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Aims and scope

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1. Medical Technology
2. Physical Therapy
3. Occupational Therapy
4. Radiologic Technology
5. Communication Disorders
6. Other related fields

Submitted manuscripts within the scope of the journal will be processed strictly following the double-blinded peer review process of the journal. Therefore, the final decision can be completed in 1-3 months average, depending on the number of rounds of revision.

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- **Original articles** must not exceed 15 journal pages (not more than 3,500 words), including 6 tables/figures, and 40 reference (maximum 40, recent and relevant).
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Effects of home-based breathing exercise on heart rate variability, cardio-ankle vascular index, respiratory muscle strength and maximum oxygen consumption in female participants with normal weight obesity

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ABSTRACT

Background: Obesity causes autonomic imbalance and decreases exercise capacity, which limit exercise and physical activity. Normal-weight obesity (NWO) is defined as normal body mass index (BMI), but increased body fat percentage (BF%) associated with cardiorespiratory impairment in early adulthood. The benefit of slow breathing has shown to enhance cardiorespiratory functions in overweight and generally obese people. Moreover, the slow breathing affects to the heart rate variability (HRV), cardio ankle vascular index (CAVI), respiratory muscle strength and indirect maximum oxygen consumption (indirect VO_2max) has not been studied in female individuals with NWO.

Objectives: To determine the effects of slow breathing exercise on HRV, CAVI, respiratory muscle strength and VO_2max in female participants aged 20-30 years, who have normal BMI (18.5-22.9 kg/m^2, n=19 each group) and high body fat (BF) (BF ≥30%), compared with a control group, which carried out routine physical activity.

Materials and methods: Participants with NWO were divided randomly into two groups: control and intervention group, which performed breathing exercise at home. All of the participants were measured for body composition, blood pressure, HRV and CAVI. An electronic pressure transducer and cycle ergometer were applied to assess respiratory muscle strength and indirect VO_2max. All measurements were recorded before and after 4 weeks when completely intervention. The demographic data between the groups was analyzed the significant difference by using the independent t test. The data at baseline and four weeks after intervention was determine by two way ANOVA. *P*-value less than 0.05 was considered statistically significant.

Results: Participants with NWO, who received breathing exercise at home, showed lower autonomic imbalance, and systolic blood pressure, whereas improved maximum inspiratory pressure (MIP), but no statistical change in maximum expiratory pressure (MEP), indirect VO_2max, CAVI or ankle brachial index (ABI) (p>0.05).

Conclusion: Slow breathing exercise can improve autonomic balance and inspiratory muscle strength in physically inactive female NWO participants.

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Introduction

Obesity is a major contributing factor in public health problems worldwide. A previous study indicated accumulated excessively regarding body fat percentage (BF%) associated with the risk of unhealthy and illness.[1] At present, the number of individuals with normal body mass index (BMI) and high body fat (BF), known as normal weight obesity (NWO), has increased in developing and undeveloped countries.[2] NWO may be prevalent in up to one-third of Asian individuals and has higher risk of causing cardiovascular diseases (CVD).[2,3]

Heart rate variability (HRV) which represents the balance of autonomic function can be used to predict the risk of disease or likelihood of death due to CVD.[4] The cardio ankle vascular index (CAVI) is a noninvasive parameter that indicates abnormality of the artery in the preclinical stages of diseases.[5,6] The adverse effect of overweight and obesity on autonomic function and arterial stiffness has been observed in numerous studies.[7-9] Individuals with normal BMI, with high BF%, tend to have greater risk of CVD due to unaware that underlying health risk behavior.[10] A normal body shape without any signs and symptoms of disease has not been diagnosed, could lead to a misleading perception of exercise. Thus, it is important to recognize and promote exercise before diseases progression.[3]

Maximal oxygen consumption (VO_2 max) is an indicator reflect to the physical fitness, which presents maximum capacity of an individual's body to carry oxygen through the vascular system to active muscles during exercise or performing physical activity.[11] The circulatory and respiratory systems are controlled by the autonomic nervous system (ANS) and important for the maintenance of physical daily life. High BF% is associated with lower lung volumes and respiratory function in young adults.[12] Demand for ventilation, increased work of breathing, respiratory muscle inefficiency and low respiratory compliance are respiratory complications in obesity.[13] Overweight and obese subjects often experience increased breathlessness and decreased efficiency of respiratory muscle function during exercise, which contribute to dyspnea, and consequently avoidance of exercise.[13,14]

The beneficial effects of slow breathing exercise at 6 breaths per min have demonstrated improvement in respiratory efficiency, arterial oxygen saturation and decreased respiratory effort.[15] A study by Rachatakarn *et al*. showed that slow deep breathing exercise improved maximum inspiratory muscle strength in younger individuals, but the study recruited a small number of participants (i.e. n=5-6 per group) and conducted in a laboratory setting. Fifty percent of all the participants dropped out because the experimental center was located inconveniently, and transportation, travel time and cost were an obstacle to regular participation in physical activity and exercise.[16,17] Additionally, previous studies showed the improvement of HRV, blood pressure and breathing pattern.[18,19] Thus, this study investigated the effects of slow breathing on HRV, CAVI, respiratory muscle strength and VO_2max in inactive NWO female volunteers, who were aged 20-30 years. It also promoted exercise at home.

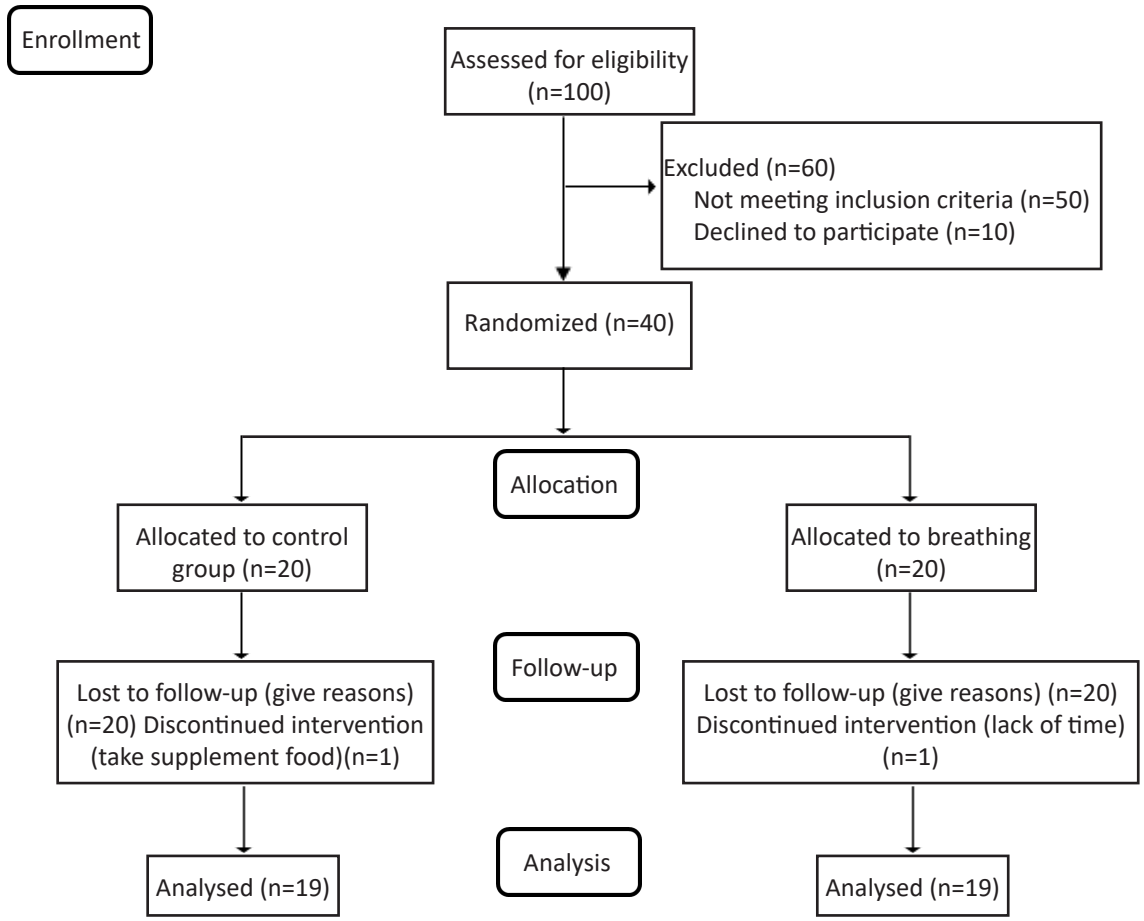
Materials and methods

Participant recruitment

Eligible participants from Naresuan University and nearby Thapho subdistrict, Muang district, Phisanulok, Thailand had enrolled for this study. The inclusion criteria included female participants, aged 20-30 years, with normal BMI (18.5-22.9 mL/kg^2)[20] and high BF (≥30%),[20,21] who performed moderate intensity exercise less than 30 minutes for 5 days per week (150 minutes per week) or vigorous intensity exercise less than 25 minutes for 3 days per week (75 minutes per week).[22,23] The exclusion criteria were as follows: people who smoke or had underlying cardiopulmonary, neurological and musculoskeletal disease, and general obesity, characterized by 25 kg/m^2. Subjects who supplemented stimulating beverages, such as alcohol, caffeine or drugs that stimulate the central nervous system (CNS) within 48 hours before the experiment, and including participants who could not completely follow the protocol were excluded.[23,24] In addition, participants who had mind–body training such as yoga, Qigong and meditation were also excluded from this study. This study was performed at the Research Laboratory, Department of Physical Therapy, Faculty of Allied Health Sciences, Naresuan University, according to the tenets of the Declaration of Helsinki and approved by the Naresuan University Institutional Review Board (IRB No.219/62). The calculation of the sample size was based on the previous mean maximum inspiratory pressure (MIP) results from the study of Rachatakarn et al. (2016).[16] The sample size was set the confidence level at 0.50, the power of the test at 0.80. The result was 16 participants per group. With the 20 percent dropout rate considered, the calculation indicated that the study required at 20 per group. All of the participants received a full explanation of the protocol and possible consequences of the experiment before signing an informed consent form and participating in the study.

Procedures

The participants were divided randomly into two groups: intervention and control (CON) (n=19 per group). The study design was randomized, experimental study, single blind intervention in physically inactive female participants with NWO. The effects of slow deep breathing on HRV, CAVI, respiratory muscle strength and indirect VO_2max were investigated. All of the participants practiced slow deep breathing at home, with a 1:1 allocation rate, according to the block plan generated by the website (www.randomization.com). Randomization was concealed by using a block randomization technique (4 participants per block) by a researcher. Allocation was performed before commencing the study program.



Experimental design

The participants were interviewed using a questionnaire and the demographic data included age, gender, occupation, personal medical history, smoking status and physical activity level. The vital signs, anthropometric composition, HRV, respiratory muscle strength and indirect VO_2max of the participants were recorded before and after 4 weeks of intervention by cardio-thoracic technologists, physiotherapist, research assistants. The participants were given written instructions, necessary information and a diary for recording exercise during the intervention period. All participants were followed to confirm completion of the protocol and ensure all the necessary information was recorded through telephone communication.

Home-based breathing exercise

The participants were instructed to put their dominant hand on their abdomen and non-dominant hand on their upper chest. All of them followed the same instruction for the breathing exercise, using a metronome application on their smart phone. Then they were instructed to slow deep breath with four seconds of inspiration and six seconds of expiration periods, and then one minute of rest interval period by a physical therapist who has more than four years of cardiopulmonary clinical experience and being the same person throughout the program. They were instructed to breathe deeply and slowly at six cycles per minute, for at least 30 minutes, continually 5 days per week for 4 weeks.[18] Those who followed the breathing exercise in accordance with the same instruction according to the protocol were included in this study. The control group performed their normal routine of activity in daily life, and recorded necessary information in their physical activity diary and food consumption. After completing the post-measurement, all participants received health and physical education.

Measuring anthropometric composition

Body composition was measured by using bioelectrical impedance analysis (BIA) (HBF 375, Omron Healthcare Co. Ltd., Kyoto, Japan). All of the participants wore light clothing in adequate privacy of the laboratory. After completing the pre criteria instructions, following the standard guideline.[25] The participants were measured BMI, visceral fat, fat free mass and body fat.[26] They were then asked to stand with their feet on electrodes in the main unit and their weight equally distributed. They kept their back and knees straight and looked straight in front of them, while gripping electrodes with dry palms and arms held straight out horizontally at a 90° angle to the body until the measuring was completed. The BMI, visceral fat, fat free mass and body fat of the participants were recorded.[27]

Heart rate variability measurement

The skin of all participants was cleaned with electrocardiogram (ECG) electrolyte gel. HRV was measured in a room with stable temperature of 25°C , and the participants laid in a resting supine position for 20 min, while the breathing rate was being controlling at 12 breaths/min by a metronome.28 Lead II was recorded the ECG activity by placing electrode on the right arm (RA) and another on the left leg (LL) by chest physical therapist. An ADinstruments lab chart version 8 with HRV module version 2.0.3 (Power Lab 4 SP, ADInstruments, Australia) was used as data acquisition software for recording ECG readings. Beat to beat intervals (R-R intervals) were calculated after correction of artifacts and entropic beats. The average from each R-R interval was measured and considered for the time and frequency domain of HRV,[29] by following the guidelines.[30] The changes in heart rate over time or beat-to-beat alterations between successive normal cardiac cycles were measured. The criteria of successive cardiac waveforms in the ECG signal included P, QRS and T waves without amount of ectropic beats (premature atrial or ventricular, supraventricular contractions). The peak of the R wave without artifacts from normal QRS complex, and the duration between two adjacent R wave peaks is measured. Time and frequency domain of HRV were analyzed though analysis of R-R intervals (the time between the two successive R waves in ECG). The time-domain indices of HRV used in this analysis were the standard deviation (SD) of the N-N intervals (SDNN) and root mean square difference of successive normal R-R intervals (RMSSD). Frequency-domain indices of HRV, including total power, Low Frequency (LF: 0.04-0.15 Hz), High Frequency (HF: 0.15-0.40 Hz), and LF/HF – ratio of absolute LF to HF power were analyzed.[30]

Ankle-brachial index and cardio-ankle vascular index measurement

After rest, all participants were assessed for arterial stiffness in the supine position using a vascular screening device (VS-1500N, Fukuda Denshi Co. Ltd., Tokyo, Japan). The ankle-brachial index (ABI) and CAVI were assessed by ECG, arm and leg blood pressure and phonograph.[5] The participants were measured for leg and arm blood pressure simultaneously, while using ECG and phonocardiography for calculating pulse wave velocity (PWV), which was then used as a factor in calculating ABI and CAVI.[31]

Respiratory muscle strength testing

The participants were familiarized with the instrument and procedure before the actual test. Maximal inspiratory pressure (MIP) and maximum expiratory pressure (MEP) measurements were conducted in accordance with the guideline of American Thoracic Society/European Respiratory Society statement on respiratory muscle testing.[32] An electronic pressure transducer (MicroRPM, Micromedical Ltd., Kent, United Kingdom) was used to measure respiratory muscle strength before and after treatment by a physical therapist. MIP testing were measured in deep inspiration from residual volume after maximum exhalation.[33] For the measurement of the MEP, the participants were instructed to forced expiration form total lung capacity.[33] Participants were allowed to rest for 1-2 minutes in between tests. The test was performed at least 3 times, and accomplished for a maximum of 5 maneuvers. The highest value of 3 measurements was chosen for analysis and compared with the reference value.[34]

Measurement of indirect maximal oxygen consumption (indirect VO_2max)

The indirect VO_2max was assessed by submaximal Astrand-Ryhming protocol by a cycle ergometer (Monark 828E, Monark Exercise AB, Vansbro, Sweden). Prior to performing the actual test, all of the participants were familiarized with the protocol and 2-3 minutes warm up period, which set a rhythm at 50 repetitions per minutes (RPM). A Kilo Pond intensity was performed initially to maintain the heart rate (HR) at between 120-170 beats/minute, which conducted for given level of submaximal work load level, using a heart rate monitor to keep a continuous record for six minutes. Constant HR at the fifth and sixth minute was determined in order to correct VO_2max as follows: 35 absolute $\dot{V}O_2$max (L/min) and relative VO_2max (mL/kg/min) were calculated from the age factor and body weight of the participants, respectively.[35] During the test, if participants with shortness of breath or wheezing, claudication or angina onset were followed according to the American College of Sports Medicine (ACSM) guidelines for exercise testing, and the prescription, the participants were stopped from the test.[36]

Statistical data analysis

Statistical difference of all data were analysis by a SPSS for Windows program, version 17.0 (IBM Corp. New York, NY, USA), and mean and standard deviation were presented when the normal distribution of data was demonstrated. The independent t test was performed for statistical analysis of the demographic data between groups, in addition, the two way ANOVA was used for comparing within and between groups. Regarding all of the parameters, $p<0.05$ was considered a statistically significant difference.

