordinated movements [28, 29].

There are two points of novelty in this result. The first point is that there was a significant increase in the motor-related areas on the lesion side, especially near the medial primary motor cortex (ch1 and 5) in R-AFO group. There is report of brain activity during walking in patients with stroke hemiplegia. There is a decrease in the activation of the primary motor cortex on the lesion side. And activation of a wide frontal lobe motor area, including the premotor cortex on the lesion side, was observed [30]. After the intervention period at R-AFO, it is expected that there was some effect around the medial primary motor cortex, which is the area of the lower limbs on the lesion side. The other point is that the significantly increased regions were symmetrical. There is also report of comparisons of cerebral blood flow dynamics with and without AFO in patients with stroke [31]. It has been reported that the activity of motor-related areas on the lesion side was limited in AFO walking compared to walking without AFO. However, the areas that were significantly increased in the AFO walking group were not symmetrical. This was considered to be related to the improvement of the left-right symmetry ratio of the step length and the one-leg standing time in the gait evaluation.

This study has some limitations. First, this is a single case study. Therefore, it is uncommon for all patients with stroke. Second, the subject is a patient with a convalescent stroke. Therefore, even if R-AFO was not used, it is possible that similar results were obtained using normal AFO and physiotherapy. Then, there is the interpretation of the results of the f NIRS device. The result of this study is the average brain activity during each task for 20 seconds. Therefore, various factors are involved, including the effects of the stance and swing phases and the psychological effects such as nervousness. Finally, assessment of cerebral hemodynamics was performed only after the R-AFO intervention period. Therefore, it is not possible to examine the aspect of changes in cerebral blood flow depending on the time.

In the future, randomized controlled trials will be needed to verify the effectiveness of R-AFO. It is expected to be a new option as one of the assistive devices in rehabilitation treatment.

ACKNOWLEDGMENTS

The authors would like to thank Enago (www.enago.jp) for the English language review.

FUNDING AND CONFLICT OF INTEREST

The authors declare no conflicts of interest associated with this manuscript.

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