Results

Baseline characteristics of the participants

The statistical results of this study found that the demographic data, age, height, weight, BMI of all participants were not significant between groups ($p>0.05$). Body composition include fat free mass, body fat and visceral fat, which is a type of body fat that stored within the abdominal cavity and around internal organs. There was no significant difference in body fat, visceral fat and fat free mass between the two groups ($p>0.05$) (Table 1). Participants in control group excluded from the study due to take a supplement food during the study, while participants in the intervention group who depart from the study due to lack of time. Beside those, all of the other participants (control group n=19, intervention group n=19) completed the study with the percentage exercise adherence was more than 90%.

Table 1 General characteristics of the participants.

Parameters	Control (n=19)	Intervention (n=19)	*p* value
Age (year)	22.95±2.37 (20-28)	22.58±2.83 (20-29)	0.507
Height (cm)	160.67±5.43 (150-165)	160.47±6.23 (153-168)	0.851
Weight (Kg)	56.92±4.58 (46.5-61.3)	57.16±5.16 (48.5-64.8)	0.747
BMI (Kg/m^2)	21.53±0.69 (20.67-22.52)	22.15±0.77 (20.72-22.96)	0.562
Body fat(%)	32.38±2.05 (30.1-35.2)	33.06±2.56 (30.4-36.8)	0.358
Visceral fat (%)	6.26±2.09 (3.8-9.2)	5.56±2.06 (3.5-8.4)	0.868
Fat free mass (%)	28.42±3.74 (23.6-33.8)	26.55±3.43 (22.4-31.2)	0.211

Body mass index; BMI, Kg/m^2; kilogram per square meter, %; percentage. p value was statistically analyzed with the independent t test.

Comparison of cardiovascular parameters, respiratory strength and indirect VO_2max

There was a significant difference of systolic blood pressure (SBP) and MIP between the two groups (p<0.05). The mean MIP in the intervention group was 87.84±10.01 cmH_2O, which showed a significant difference when compared to the control group (76.84 ± 9.74 cmH_2O). The same was observed for SBP in the intervention group (101.53±5.70 mmHg), compared to the control group (109.78±7.10 mmHg) (p<0.05). Diastolic blood pressure (DBP), MEP and VO_2max were not significantly different when compared to the control group (p>0.05) (Table 2).

Table 2 Cardiovascular parameters, respiratory strength and VO2max between groups at pre and post intervention.

Parameters	Control (n=19)		Intervention (n=19)	
	Pre	Post	Pre	Post
HR (BPM)	82.63±8.94 (70-93)	85.58±9.51 (74-98)	83.10±8.84 (70-96)	80.94±6.61 (70-90)
SBP (mmHg)	108.89±8.08 (98-120)	109.78±7.10 (100-120)	108.94±7.31 (100-120)	101.53±5.70*† (90-110)
DBP (mmHg)	68.16±6.34 (56-80)	69.95±7.12 (60-80)	67.68±5.77 (58-76)	66.11±6.03 (56-80)
MIP (cmH_2O)	78.84±10.44 (67-96)	76.84±9.74 (65-90)	79.89±8.05 (68-94)	87.84±10.01*† (75-104)
MEP (cmH_2O)	95.21±10.67 (83-115)	93.78±8.95 (82-104)	92.94±10.81 (80-110)	94.57±10.34 (80-117)
VO2max (ml/kg/min)	38.01±6.48 (30.6-45.4)	36.19±5.91 (27.8-43.2)	35.97±7.02 (27.4-45.6)	38.85±5.52 (30.3-46.8)

*HR, heart rate; BPM, beats per min; SBP, systolic blood pressure; DBP, diastolic blood pressure; mmHg, millimeter of mercury; MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure; VO_{2max}, maximal oxygen consumption; ml/kg/min, milliliter per kilogram per minute. *p<0.05 for significant differences from pre-intervention, †p<0.05 for significant differences between the groups.*

Comparison of heart rate variability analysis

The mean of SDNN and RMSSD in the intervention group, which was significantly higher than that pre-intervention (p<0.05). There was a significant difference in HF, LFnu and LF/HF between the groups (p<0.05). The mean HFnu and LF/HF, which was significantly higher than that pre intervention and between the groups (p<0.05). Furthermore, the mean of LFnu at 4 weeks of intervention in the control group was higher than pre-test. While, LFnu in the intervention group was lower than that pre-test and after 4 week of intervention, compared to control group (Table 3).

Table 3 Heart rate variability analysis (HRV) between group at pre- and post-slow deep breathing intervention.

Parameters	Control (n=19)		Intervention (n=19)	
	Pre	Post	Pre	Post
SDNN (ms)	60.03±10.52	63.70±13.74	58.36±10.71	67.74±11.22*
	(39.75-74.62)	(42.14-78.54)	(40.11-74.98)	(46.21-83.67)
RMSSD (ms)	42.23±10.14	45.04±14.36	40.91±11.05	52.69±13.73*
	(24.12-60.34)	(21.16-65.07)	(28.63-58.84)	(32.41-67.96)
LF (n.u.)	55.73±10.95	64.92±11.14*	56.44±11.58	45.43±12.30*†
	(36.69-70.33)	(47.40-79.83)	(35.46-74.27)	(20.77-65.39)
HF (n.u.)	38.77±11.27	40.07±12.89	34.32±10.24	56.06±10.62*†
	(24.93-58.64)	(23.38-64.28)	(20.08-55.17)	(36.43-74.95)
LF/HF	1.52±0.42	1.76±0.65	1.67±0.59	0.83±0.37*†
	(0.78-2.37)	(0.97-2.66)	(1.16-2.41)	(0.31-1.55)

*SDNN (standard deviation of N to N interval), RMSSD (root mean square of N to N interval), LF (low frequency), HF (high frequency), LF/HF (ratio of low and high frequency), ms (millisecond), *p<0.05 for significant differences from pre-intervention, †p<0.05 for significant differences between the groups.*

Comparison of CAVI and ABI

The mean CAVI and ABI were not significantly different between groups (p>0.05). The mean CAVI and ABI in the control group were 6.53±0.52 and 1.02±0.05, respectively, while that in the intervention group were 6.56±0.50 and 1.01±0.04, respectively (Table 4).

Table 4 Cardio ankle vascular index (CAVI) and Ankle brachial index (ABI) between groups at pre- and post-intervention.

Parameters		Control (n=19)		Intervention (n=19)	
		Pre	Post	Pre	Post
CAVI	**Right**	6.51±0.47	6.51±0.52	6.51±0.60	6.53±0.53
		(5.60-7.30)	(5.40-7.40)	(5.70-7.80)	(5.70-7.30)
	Left	6.54±0.45	6.56±0.53	6.61±0.60	6.59±0.48
		(5.80-7.30)	(5.30-7.40)	(5.80-7.90)	(5.70-7.40)
	Mean	6.52±0.45	6.53±0.52	6.56±0.60	6.56±0.50
		(5.75-7.25)	(5.35-7.40)	(5.75-7.85)	(5.70-7.35)
ABI	**Right**	1.02±0.05	1.02±0.05	1.02±0.05	1.01±0.04
		(0.94-1.14)	(0.94-1.14)	(0.98-1.16)	(0.96-1.12)
	Left	1.02±0.05	1.02±0.04	1.01±0.04	1.01±0.04
		(0.96-1.14)	(0.96-1.12)	(0.98-1.14)	(0.96-1.14)
	Mean	1.02±0.05	1.02±0.05	1.01±0.05	1.01±0.04
		(0.95-1.14)	(0.95-1.13)	(0.98-1.15)	(0.96-1.13)

CAVI: Cardio ankle vascular index, ABI: Ankle brachial index. There were no significant differences between the groups for CAVI and ABI.

Discussion

The findings of this study showed that slow breathing exercise at home could improve SDNN, RMSSD, HFnu together with decreased LF and LF/HF ratio. Moreover, the improvement of MIP and SBP were observed. DBP, VO_2max, MEP, CAVI and ABI were not significantly changed when compared to the control group (p>0.05).

Healthy obese individuals are more likely to experience dyspnea at rest or on exertion. Fat in the visceral organ may be attributed to displaced diaphragmatic excursion, respiratory muscle inefficiency and workload to the respiratory muscle.[37] Furthermore, previous research showed that a fatiguing diaphragm led to increased sympathetic outflow.[38] In the theory, HRV is a measurable reflection of autonomic balance and has been used as a marker for cardiac mortality from cardiovascular disease (CVD).[4] Previous results found autonomic imbalance in young obese people, characterized by an increase in sympathetic activity and decreasing parasympathetic activity.[39] SDNN and RMSSD were significant improved by slow breathing which reflected the improvement of autonomic balance. Moreover, slow breathing exercise at home improved autonomic function, by improving HF, decreasing LF and LF/HF, represented the sympathetic and parasympathetic balance. The study of Joseph showed that slow breathing at 6 breaths/min increased baroreflex sensitivity, reduced sympathetic activity and chemoreflex activation, therefore, it can be supposed a potentially beneficial effect of slow breathing on autonomic function.[40] Thus, it can be possibly suggested that slow deep breathing decreased sympathetic and increased parasympathetic activity in physically inactive normal weight obese participants.

Inspiratory muscle weakness may induce several impairments in both healthy and athletic individuals.[41] The balance of ANS plays an important role in respiratory performance. A fatiguing inspiratory muscle work causes sympathetic activation.[38] This study also showed improvement in MIP and observed lesser sympathetic activity in participants with NWO receiving breathing exercise. The improvement of autonomic regulation by slow breathing exercise, mediated by lesser sympathetic modulation, may help to improve respiratory muscle strength. However, this study did not measure baroreflex and/or chemoreflex sensitivity, therefore reasonable hypothesize for decreased the sympathetic activity effecting on both sensitivities by slow deep breathing exercise cannot be concluded. Further study between respiratory strength and sympathetic activity should be further investigated.

Excessive fat storage aggravates autonomic imbalance by increasing sympathetic activation and decreasing parasympathetic activity, which contribute to increased risk of cardiovascular diseases.[7] Slow breathing exercise has been demonstrated in improving autonomic function and arterial dysfunction by reduction in sympathetic activity in obese children.[42] Slow breathing exercise in our study reduced sympathetic activity and SBP, but not alternations of DBP, CAVI and ABI when compared with the control group. It suggested that SBP was reduced by decreasing sympathetic activation, but not change in DBP, which possibly depend on elasticity of conductance vessels.[43] NWO participants who have an excessive body fat percentage increase risk of subclinical arteriosclerosis.[44] Fat in blood circulation possibly played an important role in vessel elasticity.[45] Thus, our study did not found the alternation of DBP, CAVI and ABI. Nevertheless, some study showed that slow breathing for 12 weeks reduced of both SBP and DBP in healthy participants.[46] Further studies are needed to assess the long-term outcomes of slow breathing on vascular function.

Obese people mostly have difficulty to control breathing while moving body during exercise, due to increased workload, and this can lead easily to dyspnea and eventually avoidance of exercise.[47] Our results also show improvement of autonomic function and inspiratory muscle strength, but not in VO_2max or aerobic capacity after slow and deep breathing implemented completely. Additionally, the use of the submaximal Astrand-Ryhming protocol in order to predict the VO_2max may less acute value when compared to a treadmill VO_2max. Previous study in hypertensive people showed that inspiratory muscle training with the load set at 30% of MIP, for 30 minutes, 7 days per week for 8 weeks, reduced blood pressure, improved autonomic function and MIP from 82.7±28.8 to 121.5±21.8 cmH_2O, but did not change maximal functional capacity.[48] The slightly improvement of inspiratory muscle strength in this study because of no resistive loading during breathing exercise; therefore, breathing exercise should be performed with resistive load for further improving respiratory muscle strength. This study showed the importance of exercise, as just slow breathing without resistance could improve autonomic and inspiratory muscle strength. Slow breathing in obese participants help to control breathing before initially doing other types of exercise. Limitations of our study include the small sample size and lack of included male participants. The recruitment of physically inactive female adults aged 20-30 years; therefore, our findings should not be generalized to the female population as a whole.

Conclusion

Slow breathing exercise is a challenged strategy for promoting health by improving autonomic function and inspiratory muscle strength in physically inactive people that can be served as a clinical home-based program in the future.

Conflict of interest

The authors declare no conflict of interest.

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The correlation between motor proficiency and working memory of Thai school-aged children

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ABSTRACT

Background: Motor proficiency encompasses both gross and fine motor skills while cognitive abilities include language, attention, memory, and executive functions that are gradually being developed in a period of life span during childhood. Currently, there is only indirect evidence linking motor proficiency and specific working memory performance.

Objectives: Purpose of this study was to determine the correlation between motor proficiency and working memory in Thai school-age children grades 1-4.

Materials and methods: One hundred and fifteen children were randomly recruited from a primary school in the Bangkok metropolitan area. Bruininks-Osteretsky Test of Motor Proficiency 2 Short Form (BOT-2 SF) was performed to test motor proficiency. The specific working memory ability was assessed by digit span forward and backward, and visuomotor construction.

Results: There was a significant correlation between motor proficiency and working memory in Thai school-age children grades 1-4 (r=0.51, p<0.001).

Conclusion: The current study indicated that motor proficiency and working memory were significantly correlated. Therefore, the link between school-aged children's motor proficiency and working memory may provide clarity regarding the connection of these abilities in children to guide curriculum development or appropriate interventions in a school setting.

Introduction

During the development of children, they learn many motor abilities which are defined as the skills that are integrated to efficiently coordinate the actions in a particular task.[1] The definition of the total motor proficiency generally involves gross motor skills such as jumping, sprinting, and walking by the underlying physical abilities using strength of muscle power, balance, flexibility, speed and agility. Moreover, fine motor skills refer to fine motor precision and integration. In the part of bilateral body coordination, it includes the whole body engagement with bilateral coordination of both arms and legs to perform activities.[2] Cognitive skills mean the mental processes or performances of obtaining knowledge and understanding through the senses, thinking and experience.[1] Executive functions are considered as the higher order cognition which are the broader terms of cognitive processes that engage in goal-directed activities.[3] One of the essential aspect of executive functions is working memory[4] which is necessary for processing of thinking, reasoning, decision-making, and desired behavior. It is the ability to store and manipulate data in short-term memory, by which particular processes exist using verbal and visual information.[5] Working memory has been found to constantly develop across life span of childhood to adolescence.[6, 7]

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It is well documented in literature that there is a strong relationship between motor and cognitive development.[8-10] This relationship is partly ascribed to the changes in brain function and structure that take place due to physical and motor training.[11] Motor skills are strongly important to the development of brain and has a positive influence on the ability to learn whenever cognitive skills are applied.[12] Currently, several evidences show that some specific working memory is more relevant to gross motor tasks, but this point remains controversial. Cross-sectional studies in adolescents have indicated that gross motor skills are related to visuospatial working memory.[13] There are contradictory studies that have reported on the relationship of gross motor skills with verbal working memory in 10 year-old children.[13, 14] The different aspects of gross motor skills were also shown to be related in different ways to working memory; it was found that locomotor skills were related to working memory in adolescents.[15]

In the research about the implementing programs aiming to improve motor skills have also been shown the benefits to enhance working memory. It has been found that a 10-week motor program increased working memory in 9–10-year-old children.[16] A soccer program also demonstrated in beneficial effects on motor skills and specific aspects of working memory.[17] This program enhanced visuospatial working memory, but there was no effect on verbal working memory. However, one current study found that a physical activity intervention for six months improved motor skills (manual dexterity, ball skills, and balance), but again there was no effect on working memory.[18] Recently, a cross-sectional survey of Dutch children from grades 3 and 4 also showed gross motor skills were significantly related to verbal working memory, visuospatial working memory, and response inhibition.[19]

School-aged children spend a majority of their time in school; an environment that influences their overall physical and learning development.[20] From the results of nationwide study showed that two thirds of Thai children and youth were not sufficiently active. Thai children and youth engaged in a large number of physical activities but the prevalence estimate of meeting the physical activity recommendations was low.[21] As gross motor proficiency is assumed to foster academic abilities,[22] evidence obtained from developmental movement programs which have been implemented in early childhood curriculum could enhance academic skills in reading and math.[23] The above-mentioned studies suggest that a curriculum which focuses on a child's physical activity to enhance motor proficiency may benefit neurodevelopment related to specific executive functions such as working memory that can result in the ameliorate of academic achievement. With increasing supportive evidence regarding the link between school-aged children's motor proficiency and working memory, there is more clarity about the key factors contributing to the connection of these abilities in children that will enable educational professionals to plan curriculum or classroom activities in schools. Furthermore, there is no currently supporting evidence regarding specific relations between gross motor skills and working memory. Thus, it seems necessary to conduct further research concerning the benefits of motor skills and proficiency. Therefore, the aim of this present study was to investigate the relationships between motor proficiency and working memory of school-aged children.

Materials and methods

Participants

One hundred fifteen children (63 boys and 52 girls) grade 1- 4 participated in this study were recruited from 4 primary school in the Bangkok metropolitan area, Thailand with the school selected opportunistically. Inclusion criteria were able to communicate and understand Thai language and have not been diagnosed for any neurological diseases such as cerebral palsy, movement disorders, or vision and hearing deficits. Then, children were randomly recruited. Informed consent was gained from parents of the child participants after they had read an explanatory statement and research information according to ethical principles. This study was granted ethics approval from Mahidol University Central Institutional Review Board (COA No. MU-CIRB 2018/136.2307).

Materials

For the motor proficiency test, the Bruininks-Oseretsky Test of Motor Proficiency 2 short form (BOT-2 SF) for children aged 4 to 21 was used to assess all participants in this study using the standardized version that shows high reliability for motor efficiency assessment.[2] Short form is less time-consuming (15-20 min per person) compared to the complete form (CF) (45-60min per person). The developers of the BOT-2 also demonstrated that the strong correlation between SF and CF existed r=0.80 to 0.87.[24] Therefore, BOT-2 SF can be used as a tool in this study. BOT-2 SF are clustered as 15 items of four motor area composite scores including fine manual control, manual coordination, body coordination, and strength and agility. Fine manual control tasks include drawing lines (crooked), folding paper, copying a star, and copying a square. Manual coordination tasks include transferring of pennies, dropping and catching a ball (with both and each hand) and dribbling a ball (with alternating hands). Body coordination tasks include tapping feet and fingers (with same body side synchronized), jumping in place (with same body side synchronized), standing on one leg (on beam) and walking forward on a line. Strength and agility tasks include sit-ups, push-ups (with knees or full legs), stationary hopping, and jumping in place.

Based on the Baddeley's model, the most common categorizations are auditory and visual (sometimes used verbal and non-verbal, respectively) working memory assessments that used in schools and clinical settings. Therefore, the assessments should target each of the two modalities auditory and visual.[25]

This study also assessed working memory using digit span (auditory working memory) and visuomotor construction (visual working memory). The digit span forward and backward tests were designed by Martin Turner and Jacky Ridsdale and were later revised in 2004.[26] Digit forwards testing was done using the following cue: "Listen carefully as I say some numbers. When I finish, you say them." Digits were

given at the rate of one per second without any variation in pitch of voice throughout the test. The test was continued until the subject fails to repeat after the assessor on both trial pairs, then the scoring involves determining the total number of items correctly repeated forwards. For the Digit backwards the student was given the following directions: "Repeat these numbers after me, but this time I want you to say them backwards." Two practice samples of two digits were given initially. The child was reminded that the digits were to be reversed. Delivery and scoring were similar to digit forwards. Next, the standard score was calculated from the raw score. For visual working memory, the child was instructed to do the visuomotor construction using all 4 pieces of plastic shapes (one circle, one square, and two triangular shapes) to reproduce a 2-D model after examiner has displayed the model. The picture booklet which showed the 2-D model was placed on the dominant side of the child and the plastic shapes were placed on the other side. The 2-D picture was showed for 15 seconds and then the booklet was closed to allow the child to build the 2-D shape from memory within 180 seconds. Time used for construction was then measured.

Procedure

Firstly, the relevant demographic data were gathered such as age, gender, classroom grade, as well as the dominant hand, arm, and leg. Secondly, the motor proficiency test was performed and working memory tests was conducted using digit span forward and backward tests combined with the visuomotor construction, respectively. These tests were completed in a single session that took approximately 25-30 minutes to perform in a quiet room.

Statistical Analysis

BOT-2 SF, digit span forward and backward standard score and visuomotor construction time used raw scores were analyzed using descriptive statistics. Pearson correlation analysis was conducted on the relevant working memory and the overall motor proficiency value. Correlation coefficient criteria were considered as the following; r=0.90 - 1.00 as very high correlation, 0.70 -0.90 as high correlation, 0.50 - 0.70 as moderate correlation, 0.30 - 0.50 as low correlation, and 0.00 – 0.30 as negligible correlation. The statistics were performed using SPSS software (version 18.0) and the significance level was set at 0.05.

Results

Demographic data

The mean age of the boys was 8.75 years and the mean age of the girls was 8.85 years. The children were further divided into 4 different age groups. Grade 1 group consisted of 44 children (25 boys with mean age=6.8, SD=0.3 and 19 girls with mean age=7.2, SD 0.4). Grade 2 group was 29 children (11 boys with mean age=8.3, SD 0.3 and 18 girls with mean age=8.4, SD 0.3). Grade 3 group was 22 children (13 boys with mean age=9.4, SD = 0.3 and 9 girls with mean age 9.3, SD 0.2). The last group was grade 4 consisting of 20 children (14 boys with mean age=10.5, SD=0.2 and 6 girls with mean age=10.5, SD 0.3). The data also showed 107 children with right hand dominant, 8 children with left hand dominant, 107 children with right arm dominant, 8 children with left arm dominant, 106 children with right leg dominant, but 9 children with left leg dominant. Demographic characteristics of participants were presented in Table 1.

Table 1 Demographic characteristics of school-aged children.

Variable	
School-aged children	n = 115
Age	**mean±SD**
Boy	8.75±1.58
Girl	8.85±1.40
Age of each grade level	
Grade 1	
Boy	6.8±0.3
Girl	7.2±0.4
Grade 2	
Boy	8.3±0.3
Girl	8.4±0.3
Grade 3	
Boy	9.4±0.3
Girl	9.3±0.2
Grade 4	
Boy	10.5±0.2
Girl	10.5±0.3
Dominant hand	**n (%)**
Right	107±93.04
Left	8±6.96
Dominant Arm	
Right	10±93.04
Left	8±6.96
Dominant Leg	
Boy	106±92.17
Girl	9±7.83

Motor proficiency

Table 2 demonstrates the mean and standard deviations for the variables of the study. The results are shown in each subtest of BOT-2 SF and total motor score which are separated for boys and girls in the 4 grade groups. The results presented that grade 4 boys had the maximum total motor proficiency score; 73.29 (8.52) whereas grade 1 girls had the minimal total motor proficiency score; 65.32 (10.35).

Table 2 Mean±SD of standard score in each subtest of BOT-2 SF among the various grades.

Subtests of BOT-2 SF	Grade 1		Grade 2		Grade 3		Grade 4	
	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD
Fine motor precision	12.76±1.45	13.00±1.53	12.55±1.57	13.00±1.59	13.46±0.97	13.33±1.00	13.43±1.16	13.33±1.63
Fine motor integration	8.52±0.71	8.37±1.38	8.18±1.47	8.50±2.07	9.00±0.82	9.22±0.83	8.71±0.82	9.17±0.41
Manual dexterity	5.48±1.16	5.84±1.17	5.90±1.04	6.39±0.98	6.62±0.65	6.33±1.12	7.07±0.78	6.50±0.84
Bilateral coordination	6.72±0.74	7.00±0.00	6.90±0.3	7.00±0.00	6.69±0.63	6.89±0.33	6.93±0.27	7.00±0.00
Balance	7.44±0.92	7.89±0.46	7.90±0.3	7.89±0.32	7.85±0.55	7.89±0.44	8.00±0.95	8.00±0.00
Running speed and agility	8.12±0.83	8.00±1.15	7.81±1.25	8.17±1.10	8.38±0.77	8.22±1.58	8.57±1.08	8.17±0.41
Upper-limb coordination	8.00±2.47	7.37±2.54	9.45±1.86	9.33±1.75	10.08±1.93	11.00±1.58	11.14±1.35	10.17±2.23
Strength	8.36±1.52	7.84±2.12	7.55±1.86	8.72±1.63	8.62±1.76	8.67±2.18	9.43±2.10	8.00±0.89
Total motor score	65.40±9.8	65.32±10.35	66.27±9.67	69.06±9.44	70.69±8.08	71.56±7.82	73.29±8.52	70.33±6.41

Working memory

Table 3 demonstrates the average and standard deviations in subtests of forward and backward digit span and visuomotor construction for the variables of the study which divided males and females into 4 grade groups. The results show that grade 1 girls had the maximum digit forward standard score; 11.28 (2.02) whereas grade 1 boys had the minimal digit forward standard score; 9.92 (1.58). For digit backward, grade 3 girls showed the maximal digit backward standard score; 5.11 (2.47). On the contrary, grade 2 boys showed the minimal digit backward standard score; 3.00 (1.00). The last variable was visuomotor construction. The results presented that grade 3 girls used the highest time; 45.44 (46.05) whereas grade 4 boys spent the lowest amount of time; 8.93 (9.20).

Table 3 Mean±SD of working memory test.

Working memory tests	Grade 1		Grade 2		Grade 3		Grade 4	
	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD	Boys Mean±SD	Girls Mean±SD
Digit forwards	9.92±1.58	11.28 ±2.02	10.81±1.83	10.56±1.42	10.38±1.66	10.89±2.76	10.92±2.53	10.16±1.32
Digit backwards	3.44±1.26	3.11±1.72	3.00±1.00	3.67±1.71	3.46±0.66	5.11±2.47	4.14 ±1.23	4.00 ±1.41
Visuomotor construction	32.2±34.1	32.98±38.27	34.64±34.75	30.88±41.04	12±15.02	45.44±46.05	8.93±9.20	26.77±24.59

Correlation-analysis of motor proficiency and working memory

The correlation analysis between total motor score of BOT-2 SF and working memory performance including digit span and visuomotor construction indicated significant positive moderate correlations between the motor proficiency performance and in digit span (0.512, $p<0.001$). There was significant correlation between motor proficiency and digit span (working memory) in school aged children, and there was no significant correlation between motor proficiency and visuomotor construction. There was also no significant correlation between digit span and visuomotor construction. Pearson's correlations between total motor score of BOT-2 SF and working memory performance are presented in Table 4.

Table 4 Pearson's correlations between Motor Proficiency, Digit Span, and Visuomotor Construction.

	Motor Proficiency	Digit Span	Visuomotor Construction
Motor Proficiency		0.512*	-0.131
Digits Span	0.512*		-0.036
Visuomotor Construction	-0.131	-0.036	

**p<0.001*

Discussion

In this cross-sectional survey study of grades 1-4 school aged children, the motor proficiency and working memory performance were measured. Descriptive statistics showed that grade 4 boys had the maximum total motor proficiency score whereas grade 1 girls had the minimal total motor proficiency score. Agreeing with previous studies shown the effect of age category on the level of motor proficiency was different among age groups.[27, 28] Our findings of this study also revealed that motor skill increased with age. In previous and similar studies, it was also found that motor developed with increased age.[29] Our results indicated that

there were no differences with regard to gender effect on motor proficiency measured by BOT-2 SF. In contrast, the differences between boys and girls were reported, girls were better than boys in balancing backward, stand and reach, and jumping sideways. The only gender difference in motor abilities among subjects was in a coordination test whose outcome favored boys. This contradicts the study of Roth et al.[30] mentioning gender difference favoring boys only in running tasks. In general, this comparison has to be considered with caution because different tests are used.

Moreover, the gender and age differences were determined in working memory test results of this study. The maximum score of digit forward, digit backward and visuomotor construction were girls from grade 1, grade 3 and grade 3, respectively. In previous and similar studies, it was also found that cognitive abilities developed with increased age.[29] Our results indicated that there were no differences with regard to gender effect on working memory in all tests, whereby the subject aimed to remember the number sequences in both forward and backward order while the phonological loop and visuomotor construction required visual-spatial working memory. This contradicts the study of Jansen et al.[31], the gender effect for working memory shows mixed results as boys performed better in the Corsi Block-Tapping Test forward and girls performed better in the Digit-Span Test forward. Both tests were designed to retrieve information of different parts of working memory, i.e., remembering the sequences in the same order (forward) measures the phonological loop, whereas the Corsi Block-Tapping Test forward requires visual-spatial working memory, whereby the subject aimed to remember the number sequences in both forward and backward order while the phonological loop and visuomotor construction requires visual-spatial working memory. Previous studies found that boys showed better performance than girls in all motor variables.[32] Alternatively, Jansen et al.[31] showed the girls performing better in the digit span test forward which indicated that girls generally had a better auditory working memory ability than boys.

In this study, the relation between the motor proficiency and working memory was also determined. The moderate correlation between total motor proficiency standard score and standard score of working memory tests (digit span) was revealed. Regarding the relation of motor performance and working memory which is an important consideration when planning classroom activities to achieve optimal working memory. This outcome is a core aspect of executive functions to achieve learning ability for children within the school environment. The relationship between gross motor skills and working memory as executive functions is often described as an overlap in brain regions between the frontal, parietal, and motor cortices that are important for both gross motor skills and working memory.[33] These relationships are supported by recent studies indicating that the better the motor skills, the better the processes of preparation and attention, which are mainly stimulated the premotor and motor cortex and also the fronto-parietal system during a task using working memory.[34] Our study have also revealed a significant correlation between motor proficiency scores and digit span with verbal working memory in school-aged children. Cross-sectional behavioral studies have shown that gross motor skills are related to verbal working memory,[13, 35] whereas contradictory studies reported a similar relationship with visuospatial working memory.

Based on both theory and evidence, there is a continuous interest in understanding the specific relation between motor skill and working memory. The insights obtained by our study will help to understand the specificity of relations between motor skills and working memory, which will be a useful guideline for practical applications that benefit school-aged children. Some evidence also indicated the importance of individual working memory capacity on the child's ability to obtain information and new skills.[36] In a typical child, working memory scores can predict reading ability[28] and mathematical achievement. Currently, in school settings, usually the only primary focus of learning is to develop students' academic skills especially in numeracy and literacy. Consequently, there may be less given time in the school curriculum for encouraging the physical development of students, which supports the acquisition of motor proficiency towards physical activity in school.[37] Moreover, previous cross-sectional surveys suggest that only approximately 23.4% of Thai children and youth met recommended levels of physical activity.[21]

Recent studies, including the correlation between motor tests and working memory tests, have been conducted on 3 to 6-year-old children[38] and the significant relationship between cognitive variables and academic performance have been reported for school-aged children.[39] Additionally, motor proficiency appears to be associated with cognition, which underscores the importance of early motor skill development of children.[37, 40] The above-mentioned studies suggest that a curriculum which focusses on a child's physical activity to enhance motor proficiency may benefit neurodevelopment relevant to specific executive function such as working memory and can therefore improve academic achievement over time. More supportive evidence of correlation between school-aged children's motor proficiency and working memory may help develop important guidelines on how to plan curriculum or planning classroom activities in a school setting.

Limitations

Although this study provides correlation evidence between motor proficiency and working memory, it also has several limitations. First, participants were selected from only 4 schools in Bangkok metropolitan, which further impacts the generalizability of findings to Thai school-aged children. These issues will need to be addressed by future studies in order to extend throughout regions in Thailand. Second, this current study addressed the tests of working memory by digit span task which is well-known as the common tool even this test lacks of the study in psychometric properties. In the part of the visuomotor construction, it is the informal test adopted from the DOTCA-Ch which can be measured visual short-term memory. A research recommendation for the future is to use the outcome measures that can assess the visual working memory such as picture span test, simple

object span test or word span test. Lastly, we did not assess other executive functions (e.g., attention, cognitive flexibility) that may be important for motor proficiency so the next study must consider other aspects of these parameters.

Conclusion

The results of this study found the age differences in motor proficiency and working memory performance. Moreover, there are a significant correlation between motor proficiency and working memory in Thai school-aged children. It was also found that children with high levels of motor proficiency had better performances in working memory than participants with low levels of motor proficiency. The benefit of this study was to demonstrate the association between motor proficiency and working memory. This can lead to blending motor skill with cognitive skill activities within the school curriculum that may benefit school-aged children.

Conflict of interest

The authors declare no conflicts of interests.

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Increased spatiotemporal variability during unplanned gait speed transition in older adults with mild cognitive impairment

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ABSTRACT

Background: Walking in real-life situation requires an ability to rapidly change gait speed to achieve task goals or overcome environmental constraints. Gait speed transition may be compromised in older adults with Mild Cognitive Impairment (MCI) as it requires high demands on motor and cognitive integration to maintain gait stability. Gait variability is proposed to be a robust marker of cortical flexibility in regulating gait. Therefore, assessing gait variability during rapid increase in gait speed may hold promise in detecting deficits related to gait control among older adults with MCI.

Objectives: To investigate spatiotemporal parameters of gait variability during unexpected gait speed transition in older adults with and without MCI.

Materials and methods: Seventeen older adults with MCI (mean age=69.12±4.24 yrs.) and 17 cognitively intact controls (mean age=68.88±5.31 yrs.) participated in the study. The slow to fast speed transition was measured by asking participants to start walking at a slow pace and then instantaneously changing to fast pace in response to an unexpected auditory cue. Mean and coefficients of variation (CV) of step length, step width, step time and swing time were measured during slow to fast speed transition using 3-dimensional motion analysis. The Mann-Whitney U test was conducted to compare spatiotemporal gait parameters between the two groups. The statistical significance was set at $p<0.05$.

Results: Older adults with MCI demonstrated greater variability of step width (MCI group=38.81±9.44, Control group=31.45±7.67, $p=0.04$) and swing time (MCI group=16.02±5.11, Control group=12.14±3.52, $p=0.02$) than controls during fast speed transition. However, mean spatiotemporal parameters were similar between the two groups.

Conclusion: Older adults with MCI demonstrated increased step width and swing time variability during slow to fast gait speed transition. This finding suggests an impaired ability to regulate gait consistency which may predispose them to falls.

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Introduction

The transitional cognitive state between expected cognitive decline of normal aging and early dementia has been designated as Mild Cognitive Impairment (MCI).[1] Several studies have found that older adults with MCI experience a decline in cognitive and gait functions that exceed the normal aging process.[2-4] Individuals with MCI demonstrate progressive deterioration both in cognitive and gait functions over time. As both impaired cognition and gait are recognized independent risk factors of falls,[5-7] it is essential to identify the cognitive and non-cognitive features among this population for providing an early detection and targeting specific interventions aiming to ameliorate risk of falling.

Walking in real-life situation requires the ability to rapidly increase gait speed to meet task goals and environmental demand such as crossing the street within a limited time allotted. Previous studies have demonstrated that pedestrians in several countries are often forced to walk at least 1.2 m/s when crossing a street, which is beyond the normal capabilities of many older adults.[8-10] In this situation, older adults reported that they experienced some walking difficulty when crossing the street that precludes them from full community engagement.[10,11] Several studies revealed that when walking at fast speed older people failed to achieve the same increases in speed and stride length compared to young adults, therefore it would be a barrier for them to engage in a physical environment.[12-14] There is evidence suggesting that when compared to usual walking, walking at a fast pace requires more neural control on gait regulation due to its needs a rapid postural response to control accelerations acting on the body and also involving several muscle groups activity, especially in older adults.[12,14,15] It has been demonstrated that walking requires cognitive resource, especially during complex walking tasks.[16-18] Therefore, people with MCI may have trouble regulating gait pattern when they encounter a challenging walking task. Given that increased gait speed places high demands on motor and cognitive integration to maintain stable periodic movement,[19,20] it could be anticipated that the ability to adapt gait speed in older adults with MCI would be compromised. However, to the best of our knowledge, no previous studies have investigated gait modulation in older adults with MCI during an unexpected increasing in gait speed. Previous studies have commonly investigated gait performance in individuals with MCI during steady-state of walking.[2,21,22] The evidence from a limit number of studies revealed that older adults with MCI showed significant decreases in gait performance during acceleration the body from a static to dynamic state as an initiation of walking compared to those non-MCI controls.[23]

There have been some studies that have investigated the changes of mean spatiotemporal parameters under a wide range of different walking speed among healthy adults. Consistent findings demonstrated that as walking speed increases, step length and swing time increase whereas step width and step time decrease in parallel.[24-28] To date, gait variability has been proposed to be a biomarker of cortical gait control efficiency among older adults with and without cognitive limitations.[18,29] Therefore, it may serve as a potential indicator in reflecting gait integrity under a gait speed transition. The present study aimed to examine the variability of spatiotemporal parameters during a rapid increase of walking speed in older adults with and without MCI. We hypothesized that variability of spatiotemporal parameters in individuals with MCI may be more pronounced than in the control group. This information would refine the understanding of gait speed modification in older adults with MCI during coping with unanticipated increasing in gait speed and may allow early intervention of a further functional decline.

Materials and methods

Participants

Thirty-four older adults (17 MCI and 17 cognitively intact controls) aged 60 years or older participated in the study. The diagnostic criteria for MCI including (i) subjective memory complaint from the patient and/or informant report, (ii) objective cognitive deficit in one or more cognitive domains, (iii) independence in functional activities, (iv) absence of clinical dementia (determined by The National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association [NINCDS-ADRDA] criteria[30]). Cognitively intact controls with similar age, gender, and body mass index (BMI) were recruited from the community settings. The inclusion criteria included being able to walk independently and safely without a walking device for at least 10 meters and being able to follow the assessment instructions. The exclusion criteria included having neurological condition, musculoskeletal disorder that affect balance and gait (e.g. Parkinson's disease, stroke, severe arthritis, hypertension, asthma), having depressive symptoms (determined by the score on the Thai Geriatric Depression Scale-15>6 points)[31] and having uncorrected visual and hearing impairment. The research protocol was approved by the Human Ethical Review Board of the principal investigator's institute (approved number: AMSEC-61EX-087). All participants provided written informed consent before participation.

Apparatus

Spatiotemporal gait parameters during gait speed transition were evaluated using the 3-dimensional (3D) Motion Analysis® system with 10 Eagle-4® infrared cameras (Motion Analysis Corporation, Santa Rosa, California, USA) and analysed using a custom written programs in MATLAB programs (The MathWorks, Inc., Natick, Massachusetts, USA). The sampling rate of the motion analysis system was set at 120 Hz. The raw coordinate data was filtered with Butterworth low-pass filter using a fourth order with a cut-off frequency at 6 Hz.

Procedures

All participants were interviewed about the co-morbidities, medical conditions, medication usage, and history of fall in the previous 12 months. Moreover, participants were examined for the risk of falling by using the Timed Up and Go test (TUGT). The time taken to complete TUGT more than 14.5 seconds is considered as a high risk of falling.[32]

With respect to the cognitive function, participants completed standard neuropsychological tests by trained assessors including Mental State Examination T10[33] and Montreal Cognitive Assessment (general cognitive function)[34], Verbal Paired Associates Test[35] and Rey Auditory Verbal Learning Test[36] (memory), Digit Span Test[37] and Trail Making Test A (attention)[38], Trail Making Test (B-A)[38] and Stroop Color and Word Test (executive function).[39]

The reflective markers (2.0 cm of diameter) were bilaterally placed on the lateral and medial sides of the knee and ankle based on anatomical landmark that included lateral-medial femoral epicondyle, head of fibula, medial-lateral tibial malleolus, 2nd metatarsal head and calcaneus.[40] In addition, one reflective marker was placed on the participant's second sacral vertebrae (S_2), which is the approximate centre of gravity (COG) of the whole body.[41]

Prior to data collection, participants were asked to walk at their self-determined pace along 10-meter walkway over 3 walking conditions which included usual, fast, and slow speed conditions, respectively. An average value over 2 trials per condition was calculated to use as a baseline data. Following the gait testing protocol, participants were instructed to start walking at their self-determined slow speed and had to increase their gait speed as fast as possible upon the presence of the auditory cue, and then continue walking to the stopping line (10-metre). The auditory cue ('Fast') was activated in a random time point during walking. Each participant performed 4 walking trials. To discourage any response anticipation, four gait speed transition trials were randomly included within the 16 slow pace trials (1 gait speed transition trial per 4 slow pace trials, in a total of 20 walking trials). The starting and stopping lines were marked on the floor at 2 meters from the capture volume zone to eliminate the effect of gait initiation (Figure 1).

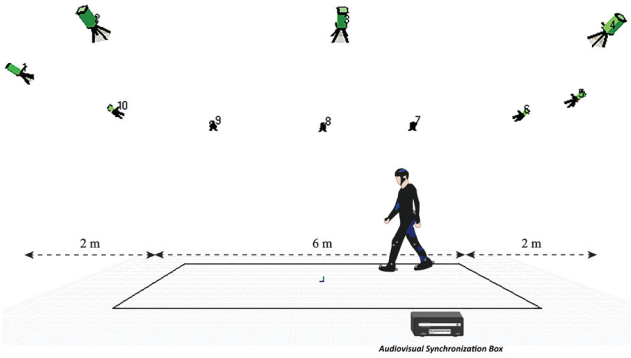

Figure 1. *Experimental setup of gait speed transition assessment.*

Gait measure definitions

The transitional gait speed phase was defined as a transient period between the presence of auditory cue using audiovisual synchronization box to reach a steady-state of fast walking speed. Spatiotemporal parameters were investigated during slow to fast speed transition including step length, step width, step time, and swing time. These spatial (i.e. step length, step width) and temporal (i.e. step time, swing time) parameters have generally been recognized as an indicator for reflecting different components of gait control including rhythmic and dynamic postural control.[42-44] Mean and variability of spatiotemporal gait parameters were calculated by averaging across the 4 slow to fast speed transition walking trials. Gait variability was quantified using coefficient of variation (CV) by the equation CV = (standard deviation/mean) x 100%. Step length (cm) was defined as the distance between the heel markers on the two feet at the time of a heel-strike event of the leading leg.[45] Step width (cm) was defined as a lateral distance between the centres of the two feet, where the centre of each foot was approximated as the midpoint between the toe and the heel markers.[45] Step time (sec) was determined as the time elapsed from the first contact of heel marker of the concurrent footstep to the first contact of heel marker of the next footstep on the opposite extremity.[40,46] Swing time (sec) was defined as the time elapsed from the last contact of toe marker of the concurrent footstep to the first contact of heel marker of the next footstep on the same extremity.[40,46]

Statistical analyses

All statistical analyses were conducted using SPSS software (version 21.0, IBM Corporation, Chicago, IL, USA). An independent sample t-tests was used to compare the demographic data between the two groups. All spatiotemporal parameters during gait speed transition were tested for normality using the Shapiro-Wilk test. The Mann-Whitney U test was used to compare spatiotemporal parameters during gait speed transition between the two groups. The statistical significance threshold was set at $p<0.05$.

Previous study suggested that a sufficient number of steps needed for acceptable valid and reliable measures of gait variability were at least 10-12 steps.[47] Therefore, in the present study, variability of spatiotemporal parameters during gait speed transition was calculated from at least 12 steps to ensure the stability of gait variability measures.

Results

Demographic characteristics of the participants are illustrated in Table 1. Participants in the MCI group had a significantly lower education attainment than those in the control group ($p=0.001$). There was no significant difference between the two groups for baseline gait speed including slow, usual, and fast-pace walking ($p>0.05$). With respect to the cognitive tests, the MCI group was worse performance on the MSET10 ($p=0.01$), MoCA ($p=0.001$), RAVLT ($p=0.01$), DST ($p=0.01$), and TMT B-A ($p=0.04$) than the control group.

Table 1 Demographic characteristic of the participants.

Variables•	Control group (n=17)	MCI group (n=17)	*p* value
Age (yrs)	68.88±5.31	69.12±4.24	0.89
Height (cm)	155.12±0.90	156.23±0.90	0.68
Weight (kg)	56.58±8.59	58.24±6.87	0.54
BMI (kg/m^2)	23.44 ± 2.66	23.90±2.46	0.60
Male: Female	2:15	2:15	
Educational level	13.70±2.87	8.76±4.59	0.001*
Falls in the past year (n)	0.47±0.72	0.53±0.80	0.17
Number of drugs taken daily (types)	0.94 ± 1.09	1.53±1.37	0.82
TUGT (sec)	7.10±0.92	7.88±1.35	0.06
Gait speed (m/s)			
Slow gait speed	0.96±0.13	0.97±0.22	0.94
Usual gait speed	1.10±0.14	1.09±0.18	0.85
Fast gait speed	1.44±0.24	1.39±0.21	0.47
TGDS-15 (score, total score =15)	1.35±1.41	1.59±1.58	0.65
MSET10 (score, total score=29)	27.47±1.33	25.65±2.09	0.01*
MoCA (score, total score=30)	25.53±1.94	20.23±1.89	0.001*
VPAT (words, total score=24 words)	17.18±4.10	14.41±3.86	0.05
RAVLT (words, total score=75 words)	52.47±7.15	43.88±10.52	0.01*
DST (score, total score=28)	15.76±3.90	12.47±2.62	0.01*
TMT A (sec)	50.38±24.26	59.18±17.98	0.24
TMT B-A (sec)	40.82±23.18	92.80±92.90	0.04*
SCWT (interference score)	-4.30±6.50	-4.60±6.43	0.89

Note: *•Data are shown as mean±SD, *Independent t-test, significant difference at p<0.05. MSET10: Mental State Examination T10, MoCA: Montreal Cognitive Assessment, TGDS-15: Thai Geriatric Depression Scale-15, VPAT: Verbal Paired Associates Test, RAVLT: Rey Auditory Verbal Learning Test, DST: Digit Span Test, TMT A: Trail Making Test Part A, TMT B-A: subtracting Part B from Part A, SCWT: Stroop Color and Word Test.*

Spatiotemporal gait parameters during gait speed transition

Mean, median, quartiles, and variability of spatiotemporal parameters during gait speed transition are shown in Table 2. The Mann-Whitney U Test showed no significant differences for all mean spatiotemporal measures between the two groups. However, there was a statistically significant difference between the two groups for variability of spatiotemporal parameters. Specifically, variability of the step width (p<0.04) and swing time (p<0.02) were significantly greater in the MCI group compared with the control group under slow to fast speed transition.

We further explored the number of steps, total distance and total time during gait speed transition. The results demonstrated that there was no statistically significant difference between the two groups for all gait parameters. With respect to gait speed before and after a transition phase, gait speed at slow pace prior to changing to fast pace (MCI group =0.85±0.18 m/s, Control group =0.80±0.12 m/s) and during reaching to fast pace (MCI group =1.69±0.31 m/s, Control group =1.66±0.26 m/s) was not different between the MCI and control groups (p<0.05).

Variability of spatiotemporal parameters during steady-state of walking

The variability of spatiotemporal parameters during steady-state of walking are presented in Table 3. The Mann-Whitney U Test showed no significant difference between the two groups for variability of spatiotemporal parameters across the 3 walk conditions including slow, usual, and fast-pace walking (p>0.05).

Table 2 Spatiotemporal parameters during gait speed transition of the MCI and control groups.

Parameters	Control group (n=17)			MCI group (n=17)			*p*-value
	Mean±SD	Median	Q25 - Q75	Mean±SD	Median	Q25 - Q75	
Mean spatiotemporal							
Step length (cm)	62.78±9.62	63.70	53.50-71.05	62.62±7.74	63.70	57.00-68.05	0.88
Step width (cm)	6.98±2.31	6.93	4.93-9.44	7.10±2.65	6.37	5.09-9.33	0.93
Step time (sec)	0.52±0.05	0.52	0.50-0.54	0.52±0.04	0.51	0.49-0.55	0.76
Swing time (sec)	0.46±0.03	0.46	0.44-0.48	0.46 ± 0.05	0.47	0.41-0.49	0.80
Coefficient of variation							
Step length variability (%)	9.97±3.08	9.31	7.44 -12.51	12.49±6.30	10.32	8.17-15.31	0.38
Step width variability (%)	31.45±7.67	30.62	24.42-37.29	38.81±9.44	39.34	32.35 -43.04	0.04*
Step time variability (%)	12.77±2.64	12.49	10.62-14.60	14.39±4.70	12.30	10.85-18.33	0.48
Swing time variability (%)	12.14±3.52	10.54	9.35-14.82	16.02±5.11	16.79	11.52-19.41	0.02*
Other parameters							
Number of steps	4.22±0.70	4.25	3.88-4.50	3.96±0.89	3.75	3.13-4.38	0.34
Total distance (cm)	261.43±45.98	274.40	231.45-289.80	246.86±60.57	230.70	204.60-268.40	0.44
Total time (sec)	2.17±0.42	2.08	1.91-2.38	2.03±0.49	1.98	1.66-2.19	0.39

***Note**: * Mann-Whitney U Test revealed significant difference at p<0.05.*

Table 3 Variability of spatiotemporal parameters during steady-state of walking of the MCI and control groups.

Parameters	Control group (n=17)			MCI group (n=17)			*p*-value
	Mean±SD	Median	Q25 - Q75	Mean±SD	Median	Q25 - Q75	
Slow gait speed							
Step length variability (%)	4.78±1.31	5.11	3.51-5.53	4.56±1.14	4.72	3.59-5.30	0.50
Step width variability (%)	26.81±8.61	27.13	17.23-34.05	32.07±8.81	33.85	24.33-38.91	0.10
Step time variability (%)	7.43±3.18	6.53	4.70-10.11	6.70±2.61	6.35	4.81-8.67	0.72
Swing time variability (%)	7.78±3.01	8.06	6.05-8.68	6.12±2.93	5.35	3.78-7.67	0.07
Usual gait speed							
Step length variability (%)	4.79±1.41	4.57	3.76-5.46	4.48±1.32	4.36	3.10-5.33	0.69
Step width variability (%)	27.23±6.99	26.74	21.90-32.96	33.19±9.40	30.98	25.11-41.84	0.08
Step time variability (%)	5.88±1.76	6.11	4.32-6.64	6.09±2.27	5.82	3.97-7.38	0.89
Swing time variability (%)	7.58±3.24	6.58	5.37-9.53	5.92±1.85	5.67	4.37-6.83	0.16
Fast gait speed							
Step length variability (%)	4.51±1.28	4.65	3.44-5.31	4.14±1.34	4.27	2.81-5.06	0.34
Step width variability (%)	24.40±5.78	25.65	18.92-28.89	23.25±4.29	22.54	19.98-27.18	0.70
Step time variability (%)	4.40±1.28	4.08	3.06-5.51	4.89±1.77	5.01	2.95 -6.35	0.66
Swing time variability (%)	6.31±2.06	6.39	4.49-8.33	5.25±2.60	4.83	3.02-6.97	0.15

***Note**: * Mann-Whitney U Test revealed significant difference at p<0.05.*

Discussion

The main goal of this study was to investigate gait parameters in older adults with MCI during a transition gait speed task when compared to those cognitively intact controls. Our findings showed that older adults with MCI increased their variability of the step width and swing time during slow to fast speed transition compared with controls. However, the effect of gait speed transition on means of spatiotemporal parameters was similar between the two groups. Our findings are in agreement with previous studies that have suggested that an increased challenge in stability was not captured by means but by the variability of parameters.[48,49] Therefore, gait changes in older adults with MCI can be revealed during coping with a challenging walking condition and by using gait variability as the assessment measure.

As expected, older adults with MCI performed worse on general (i.e. MSET10 and MoCA) and specific cognitive tests (i.e. RAVLT, DST, and TMT B-A) than those controls. Consistent findings have revealed that deficits in general and specific cognitive domains including memory, attention, and executive function can be detected early in the course of MCI.[50-53] With respect to educational level, the present study found that the MCI group had a lower

educational level than the control group. Previous study has reported that there was no significant difference in gait speed between the low and medium education elderly and high education elderly.[54] Our results are in agreement with a previous report that gait speed of participants in the MCI group whose lower education was similar to those of the control group. Therefore, the difference of educational status between the two groups would not influence our findings.

Previous studies have extensively investigated gait performance in older adults with MCI during steady-state of walking compared to non-cognitive impaired persons and the findings were still inconsistent.[2,21,22,55,56] Consistent with previous studies,[55,56] gait speed under steady-state when walked at slow, usual, and fast pace in older adults with MCI was similar to those of healthy older adults. There was an evidence that usual walking speeds for community-dwelling older adults who are healthy generally ranged from 0.90 to 1.30 m/s.[57-59] Moreover, variability of spatiotemporal parameters during steady-state of walking at self-selected slow, usual, and fast paces did not differ between the two groups (as shown in Table 3). Therefore, it would be suggested that older adults with MCI in the present study appeared to be healthy and low risk of falling (as determined by their gait speed and variability of gait under steady-state of walking, performance on TUGT, and their fall history, Table 1 and 3).

Walking in real life situation requires cognitive resources and postural control for maintaining optimal walking task. Therefore, an instantaneous and non-volitional change in walking speed would be considered because it can determine the individual's ability to maintain safe gait in response to environmental constraint. A previous study supported that the ability to adapt gait pattern reactively had been identified as a critical feature of community ambulation.[60] To the best of our knowledge, this paper is the first to study spatiotemporal gait variability during gait speed transition in older adults with and without MCI. The relevant studies demonstrated that assessing gait variability under challenging situations such as walking at different speeds may represent cortical flexibility in controlling gait.[61,62] Findings demonstrated that despite similar gait speed, participants in the MCI group had greater gait variability than those cognitively intact controls during gait speed transition. It is possible that compared to steady-state walking, transitional accelerate of gait speed, both rapidly and unexpectedly, may require more demand on neuromuscular and balance control for adapting gait pattern in response to time-constraints. As we found, the variability of swing time and step width was significantly increased in older adults with MCI. Frenkel-Toledo et al[63] suggested that variability of swing time was a robust marker of gait dysrhythmicity and instability that was independent of gait speed. In addition, step width variability was proposed to be a determinant of balance control ability and closely related to fall risk in relatively healthy older adults who did not walk slowly (gait speed ≥1.0 m/sec).[42,64] Moreover, previous studies reported that variability in centre of mass (COM) mediolateral that reflect dynamic balance stability appeared to increase with advancing age whereas other gait dynamic stability (i.e. anteroposterior and vertical) was similar across ages.[65,66] Therefore, an increased swing time and step width variability in older adults with MCI in our study may reflect a neural control problem on regulation of balance control when coping with challenging walking task as fast speed transition. Together, evidence from the present work suggests that gait impairment in older adults with MCI would be detected by using sensitive measure as variability of gait and challenging walking condition as unexpected fast speed transition task. The clinical implication that arises from this study is an assessment of spatiotemporal parameters of gait variability during gait speed transition may be used as a potential approach for unveiling walking-related cortical changes among older adults. If gait changes can be identified at early stage, an early intervention aims to prevent future fall may be achieved.

The present study has some limitations. Our sample size was small that might not be detecting to the changes of some gait parameters. Therefore, the larger sample sizes should be enhanced the power analysis and external validity in future study. Another limitation is concerning the use of a laboratory setting rather than real life situations. Given that the demanding of the walking task in everyday life is highly complex. Therefore, the assessment of gait speed transition in real world situations, where individuals require unplanned rapid changes in gait speed under a range of environmental stimuli or concurrent task, is needed. Further study should also investigate gait adaptation in older adults with MCI under various walking speeds such as fast to slow speed transition. Finally, a longer walk-way length would yield greater consistency among measures of gait variability and also allow a wider range of distance to randomly activate an auditory cue.

Conclusion

Older adults with MCI demonstrated a significant increase in the variability of swing time and step width as compared to cognitively intact controls. These findings suggest that older adults with MCI had an impaired ability to regulate their gait consistency during attempt to increase walking speeds rapidly which may predispose them to falls.

Conflict of interest

The authors report no conflicts of interests in this study.

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Effects of occipito-frontal release with dorsiflexion technique (OFRDF) for improvement of superficial back line flexibility

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ABSTRACT

Background: Hamstrings tightness is a major risk factor concerning lower back pain and lower extremity injuries. Occipito-frontal release with dorsiflexion technique is a novel technique developed to improve the superficial back line (SBL) flexibility. This technique combines passive and active loading at the cephalic end, and caudal end of the SBL, respectively.

Objectives: To compare the effects of OFRDF and passive static stretching aimed at improving SBL flexibility in sedentary participants.

Materials and methods: Fifty-six participants demonstrating bilateral hamstring tightness (passive knee extension angle test greater than 20 degrees) were recruited. Participants were allocated via stratified block randomization (block size 4 and 6). Participants in the experimental group partook in OFRDF technique, whereas participants in the control group partook in passive static stretching. Both groups performed each intervention 3 times a week. Outcome measures were passive knee extension angle (PKE), craniovertebral angle (CVA), and sit and reach (SR) distance. Outcomes were measured at baseline, after the primary intervention, and post third intervention. A mixed-model ANOVA was used to compare mean difference within both the OFRDF and control groups and to compare between groups..

Results: A 3 (time) x 2 (group) mixed-model ANOVA demonstrated that both techniques shown to significantly decrease PKE angle on both sides, increase CVA and SR when compared between the third and initial intervention. However, all outcomes exhibited non-significant differences when compared between groups.

Conclusion: OFRDF and passive static stretching of the hamstrings can both similarly improve SBL flexibility.

Introduction

Hamstring muscle tightness is a key risk factor in regard to lower back pain.[1-3] This condition increases inappropriate posterior pelvic tilting. Flat-back is consequently induced abnormal stress and strain on lumbar structures.[4] In addition, hamstring muscle tightness is associated with various musculoskeletal disorders, such as lower extremity injuries[5], and walking and running inability.[6]

Passive static stretching is a popular method to improve hamstring flexibility among physical therapists. The unique characteristics of passive static stretching are that it exhibits a gentle style and is comfortable amid application.[7,8] Because hyperalgesia of hamstrings is an important symptom for consideration in some musculoskeletal conditions, passive static stretching is not a suitable method to treat acute hamstring strain or sciatica pain.[9] In these situations,

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direct technique to hypersensitive muscle should be avoid. Thus, this study paid attention to the indirect technique instead.

An important fundamental technique is Anatomy trains, as claimed by Myers. OFRDF was designed to apply force to the superficial back line (SBL) which is the meridian at the back of the human body.[10] Many strong evidences have incorporated both anatomic[11-13] and functional studies.[9,14-17] Moreover, the hamstring muscles is one component of the SBL which is located superiorly to the plantar fascia, achilles tendon, gastronomies muscles, and sacrotuberous ligament. Hamstrings are inferiorly positioned to the thoracolumbar fascia, erector spinae muscles, and occipito-frontalis muscles.[10] According to basic biomechanics, force application to the caudad and cephalad structures of serial connection may indirectly improve SBL component flexibility. This method was designed to passively force application to the occipito-frontalis muscle, and active force to the plantar fascia and gastronomies muscles.[17] Hence, for this particular study, SBL was selected as the target meridian. Previous study found that OFRDF can increase the SBL flexibility when comparing with rest.[10] Although, the immediate effect of OFRDF was revealed, the standard method should be compared to elucidate the effectiveness of technique.

This study chose to represent the SBL flexibility in three parts. Firstly, craniovertebral angle test (CVA) is used for measuring flexibility of the upper part of the SBL. In this study, we applied the 3-points marker detection program to assess CVA. This method demonstrated superior agreement between this method and goniometry.[18] SR was utilized in this study for flexibility measuring of the middle part of the SBL. Secondly, sit and reach test (SR) is used to assess middle part of the SBL for the reason that it is the general flexibility test which related to multiple body segments. In more detail, it also has the ability to reveal the lower back flexibility. Moreover, it is frequently applied amid studies involving the SBL.[9,16] Lastly, passive knee extension angle test (PKE) is the gold standard for represent hamstrings flexibility[19] which is the lower part of the SBL because PKE does not aggravate neural tension, 20 does not involve participants' quadriceps strength,[19,21] and incorporates less pelvic rotation.[19,21,22]

This study hypothesized that OFRDF and passive static stretching of hamstrings can increase the SBL flexibility similarly. Therefore, this study was carried out to compare effects of treatment technique between OFRDF and passive static stretching on SBL flexibility.

Materials and methods

Participants

Fifty-six participants with bilateral hamstring muscle tightness were recruited for testing. The sample size was calculated according to popliteal angle test (PA) in a 2015 study of Cho *et al*. who presented the effect of the suboccipital inhibition technique and self-myofascial release technique on hamstrings flexibility. The number of participants in their study was 50 (suboccipital inhibition group=25 and self-myofascial release group=25, s_1=7.1, s_2=6.5). Fifteen Significance level was lower than 0.05 ($Z_{\alpha/2}$ (0.025)=1.96) and power of test at 80% (Z_{β} (0.2)=0.84) were applied for calculation with 5% drop-out.[23] The screening of bilateral hamstrings tightness using passive knee extension angle test was performed by the assessor. The inclusion criteria consisted of male or female with bilateral hamstrings tightness (passive knee extension angle test greater than 20 degrees)[9,24] aged between 18 to 24 years, 1) BMI 18.5-24.9 kg/m^2, and 2) presenting a sedentary lifestyle including activities such as using a tablet or mobile phone, lying down, sleeping, sitting, watching television, and physical activity did not exceed 30 minutes/day, 3 days/week. The exclusion criteria consisted of participants with 1) spinal disorders (cervicogenic headache, neck pain, upper back pain, or lower back pain during the study period), 2) vertebrobasilar insufficiency, 3) regular stretching exercises (yoga or stretching exercises), 4) using muscle relaxants or nonsteroidal anti-inflammatory drugs (NSAIDs) 24 hrs prior to, and during the study period, 5) a history of whiplash injury, 6) presenting a history of fractures of the spine and/or lower extremities, 7) hamstring muscles tendinitis or muscle strain prior to the study, 8) hypermobility (Beighton score >4), 9) a severe orthopedic condition (scoliosis, kyphosis, flat-feet, high arch, or leg-length discrepancy), 10) a severe neurological condition (brain injury, spinal cord injury, nerve root compression, hyperalgesia, hypereflexia or hyperalgesia), and 11) those unable to perform the positioning required amid intervention or assessment.

The participants were randomized using a stratified block randomization technique (4 and 6 participants per block) and were stratified by gender, and degree of hamstring tightness (20 to 35 degrees, and 35 to 50 degrees).[24] The concealed envelop in each block was achieved using random numbers generated via the https://www.sealedenvelope.com/simple-randomiser/v1/lists. This study was approved by the Khon Kaen University Ethics Committee for Human Research (HE 622270), participants were recruited via advertisement. The assessor performed screening and physical examination amid the selecting of participants. Participants meeting inclusion criteria were invited to sign a participation consent form.

Procedures

This study was an assessor-blinded randomized controlled trial conducted at the School of Physical Therapy, Faculty of Associated Medical Sciences, Khon Kaen university, Thailand. Participants were informed about scope and study details. They were then allocated into two groups. Participants in the experimental group partook in OFRDF technique, whereas participants in the control group engaged in passive static stretching. Both groups performed their respective exercises amid each intervention for 3 days within a one-week period.[19] The physical therapist who performed OFRDF differed from the physical therapist who assessed outcome measurements. Notably, he boasted clinical experience of greater than 4 years in addition to a training period with a specialist over 10 hours. Furthermore, the assessor was a physical therapist with greater than 5 years of clinical experience. Subsequent to the training period (10 hours), the assessor performed intra-rater reliability of the passive knee extension angle test, the craniovertebral angle test, and the sit and reach test. The results of all tests were

excellent (ICC=0.985-0.992). All outcome measurements were assessed throughout 4 P.M-7 P.M. She assessed outcome measurements prior to experimentation to establish baseline. Measurement recording was then conducted 5 mins after the initial intervention for immediate effect, and after the third intervention to compare repetitive effect. Participants rested between each outcome measurement for 2 mins.

Interventions

Occipito-frontal release with dorsiflexion (OFRDF) technique

A participant comfortably lies on his/her back. The physical therapist flexes and extends the participant's upper cervical spine utilizing passive shearing force via soft movement cyclic loading. During flexion, each participant bends his/her ankle joint by way of dorsiflexion. In addition, the participant bends his/her ankle joint by way of plantar flexion (Figure 1). With their hands the physical therapist ensures a uniform intensity of force throughout palpation of occipito-frontalis muscle tension and the anatomical barrier of occiput movement. Treatment cycle times were compared with metronome. OFRDF is performed throughout 5 mins incorporating 10 repetitions per set within 1 minute, totaling 3 sets and 1-minute rest between sets.[17]

(a) Starting position

(b) Occipito-frontal release with dorsiflexion technique (OFRDF)

Figure 1*. Occipito-frontal release with dorsiflexion technique (OFRDF).*

Passive static stretching of hamstrings

A participant comfortably lies on his/her back. The physical therapist slowly flexes each participant's hip with knee extension from 0 degree as far as possible (not beyond 90 degrees). Determination of the end point of passive movement is a tight sensation without pain at the posterior thigh (Figure 2). The physical therapist should avoid combined movement of the hip joint. Direction of load application should be pure hip flexion without hip rotation. This technique is performed over a total time of 5 mins. In one set of stretching, the physical therapist performs this technique 30 seconds per time incorporating 3 repetitions per set. After each stretching occurrence, the participant rests for 20 seconds with the process repeated on the other side.[25–27]

(a) Starting position

(b) Passive static stretching of hamstring muscles

Figure 2*. Passive static stretching of hamstring muscles.*

Outcomes

Sequencing of outcome measurements were the passive knee extension angle test, the craniovertebral angle test, and the sit and reach test.

The passive knee extension angle test: PKE

A participant comfortably lays on his/her back and the assessor bends the participant's examined hip to 90 degrees of hip flexion. The assessor places an inclinometer at the most anterior portion of the tibial shaft utilizing straps. The contralateral limb is fixed in its full extension using a table and belt. After that, the assessor passively extends the participant's knee until they feel a strong yet tolerable stretch at the posterior thigh, with the assessor recording the angle. This test is performed three times with average score recorded.[21] (Figure 3)

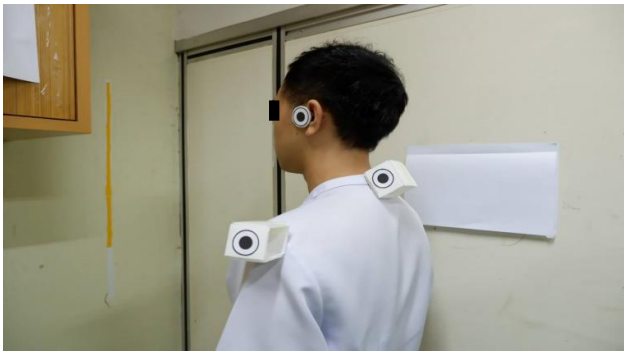
The craniovertebral angle test: CVA

A participant stands in a relaxed position. The assessor then places markers on the spinous process of C7 and tragus of the selected ear side. The 3-point marker detection program is used to assess CVA. The digital camera is located 1 meter from the participant with the image taken once a participant performs spot marching five times. In this study 3-point marker detection is utilized with digital image processing to calculate real time angles between markers. This program begins with searching markers, and then automatically calculates distance between markers (Figure 4). Moreover, the program can transform selected variables to be a CVA base amid trigonometric function.[18]

(a) Starting position

(b) Passive knee extension angle test

Figure 3*. Passive knee extension angle test.*



(a) Starting position

(b) Craniovertebral angle test

Figure 4*. Craniovertebral angle test.*

The sit and reach test: SR

A participant sits on the floor with both knees extended with the feet flat against the measuring box. The assessor asks a participant to reach forward over the measuring box and hold that position for 2 seconds. This test is performed twice selecting the maximum flexibility value in centimeter.[9] (Figure 5)

(a) Starting position

(b) Sit and reach test

Figure 5*. Sit and reach test.*

Statistical analysis

Descriptive statistic was used to describe demographic participants' data. Mean and standard deviation (SD) were employed to describe both demographic data, and outcome value measurements. Kolmogorov-Smirnov was applied to test for normality of data. A mixed-model ANOVA was used to compare mean difference within both the OFRDF and control groups and to compare between groups. Significance level was set at $p<0.05$. In this study, we employed SPSS version 23.0 for Windows for data collection and data analysis.

Results

Demographic data, health status, and baseline characteristics

Sixty-eight participants were recruited and screened by the assessor throughout January 29 to February 19, 2020. Fifty-six eligible participants were subsequently included in the study; of the 12 participants excluded half were excluded due to lower back pain, with the remaining reporting hamstring muscles strain. Eligible participants had PKE tested on both sides to represent bilateral hamstring muscles tightness. CVA and SR were also tested to establish baseline values as shown in Figure 6. The demographic data and baseline characteristics were shown in Table 1.

Mean and standard deviation of outcome measures in OFRDF, and the control groups were presented. Kolmogorov-Smirnov showed normal distribution of data ($p>0.05$). Therefore, a mixed-model ANOVA was used to compare mean difference within both the OFRDF and control groups and to compare between groups as seen in Table 2. The within subject effect and the between subject effect showed no interaction effect ($p>0.05$).

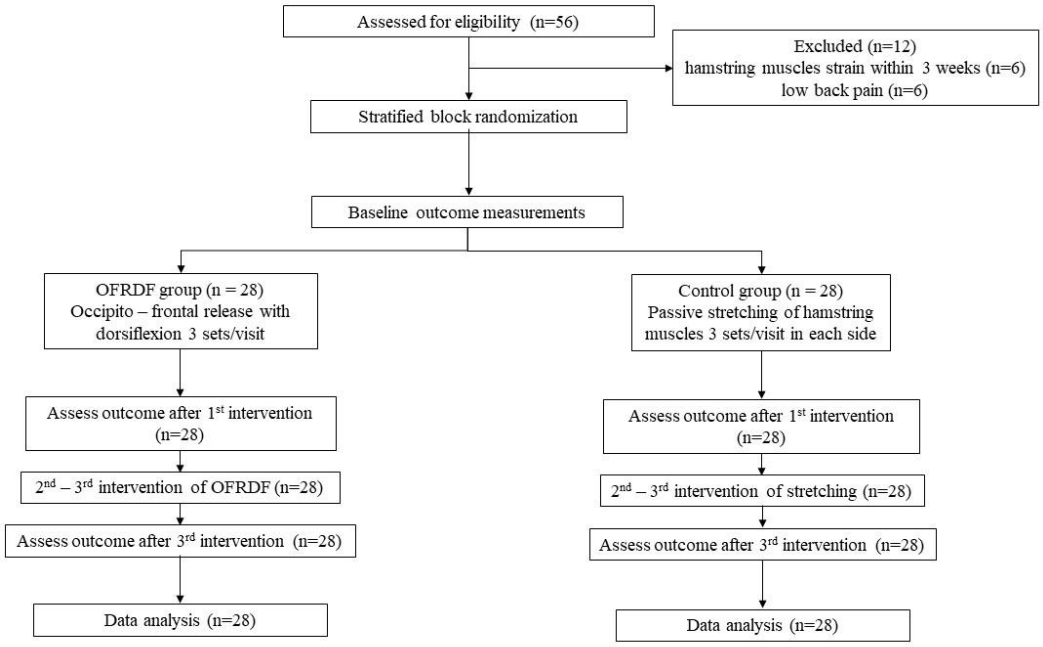


Figure 6*. Flow of participant procedures .*

Table 1 Demographic data and health status amid main study.

Baseline characteristics	Mean±SD	
	OFRDF	Control
Age (years)	20.75±1.8	20.93±1.68
Gender; n of male (%)	11 (39.29%)	13 (46.43%)
Weight (kg)	59.16±11.97	62.5±15.13
Height (centimeters)	164.79±7.83	167.04±8.56
Body mass index	22.93±0.87	23.33±1.34
Marital status (n)		
Single	28	28
Married	0	0
Divorced	0	0
Occupation (n)		
Student	23	26
Physical therapist	4	2
Teacher	1	0
Underlying diseases (a person exhibiting more than one underlying disease) (n)		
Non	27	22
Allergy	1	4
Asthma	0	1
G6PD	0	1
Gastritis	0	1
Exercise (n)		
Non	19	19
Once a week	4	3
Twice a week	3	3
3 times a week	2	3

Table 2 Comparison of the outcome measurements within the OFRDF and control groups, and between groups.

Outcome measurements	OFRDF			Control		
	Time interval			Time interval		
	1	2	3	1	2	3
Rt.PKE (degrees)	66.12±8.39	63.51±9.22	60.5±9.3*	62.71±7.92	58.41±9.85	57.75±11.63^
Lt.PKE (degrees)	68.64±8.73	66.12±9.63	62.99±9.96*	66.24±7.41	62.27±9.35	60.85±10.4*
CVA (degrees)	40.63±4.74	41.95±5	42.33±4.64*	40.13±5.53	41.24±4.75	42.3±5.42*
SR (centimeters)	-6.88±7.6	-5.17±8.02	-3±8.12*	-6.72±9.18	-4.02±9.25	-3.08±9.01*

*Rt.PKE=the passive knee extension angle test (right side), Lt.PKE: the passive knee extension angle test (left side), CVA: the craniovertebral angle test, SR: the sit and reach test, 1: baseline, 2: initial intervention, 3: third intervention, *Statistically significant differences between third intervention and baseline (p<0.05)*

Variables

A 3 (time)x2 (group) mixed-model ANOVA revealed a significant main effect for time, $F_{(2,100)}$=31.646, p<0.01, eta-squared=0.369. However, the main effect for group was not significant, $F_{1,54}$=2.435, p>0.05, eta-squared=0.043. Thus, there was no overall difference in the right passive knee extension angle of OFRDF compared with passive static stretching.

A time x group mixed-model ANOVA demonstrated a significant main effect for time, $F_{(2,92)}$=30.489, p<0.01, eta-squared=0.361. Although, the main effect for group was not significant, $F_{1,54}$=1.424, p>0.05, eta-squared=0.026. Therefore, there was no overall difference in the left passive knee extension angle of OFRDF compared with passive static stretching.

A mixed-model ANOVA showed a significant main effect for time, $F_{(2,98)}$=12.974, p<0.01, eta-squared=0.194. In contrast, the main effect for group was not significant, $F_{1,54}$=0.106, p>0.05, eta-squared=0.002. Hence, there was no overall difference in craniovertebral angle of OFRDF compared with passive static stretching.

A mixed ANOVA demonstrated a significant main effect for time, $F_{(2,99)}$=32.24, p<0.01, eta-squared=0.374. However, the main effect for group was not significant, $F_{1,54}$=0.035, p>0.05, eta-squared=0.01. Henceforth, there was no overall difference in sit and reach distance of OFRDF compared with passive static stretching.

Discussion

Our primary objective was to compare the effects of OFRDF and passive static stretching on SBL flexibility. According to the results, OFRDF and passive static stretching presented similar effects in terms of decreasing hamstring muscles tightness (lower part of the SBL), increasing sit and reach distance (middle part of the SBL), and increasing craniovertebral angle (upper part of the SBL). The results supported the hypothesis of the study that OFRDF and passive static stretching of hamstrings can increase the SBL flexibility similarly.

OFRDF is a novel technique combining passive as well as active myofascial release. Hence, it should be compared with standard interventions for the elucidation of the exact effects amid flexibility dimensions.[17] Passive static stretching was chosen as a comparative procedure to assess hamstring flexibility.[7,8,25–27] Although, passive static stretching can increase hamstring flexibility, it may cause injury in some conditions, such as in acute hamstring strain or sciatic pain.[9] The unique characteristic of the OFRDF method is a cyclic loading application which is employed to progressively stretch myofascial components in a pain-free movement. Importantly, OFRDF does not produce overstretching.[17] In the clinical field, OFRDF ought to be applied amid further study pertaining to musculoskeletal disorders incorporating lower back pain and hamstring tightness.

OFRDF and passive static stretching showed a significant decrease in knee extension degree in PKE on both sides as well as a significant increase in SR. These findings are supported by previous studies which utilized a different technique (suboccipital inhibition).[9,14,15,28] To clarify, suboccipital inhibition comprises of a passive myofascial release technique whereby the therapist applies passive tension and shearing forces on the suboccipital muscles. OFRDF observes a similar style, though participants actively bend their ankles upwards.[17]

According to thixotropic properties, cyclic loading and surface contact amid manual therapy may provide mutual heat generation[29] which increases heat and blood circulation in the selected muscles.[30] Alterations in tissue viscosity may increase tissue flexibility and ROM.[31]

OFRDF may enhance flexibility resultant of autogenic inhibition[31] and cyclic loading. Besides that, OFRDF may provide afferent feedback from the Golgi tendon organs (GTOs), at the myotendinous junction, and from the fascia to spinal cord. Because GTOs attach a series of muscle connections,[30] stimulation of GTOs via active ankle dorsiflexion[32] can decrease motor unit firing rate and normalize muscle tension.[33] Moreover, cyclic loading may also progressively increase strain on selected myofascial components.[17]

According to neuromechanical properties, OFRDF and nerve mobilization are similar in style, as both procedures utilize cyclic loading to indirectly move or stretch nervous tissue. The external passive force at the cervical region promotes nerve sliding in the vertebral canal. A previous study also suggested that nerve sliding in the vertebral canal can improve nerve mobility superiorly to localized stretching.[34] It is possible that free nerve movement may enhance the effectiveness of neuronal transduction to the muscles, bones, and joints. Thus, improvements in hamstring flexibility may be involved with the indirect effect from nerve to muscle.

In contrast, the control group engaged in passive static stretching. Findings supported the results of previous studies which employed SLR to stretch the hamstrings.[27,35] The mechanism of passive static stretching in increasing body flexibility is involved with autogenic inhibition, and thixotropic property as described prior.[31,36]

Interestingly, different techniques can demonstrate similar therapeutic effects; for example, OFRDF produced the immediate effect of significantly increasing CVA. According to a similar style presented by both techniques, the current result was supported by a study by Jeong and coworkers who applied the suboccipital inhibition technique.[28]

Passive static stretching of the hamstrings can increase CVA when comparing between the third intervention and baseline. This result was consistent with a study by Hyong and Kang who revealed that passive static stretching of the hamstring muscles can increase cervical range of motion.[37] These results may be explained by the force transmission of the SBL. Loosening the musculofascial component in one area may increase the flexibility of the same component in the distant area on the same meridian.[9,14–16,28,37,38]

In contrast, both PKE, CVA and SR were not statistically significantly different amid comparison between the third intervention and first interventions in both groups. The results may relate to participants' lifestyles due to the fact that we recruited participants exhibiting sedentary lifestyles. Accordingly, their activities involved mobile phone usage

and prolonged posture. This sustained position may as a consequence, induce tightness of hamstrings and cervical extensor.

In consideration of the comparison in therapeutic effects between groups, there was a non-statistically significant decreasing degree of PKE amid both sides, an increasing CVA, and SR distance. These results corroborate with a study conducted by Krause and coworkers[39] who proved that local stretching of the cervical region or hamstring stretching can increase cervical ROM similarly. This result is supported by Anatomy Trains theory which claims the remote effect of the selected member amid the same meridian. In this study, passive static stretching of the hamstring muscles affected upper cervical extensor flexibility (cranio-vertebral angle). Stretching of the hamstrings –the SBL component- may alternate overall flexibility of the same meridian. Hence, force application on one component of the selected meridian may affect another component of the same meridian, which in turn leads to similar effects amid both techniques.

This study has some limitation points for consideration. Firstly, the markers for CVA assessments were placed on the cloth of participants according to the culture and may lead to inaccurate of the results. Secondly, we could not entirely control participants' activities of daily living. Due to diversity of activities, participants may perform other activities which disturb the therapeutic effects of treatment. For example, prolonged sitting or standing may activate muscle loading and disturb the body's flexibility. Thirdly, SR reflects non-specific bodily flexibility. Increased flexibility resultant of utilizing SR cannot solely produce SBL flexibility. In some cases, participants demonstrated shoulder-flexibility augmentation. Hence, subjects were able to easily perform the sit and reach test. Thus, body flexibility values are increased consequence of SR. Lastly, we included participants aged 18 to 24 years meaning it is difficult to extrapolate the results to other groups.

Conclusion

OFRDF and passive static stretching of the hamstrings can similarly improve the SBL flexibility. In case of hamstrings hyperalgesia, it is possible that a physical therapist can apply OFRDF to improve hamstrings flexibility in patients exhibiting hamstrings strain or sciatica pain for the prevention of unwanted adverse effects.

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Reliability and validity of culturally adapted executive function performance test for Thai people with substance-induced disorders

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ABSTRACT

Background: Recently, the executive function assessment tools in Thailand are mainly administered as the bottom-up approach using separate tasks of client skills more than as the top-down approach using activities in daily life contexts. These bottom-up assessments are focused on the components of executive function which are not relevant to client's participation in real situations.

Objectives: The aims of this study were to develop and appraise the standardization of Executive Function Performance Test in Thai version (EFPT-Th) which was culturally adapted as the performance-based executive function tests for Thai contexts.

Materials and methods: Back-translation process and expert's agreement were introduced to develop EFPT-Th. Thirty participants diagnosed with substance-induced disorders were recruited to examine the internal consistency, intra-rater reliability and inter-rater reliability. Moreover, the criterion validity was analyzed by the correlation with Behavioral Assessment of the Dysexecutive Syndrome (BADS).

Results: The internal consistency of EFPT-Th was considered to be acceptable (Cronbach's alpha=0.72). For intra-rater and inter-rater reliability of EFPT-Th total score demonstrated high level of coefficients (ICC=0.98 and 0.88, respectively). The criterion validity of EFPT-Th was reported significantly high negative correlations between the total EFPT-Th scores and the BADS total profile scores (r=-0.63, p<0.01).

Conclusion: The present study provides that EFPT-Th is the performance-based test of executive function which is culturally appropriate adaptation for Thai contexts. EFPT-Th also could be the benefit to occupational therapists to evaluate the executive function and determine the level of assistance for clients with executive dysfunction to engage in the instrumental activities or complex daily tasks.

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Introduction

Currently, it was reported that 225 million individuals worldwide possessed a drug addiction.[1] Chronic drug dependence correlated with cognitive impairment and executive dysfunction. Previous research showed that the long-term drug use can lead to the disturbances in synaptic functioning, receptor sensitivity and the synaptic reuptake mechanism in the brain. Especially, the prefrontal cortex is altered by chronic exposure to drugs causing executive dysfunction.[2-6]

Executive Function (EF) is an higher cognitive ability to conduct, prepare and combine information involving thought process, goal-directed action and self-regulation.[7] Hughes and colleagues in 2005 also defined EF which comprises of inhibitory control, working memory, and attention flexibility.[8] Lezak model divided EF into volition, planning, purposive action and effective performance that linked into the aspect of occupational therapy.[9, 10] In occupational therapy, EF is a critical thought process of how individuals can participate in complex activities, non-routine tasks or unstructured actions.[7] Therefore, executive dysfunction may cause the interference of complex activities in daily living such as housing application, childcare, driving a vehicle, instrumental activities of daily living, work, social skills and participation in community life.[11, 12] An occupational therapist has a role in the rehabilitation that establishes the clients with executive dysfunction to independently participate and engage in activities.

Occupational therapists evaluate and treat substance-induced disorder in the area of executive dysfunction by conducting to promote learning strategies to participate the meaningful activities. Thus, the evaluation process to identify the EF problems is extremely crucial and important. Generally, the majority of the assessment are standardized neuropsychological tests i.e. Trail Making Tests,[13] Digit span forward and backward: Wechsler Memory Scale-Revised[14] and the Behavioral Assessment of the Dysexecutive Syndrome (BADS).[15] These bottom-up assessments are examined EF components which did not link to the actual daily activities. Therefore, these neuropsychological tests cannot predict the capacity of EF in the real environment and context of the clients.[16] According to the limitation of general EF tests, the Executive Function Performance Test (EFPT) is top-down assessment and has been developed by occupational therapists.[17] Moreover, EFPT is a standardized performance-based EF test which is compiled with the Lezak model of EF components.[9, 10] EFPT had been translated and culturally adapted into several languages and had been studied the psychometric properties in various groups including stroke, schizophrenia, homeless individuals and multiple sclerosis.[18-23] In Thailand, the international assessment instruments are mainly used to evaluate EF which are not relevant to client's participation in real situations. Therefore, occupational therapists need the standardized test that has the properties to evaluate EF components on the daily live activities within Thai context using timeless and low-cost expenses. Finally, the interpretation of EF test will be able to utilize planning and outcomes of occupational therapy programs as well as communicating with clients and multidisciplinary team.

EFPT had been translated and altered in many countries, for example, Sweden,[19] United States,[20] Korea[22] and Israel.[24, 25] However, Thailand has significant cultural variants from other countries. Hence, the adopting EFPT would be considered to change and add the tasks including instruments and materials which are familiar with the Thai cultural contexts. Therefore, the purpose of this study was to establish the Executive Function Performance Test in Thai version (EFPT-Th). The psychometric properties of EFPT-Th including content validity, internal consistency, criterion validity, intra-rater and inter-rater reliability, were studied in the people with substance-induced disorders.

Table 1 Tasks replaced in agreement with the Thai culture in EFPT-Th.

EFPT tasks	EFPT-Th tasks
Making oatmeal	Making instant rice porridge (Simple cooking Task 1) Making omelet (Simple cooking Task 2)
Ordering groceries from local grocery store by phone	Requesting delivery of food from the restaurant by telephone
Compensate cable and telephone bills utilizing check	Compensate electricity bills and telephone bills utilizing cash

EFPT: Executive function performance test, EFPT-Th: Executive function performance test: Thai version

Materials and methods

Translation and Cultural Adaptation

The process of adapting the original EFPT version to Thai version comprised of 4 steps: The first step was the forward and backward translation. Two bilingual lecturers of occupational therapy were used for the forward translation then two bilingual experts who had 5- and 10-years' experience in psychosocial field were used for the backward translation. Lecturers and experts hadn't previously seen EFPT. For this step, EFPT-Th draft 1 was obtained.

The second step, there also were three occupational therapists with 5 years cognitive rehabilitation experience to agree and discuss of comparing the variances then rectifying the difference points until EFPT-Th was accomplished. EFPT-Th draft 2 was added and adapted the tasks familiar with the Thai context but it still composed of content, method and detail of EFPT original version as shown in Table 1.

The third step was the content validity. Three professionals were designated to fill agreement on the Index of item-Objective Congruence (IOC) and comment.[26]

IOC for the components in each task exhibited a high level of agreement (IOC=0.67-1.00). EFPT-Th draft 3 was gained.

The final step was to test EFPT draft 3 with the healthy participants aged between 20-40 years. The results were examined as the pilot study to adjust and rectify the assessment. For this step, the completed EFPT-Th was achieved.

Psychometric properties study

Psychometric properties of EFPT-Th were studied including internal consistency, inter-rater and intra-rater reliability and criterion validity. Thirty participants were diagnosed with substance-induced disorder, participants were in occupational therapy programs at Somdet Chaopraya Institute of Psychiatry by a purposive sampling. The inclusion criteria were as follows: (1) who had been diagnosed with substance-induced disorder by Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 (2) who had been screened from occupational therapists for cognitive problems with screening test, Montreal Cognitive Assessment (MoCA) and Trail Making Test (TMT) (3) aged between 20-40 years (4) who had got Mini-Mental State Examination-Thai version (MMSE-Th) scores of 22 or more (5) who had no visual, auditory, and communication impairments. The exclusion criteria included (1) who were diagnosed with substance-induced psychotic disorder (2) who had the problems of emotional and behavioral controls. Participants were informed about the research study according to ethical principles. This study was granted ethics approval from Mahidol University Central Institutional Review Board (COA No. MU-CIRB 2018/217.0511).

Measurements

EFPT is the performance-based standardized assessment that is used to assess the cognitive function[27] It composes of a macro-level view of cognition which all functional operations are examined as individual capacity. Because of the limitation in micro-level assessments, there is no transfer from cognitive process deficiencies to performance dysfunction.[28, 29] EFPT is used to measure EF capacity and functional processing in the environmental context which were similar and adaptable to real life. EFPT scores derive from the assessment by tasks which are important for independent living and self-care, as follows, (1) simple cooking skills, (2) using a telephone, (3) medication management and (4) paying bills. In this study, EFPT-Th was adjusted and added tasks that were relevant to Thai culture and contexts. For EFPT-Th, the simple cooking tasks 1 and 2 were the making instant rice porridge and the making an omelet. While the participants performed each task of EFPT-Th, the five behavioral performance were scored including initiation, organization, sequencing, safety and judgment and completion. Scores were rated into 6 scales according to the cueing system (0=no cue required, 1=verbal guidance, 2=gestured guidance, 3=direct verbal assistance, 4=physical assistance and 5=therapist does the component for participant). The greater average score, the more needed cues and the more severity of executive function deficiencies.

Behavioral Assessment of the Dysexecutive Syndrome (BADS)[15] is a neuropsychological test, comprising 6 subtests, that measures the EF components including mental flexibility and shifting, planning and problem solving, systematic planning and spatial search, adherence to rules, time estimate, and switching between different tasks. The assessment process was established by 6 activities: The Rule Shift Cards test, Action Program test, Key Search test, Temporal Judgment test, Zoo Map test, Modified Six Elements Test. Each subtest has scores from 0 to 4 with the total score being 24. This assessment has been studied for reliability and validity in healthy, acquired brain injury, and schizophrenia samples.[30-33] BADS can be assessed in the age range from 16-87 years and takes relatively 40 minutes to assess. This assessment is considered as a gold standard test because it is acknowledged as a standardized test for evaluating core functions of the executive function. In this study, BADS was utilized for the criterion validity of EFPT-Th.

EFPT-Th was used to assess thirty participants with substance-induced disorders. The performance was videotaped during the assessment process. The researcher rated scores following the criteria of EFPT-Th then summarized the scores in each task and the total score of EFPT-Th for determining the internal consistency. Additionally, the samples were assessed with 6 activities of the BADS. After that, the scores of EFPT-Th and the scores of the BADS were analyzed the correlation for measuring the criterion validity. Inter-rater reliability was also evaluated using thirty participants with substance-induced disorders by two occupational therapists who had clinical experience more than 5 years. Two occupational therapists independently rated the scores of EFPT-Th by observing video footages of performance. The scores of EFPT-Th from two raters were analyzed the correlation to determine the inter-rater reliability. For the intra-rater reliability, one occupational therapist was assigned to rate the scores of EFPT-Th by observing video footages of performance for two periods with 7 days interval to decrease the effect of recall bias.[34] The scores of first and second period were analyzed the correlation.

Statistical Analysis

All statistical analyses in this examination were performed by SPSS for Windows (Version 17.0; SPSS Inc., Chicago, IL). Demographic characteristics were calculated using descriptive statistic. Cronbach alpha coefficient were analyzed the internal consistency because EFPT-Th was scored with the Likert scale; which was considered to be ordinal scale. Spearman's rank correlation was considered to examine the criterion validity. Lastly, intra-class correlation coefficients (ICCs) were used to determine intra-rater reliability and inter-rater reliability.

Results

Descriptive data for the characteristics of the participants presented in Table 2. The sample group composed of thirty participants with twelve males (40%) and eighteen females (60%). The mean age of the sample was 31.10 (SD=6.23, range =20-40). The mean time of substance induced disorder onset was 8.82 years (SD=7.30, range=0.08-25). Most of participants had lower secondary level education (43.33%). The majority (86.67%) of the participants had used stimulant drugs. The mean of MMSE score was 25.68 (SD=2.36, range=22-29).

Table 2 Demographic characteristics (n=30).

Characteristics	Participants	Percentage
Sex		
Male	12	40
Female	18	60
Substance type		
Alcohol	4	13.33
Cannabinoids	7	23.33
Stimulants	26	86.67
Education		
Primary education	11	36.67
Lower Secondary Education	13	43.33
Upper Secondary Education	4	13.33
Bachelor's Degree	2	6.67
	Mean (SD)	Range
Age (years)	31.10 (6.23)	20-40
Duration from onset (Years)	8.82 (7.30)	0.08-25
MMSE-Th score	25.68 (2.36)	22-29

MMSE-Th: Mini-mental state examination-Thai version

Intra-rater and inter-rater reliability

The average and range of the participants' scores in EFPT-Th were shown in Table 3. Mean of EFPT-Th total score was 12.86 (SD=4.01, range=3-24). The results indicated that participants required higher levels of assistance in the task using the telephone (mean=3.40, SD=1.44) and paying bills (mean=3.37, SD=0.86) than simple cooking task 1 (mean=2.80, SD=1.44), simple cooking task 2 (mean=1.70, SD=1.37) and medicine management (mean=1.60, SD=1.39). Sequencing (mean=7.80, SD=2.49) and organization problems (mean=4.20, SD=1.88) were found the difficulties more than initiation (mean=0.00, SD=0.00), safety and judgement (mean=0.83, SD=1.06) and completion (mean=0.07, SD=0.13). The internal consistency of EFPT-Th considered to be high and acceptable (Cronbach's alpha=0.72) with the results of the internal consistency for each task range 0.58-0.80 as presented in Table 4.

Table 3 Mean, standard deviations and range scores of patients with substance induced disorder on the EFPT-Th (n=30).

Test	Mean (SD)	Range
EFPT-Th tasks		
Simple cooking Task 1 (Making instant rice porridge)	2.80 (1.44)	0-9
Simple cooking Task 2 (Making omelet)	1.70 (1.37)	0-6
Telephone use	3.40 (1.44)	0-7
Medication management	1.60 (1.39)	0-6
Bill payment	3.37 (0.86)	1-5
EFPT-Th components		
Initiation	0.00 (0.00)	0-0
Organization	4.20 (1.88)	0-9
Sequencing	7.80 (2.49)	2-14
Safety and judgment	0.83 (1.06)	0-3
Completion	0.07 (0.13)	0-2
Total score	12.86 (4.01)	3-24

EFPT-Th: Executive function performance test: Thai version

Table 4 The internal consistency of the EFPT-Th.

EFPT-Th	Cronbach's alpha
Items of all tasks on EFPT- Th	0.72
	Correlation of each task with the total score
Simple cooking (Making instant rice porridge)	0.67
Simple cooking (Making omelet)	0.80
Telephone use	0.68
Medication management	0.58
Bill payment	0.59

Intra-rater reliability was conducted on EFPT-Th score. The ICC were analyzed for the total score and each subtest scores. The results demonstrated the moderate to high intra-rater reliability of EFPT-Th. For the total EFPT-Th score, the ICC was 0.98 whereas the subtest ICC scores were 0.98 for simple cooking task 2 (making an omelet), 0.97 for simple cooking task 1 (making instant rice porridge), 0.97 for medication management, 0.94 for using the telephone and 0.57 for paying bills. Additionally, the inter-rater reliability of the total EFPT-Th score, the ICC was 0.88, and subtest ICC scores were 0.91 for simple cooking task 1 (making instant rice porridge), 0.73 for managing medication, 0.70 for simple cooking task 2 (making omelet), 0.59 for telephone use and 0.58 for paying bills. These coefficients indicated that EFPT-Th had moderate to high levels of inter-rater reliability as shown in Table 5.

Table 5 Intra-rater and inter-rater reliability of EFPT-Th as demonstrated by intraclass correlation coefficients (ICC) and 95% confidence interval (CI).

	Intra-Rater ICC (3,1) (95% CI)	*p*	Inter-Rater ICC (2,1) (95% CI)	*p*
Simple cooking Task 1(Making instant rice porridge)	0.97 (0.94-0.99)	0.000	0.91 (0.80-0.96)	0.000
Initiation	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Organization	0.82 (0.62-0.91)	0.000	0.97 (0.94-0.99)	0.000
Sequencing	0.66 (0.28-0.84)	0.003	0.97 (0.94-0.99)	0.000
Safety and judgment	0.94 (0.88-0.98)	0.000	0.95 (0.90-0.98)	0.000
Completion	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Simple cooking Task 2 (Making omelet)	0.98 (0.95-0.99)	0.000	0.70 (0.37-0.88)	0.001
Initiation	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Organization	0.86 (0.70-0.93)	0.000	0.96 (0.91-0.98)	0.000
Sequencing	0.66 (0.28-0.84)	0.003	0.98 (0.97-0.99)	0.000
Safety and judgment	0.94 (0.88-0.97)	0.000	0.97 (0.94-0.99)	0.000
Completion	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Telephone use	0.94 (0.87-0.97)	0.000	0.59 (0.14-0.81)	0.009
Initiation	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Organization	0.84 (0.66-0.92)	0.000	0.96 (0.93-0.98)	0.000
Sequencing	0.77 (0.52-0.89)	0.000	0.91 (0.82-0.96)	0.000
Safety and judgment	0.87 (0.72-0.94)	0.000	0.98 (0.95-0.99)	0.000
Completion	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Medication management	0.97 (0.94-0.99)	0.000	0.73 (0.42-0.87)	0.000
Initiation	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Organization	0.59 (0.07-0.77)	0.000	0.96 (0.91-0.98)	0.000
Sequencing	0.82(0.61-0.91)	0.000	0.98 (0.95-0.99)	0.000
Safety and judgment	0.79 (0.57-0.90)	0.000	1.00 (0.00-0.00)	0.000
Completion	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000

Table 5 Intra-rater and inter-rater reliability of EFPT-Th as demonstrated by intraclass correlation coefficients (ICC) and 95% confidence interval (CI). (continues)

	Intra-Rater ICC (3,1) (95% CI)	*p*	Inter-Rater ICC (2,1) (95% CI)	*p*
Bill payment	0.57(0.12-0.75)	0.045	0.58 (0.12-0.80)	0.000
Initiation	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Organization	0.79 (0.56-0.90)	0.000	0.98 (0.96-0.99)	0.000
Sequencing	0.70 (0.38-0.86)	0.000	0.91 (0.80-0.96)	0.000
Safety and judgment	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
Completion	1.00 (0.00-0.00)	0.000	1.00 (0.00-0.00)	0.000
EFPT-Th total score	0.98 (0.97-0.99)	0.000	0.88(0.74-0.94)	0.000

EFPT-Th: Executive function performance test: Thai version

Criterion Validity

Table 6 presented the Spearman correlation coefficients between the total EFPT-Th scores and the BADS total profile scores. The results reported significantly high negative correlations (r=-0.63, p<0.01). Additionally, statistically significant low to moderate correlations were found between the individual EFPT-Th task and the BADS total profile scores ranged from -0.33 to -0.52. The lower scores of the BADS indicated the greater EF problems (mean=67.27) whereas, the higher scores of EFPT-Th indicated the more cues were needed reflecting the greater executive dysfunction (mean=12.86).

Table 6 Spearman' rank correlation between EFPT-Th total score and Behavioral assessment of the dysexecutive syndrome (n=30).

EFPT-Th tasks	BADS total profile scores
Simple cooking (Making instant rice porridge)	-0.42*
Simple cooking (Making omelet)	-0.52**
Telephone use	-0.33*
Medication management	-0.35*
Bill payment	-0.33*
EFPT-Th total scores	-0.63**

*EFPT-Th: Executive function performance test: Thai version, BADS: Behavioral assessment of the dysexecutive syndrome, *p<0.05; **p<0.01*

Discussion

Although, this study showed the difference in some backward translation of EFPT-Th from the original one but it presented in the same meaning because the process of translation was tailor-made for the Thai culture and contexts using occupation-based assessment. EFPT-Th can be used to assess people who perform activities in the real contexts. The quality and integrity of the translation process plays an important role to ensure that the cross-cultural research findings were accurate and not be weakened by the errors of translation.

The studies in various countries demonstrated that the method of operating the tasks of EFPT was varied in each culture by altering, adjunct, and determined cultural validity of tasks by professional recommendation. For instance, in Korea, the simple cooking task was altered from the oatmeal menu to rice porridge and modified the method of the using telephone task from calling the grocery store to ordering delivery food from restaurants.[22] The study in Brazil, oatmeal was replaced by making coffee while calling the grocery store was replaced by calling to a pharmacy.[23] Thus, following the translation process the researcher considered and modified the content, method, and procedures of tasks. EFPT-Th, the in the basic cooking task of oatmeal was replaced with making instant rice porridge because Thai people are not familiar with oatmeal. Instant rice porridge is a ready meal menu which has few sequences of actions to complete. Additionally, EFPT-Th also was considered to add Thai favorite simple cooking menu with more complex and sequenced tasks and to clarify the deficiencies in executive function which was an omelet menu. This result conforms to Goverover and colleague study[18] that EFPT was used in multiple sclerosis. They added the casserole menu in the simple cooking task. The method and sequence of task for paying bills by check was altered because Thai people are familiar to pay a bill by cash rather than by check. Moreover, cable and telephone bills were replaced by electricity and telephone bills because they are more recognizable. These results were complied with a recent study in Korea. The task was altered from compensation by check to bank transfer which is more well-known with the Korean lifestyle.[22]

The content validity of EFPT-Th presented that the IOC was average to high level (IOC=0.67-1.00). This result

suggested that the contents of the assessment were coherent with the executive function components. The internal consistency of EFPT-Th score was acceptable while the score on each subtest of EFPT-Th was also considered to be acceptable. Additionally, the reliability of EFPT-Th showed that the intra-rater reliability was high level as well as Inter-rater reliability was high level. The results were similar to previous studies of EFPT in various groups and countries.[18-23] Many factors may affect high levels of intra-rater reliability and inter-rater reliability. Firstly, the instruction of each task assessment has the consistency of words and directions. Secondly, EFPT have clearly scoring system and the score level can be separated into five levels of cueing which are identified the characteristic of assistance which, the assessors can precisely decide the score. The higher scores represent the more cueing need reflecting the greater EF problems. In this study, EFPT-Th has been confirmed with the EF related content, rating score system and the standard with high level of the psychometric properties.

For the criterion validity, the significant high correlations were found between the total scores of EFPT-Th and BADS total scores. This result consist with the previous studies in a schizophrenic population that present high correlation between EFPT and BADS.[19] However, the correlations between the simple cooking tasks in EFPT-Th and the BADS total scores show moderate significant correlations while the another tasks; telephone use, medication management and bill payment had the low correlations. These results might be affected by the characteristics of tasks in EFPT-Th which were familiar with everyday tasks whereas the assessment tasks in BADS are novel tasks. The more novel and complex than everyday routine tasks, the more requiring higher-level thinking abilities to planning, organization and problem solving. These reasons may affect the correlation between EFPT-Th and BADS scores. BADS is the standardized test for measuring various aspects of executive function and it is bottom-up assessment that can be identified the separate problem of client's executive function. Therefore, this test cannot provide the information of capability, strategies or environment factors to perform the tasks.[35] On the contrary, EFPT-Th is top-down assessment that can be assessed the client's occupational performance in real life context providing the information of capability, strategies or environment factors during perform real tasks.[35] The result of present study supported that EFPT-Th demonstrated the psychometric properties to be the standardized test for the executive function assessment in Thai culture and contexts.

Limitation

Limitation of this study was a small sample size. The samples were between the ages of 20-40 and the majority of participants had been diagnosed stimulant drug use. All participants were in the same therapy setting. For the future study should be operated with a large sample size, use various age ranges with various diagnosis of drug use. Moreover, the participants were not excluded depression symptom that might be seen in the psychiatric patients with substance abuse which was the confounding factor affecting cognitive assessments

Conclusion

EFPT-Th is performance-based executive function test that demonstrated the psychometric properties to use in the Thai culture and contexts. EFPT-Th was performed in participants with substance-induced disorder for the validity and reliability studies and presented outcomes of content validity, internal consistency, criterion validity, inter-rater reliability and intra-rater reliability of EFPT-Th were average to high. In summary, it was confirmed that EFPT-Th can be evaluated individuals with executive dysfunction.

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Conflicts of interest

The authors declare no conflicts of interests.

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Correlation of modified micro-ESR method with the Westergren method for the determination of erythrocyte sedimentation rate

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ABSTRACT

Background: Erythrocytes sedimentation rate (ESR) is the rate of red blood cell sedimentation. It is a non-specific measurement of inflammation. The Westergren ESR (conventional ESR) is the standard method for measuring the ESR. However, this technique requires a large blood volume. Therefore, it is not suitable for patients contributing only a small blood volume.

Objectives: The aim of this study was to verify the micro-ESR method compared to conventional Westergren method.

Materials and methods: The ESR was performed on 170 blood samples using both the standard Westergren and modified micro-ESR method. Blood samples anticoagulated in 3.8% sodium citrate at a ratio of 4 : 1 (blood : sodium citrate) were used for the Westergren method, whereas blue-tipped plain microhematocrit tubes (1.2 mm x 75 mm) were used for the modified micro-ESR method. Duration of test was 1 hr for the standard Westergren method. However, ESR values were read out at different time points for the modified micro-ESR. Correlation of ESR results obtained by both techniques were determined using Pearson and Spearman's coefficients. A regression equation was derived to predict conventional ESR values from those obtained from the modified micro ESR results. Finally, the agreement of two measurements was demonstrated using the Bland-Altman plot.

Results: Statistical analysis demonstrated the significant correlation of results of the modified micro-ESR results read at 30 min with those obtained from the standard Westergren ESR (r=0.979, p<0.05) and the Bland-Altman plot showed an acceptable agreement (-6.6%) between the modified micro-ESR and the standard Westergren method.

Conclusion: The modified micro-ESR method appears to be a faster, cheaper, and requires a smaller blood volume than the conventional Westergren ESR method. The modified micro-ESR results read at 30 min had an acceptable correlation with the standard Westergren method. Therefore, this modified micro-ESR could be performed in pediatrics clinics.

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Introduction

Erythrocyte Sedimentation Rate (ESR) is the rate at which red blood cells sediment.[1] It is a non-specific measure of inflammation. ESR is a nonspecific reaction; it is a measure of the present severity of pathological processes. In general, the ESR is increased for all acute and inflammatory conditions. Variations in the ESR depend on the nature and severity of the processes. Although it's a non-specific marker of inflammation, it is used in combination with a patient's clinical history and physical examination, which aids in diagnosis, management, and follow-up for different auto-immune diseases, acute and chronic infections and tumors. One of the most important uses of the ESR is in screening for the presence of more or less occult disease and as such, is considered a valuable routine procedure.[1, 2] The most satisfactory method of performing the test was introduced by Westergren in 1921.[3, 4] In 1988, the International Committee on Standardization in Hematology (ICSH) (Leuven, Belgium) described an ESR validation procedure as well as a method for producing ESR reference material (ICSH reference method) in the laboratory where it is to be used.[5]

In 2011, the ICSH and Clinical and Laboratory Standards Institute (CLSI) confirmed the Westergren Method as the gold standard method for ESR evaluation.[3, 4, 5] The basic principle of ESR is that RBCs normally settle quite slowly when anti coagulated blood is placed in a vertical column. This occurs due to repulsion of RBCs from each other by virtue of negative charge present on their surfaces (Zeta potential) and a large surface area to volume ratio.[5, 6, 7, 8]

The Westergren ESR (conventional ESR), technically, takes one hr to complete the test, and requires a large blood volume which is not suitable for blood samples with small volume.[9, 10, 11, 12] To overcome these drawbacks, several modifications were performed such as Micro-ESR method, centrifugation method and automatic ESR analyzer method. This report compares performance of the modified micro-ESR and the standard Westergren methods for determining ESR values.

Materials and methods

The study protocol was approved by the Ethics Committee of the Human Research Ethics Unit Faculty of Associated Medical Sciences, Chiang Mai University. In this study, 170 blood samples with hematocrit in the range 38-48% were collected from the Clinical Microscopy, Diagnostic Laboratory, Maharaj Nakorn Chiang Mai Hospital. There were 70 males and 100 females within 20-45 years of age. All blood samples used for the Westergren method were prepared by mixing 4 parts of blood with 1 part of 3.8% sodium citrate. Thereafter, the mixture of citrated blood was aspirated into the Westergren tubes until the top-most layer of blood reached the zero scale of the tubes. The Westergren tubes were then placed vertically for exactly on hour before reading the ESR in millimeter/hr unit. For the modified micro-ESR method, the citrated blood was aspirated into the blue-tipped plain microcapillary tubes until the length of blood inside the tube reached 70 millimeters. The end of the microhematocrit tube was then sealed with critoseal or clay and the tube placed vertically, away from any vibrations. The length of sedimented red blood cells in milliliters was read at 10, 15, 20, 25, 30, 40, 50, and 60 min. The ESR values were then reported in milliliter per time (in minute) of each reading.

The statistical analysis

The Data was analyzed using SPSS version 15.0. Correlation of the modified micro-ESR at different time (10, 20, 30, 40, 50, and 60 min) and the standard Westergren was determined with Pearson and Spearman correlation methods. ESR values obtained from the modified micro-ESR were transformed to those obtained by the Westergren method by calculating regression analysis. Finally, a Bland-Altman plot was performed to assess agreement of the ESR values obtained from both methods.

Results

Pearson correlation analysis demonstrated that significant correlation was seen when the modified micro-ESR values was read at 30 min as shown in Figure 1 (r=0.979, p<0.001). The regression analysis was then performed to establish the regression equation which was as follow: Conventional Westergren ESR values = 3.0 X Modified micro- ESR values read at 30 min +1.31. The Bland-Altman analysis showed acceptable agreement between the two methods (bias= -6.6%). It also showed better agreement at lower values of ESR (Figure 2).

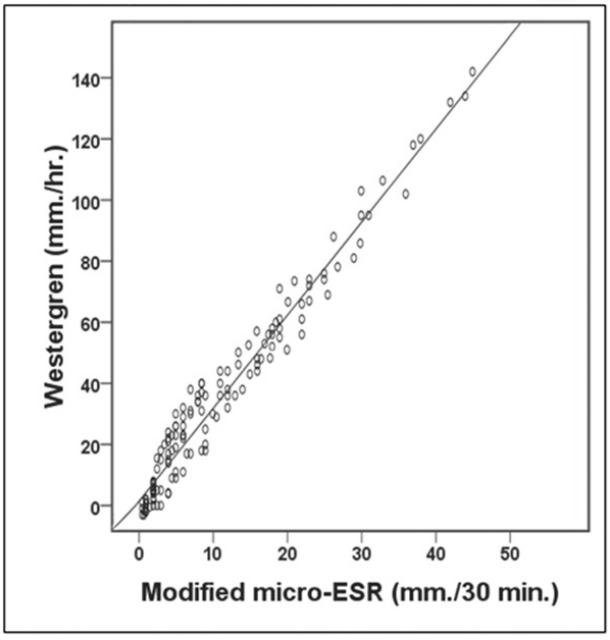

Figure 1. *Correlation of the modified micro-ESR read at 30 min and conventional Westergren method at 1 hr (r=0.979, p<0.001). The regression equation is: Conventional ESR (Westergren) values = 3.0 X Modified micro-ESR values read at 30 min +1.31.*

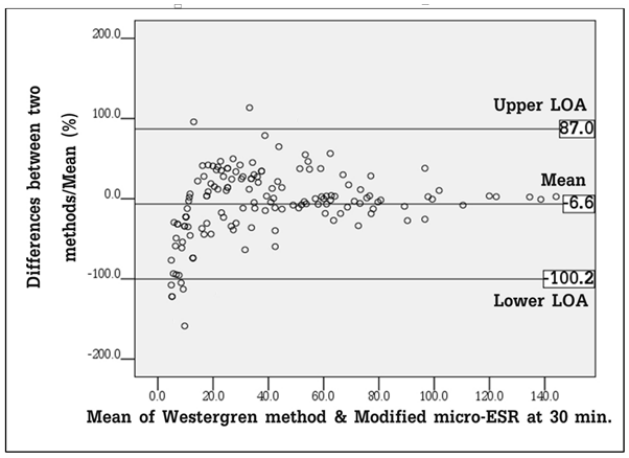

Figure 2. *Bland-Altman plot for assessment of agreement rate between the mean measurements of conventional ESR (Westergren) and the modified micro ESR read at different ESR values.*

Discussion

The study results showed that the modified micro ESR read at 30 min had significant correlation with the conventional Westergren ESR. This meant that the modified micro- ESR results can be successfully performed for 30 min, not 1 hr as performed by the standard Westergren method. Furthermore, it was shown that accurate estimations of the conventional Westergren ESR could be made through correcting modified micro ESR measurements at 30 min by a simple formula presented here. The correlation seen between the results of modified micro ESR and conventional ESR was proved excellent in normal blood samples with hematocrit ranging from 38% to 48%. The result of micro-ESR method totally agreed with the Westergren method. Similar results have also been shown by Adhikari BC *et al* [9] and West BA *et al* [10]. ESR determination is one of the most basic tests performed in diagnostic laboratories. However, the conventional method of Westergren, suggested by the International Committee for Standardization in Hematology as the standard procedure, is time consuming and requires a relatively large volume of patient's blood. This is especially cumbersome for critically ill patients requiring multiple samplings, infants, and neonates.[11, 12]

Conclusion

The result of the modified micro ESR using the formula: Conventional ESR values = 3.0 X Modified micro ESR values read at 30 min +1.31) for calculating conventional ESR has an acceptable correlation with convention ESR, when read at 30 min. This method is specially recommended for Pediatric patients and patients with less palpable veins.

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The validity and reliability of the Thai version of M.D. Anderson dysphagia inventory and correlation between quality of life and dysphagia severity in patients with head and neck cancer

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ABSTRACT

Background: Dysphagia is one of the most significant side effects of head and neck cancer (HNC) treatments, which increases the symptom rate after treatments. This has negative effects on patient quality of life (QoL); therefore, the evaluation of quality of life by standardized instruments is essential to patient-reported outcomes.

Objectives: The purpose of this study was to translate and validate the M.D. Anderson Dysphagia Inventory (MDADI), which is a specific QoL instrument that evaluates the impact of dysphagia on QoL in HNC patients, into the Thai language by a cross-cultural adaptation process. This subsequently determines the reliability of the Thai version of MDADI (MDADI-TH), and to verify a correlation between dysphagia severity and QoL in HNC patients.

Materials and methods: The six steps for a cross-cultural adaptation process, which include: forward translation, translation synthesis, backward translation, expert committee review, pretesting, and final proof reading were performed. Sixty-five HNC patients with dysphagia were included in this study. The patients completed the same questionnaires two weeks after first enrollment, to determine the reliability. The Reliability was determined by internal consistency (Cronbach's alpha) and test-retest reliability. The correlation was verified between the total score of MDADI-TH and Penetration-aspiration scale, from a video-fluoroscopy swallowing study (VFSS) by independent t-test.

Results: Validation was achieved by a cross-cultural adaptation process, except for one question (E7), which was not equivalent to the original version in semantic proposition. A total of twenty-nine patients completed the same questionnaires two weeks later. The MDADI-TH subscale and total scores showed acceptable internal consistency reliability (ranging from 0.71-0.94), and test-retest reliability (ranging from 0.86-0.99). For the correlation study, a total of sixty patients were able to be examined by VFSS. The results showed that correlation between dysphagia severity and QoL was significant in total scores, the emotional subscale, and the functional subscale (p<0.05).

Conclusion: The MDADI-TH showed good reliability; therefore, the MDADI-TH can be a useful dysphagia-specific QoL instrument, for measuring QoL in Thai patients with HNC. Patients with more severity of dysphagia showed it had a compromising effect on the quality of life, especially in the emotional and functional domains.

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Introduction

Head and neck cancer (HNC) are the sixth most common cancer, and the eighth most cause of cancer death worldwide. The incidence rate of this cancer has increased in tendency.[1] Dysphagia is one of the most common side effects in HNC patients, which may occur before or after treatments; however, it mostly increased in rate after treatments.[2-4] HNC patients experiencing dysphagia may have health impairment[5-7], from dysphagia complications (malnutrition, dehydration, and aspiration), leading to an impaired quality of life (QoL).[8,9] Particularly aspiration; which is one of the complications and significant symptom signs of dysphagia, occurring in approximately 50%[10] of patients, and this is a risk factor that causes life-threatening aspiration pneumonia.[11] Likewise, aspiration also affects patients health and emotional well-being; hence, diminishing the patient's QoL.[12] As a result, dysphagia has a strong impact on QoL.[9, 13]

Currently, the evaluation of QoL plays an important role of patient-reported outcomes to promote clinical care, for improving therapeutic regimens and indicating effective treatments.[14, 15] As to the impact of dysphagia on QoL evaluations, the dysphagia-specific related QoL questionnaire is recommended, as it provides potential information regarding the impact of dysphagia on quality of life resulting from symptoms, and related treatments; so as to conduct effective symptom management.[16, 17]

M.D. Anderson Dysphagia Inventory (MDADI) is a dysphagia-specific QoL instrument to evaluate the impact of dysphagia on the quality of life in HNC patients. The MDADI contains 20 questions, divided into 4 domains (global, emotional, functional, and physical). The questions of the MDADI were developed by HNC patients with dysphagia, and their families by interviewing[18], so as that they may guarantee the questions are directly associated with the symptoms resulting from HNC, and its treatment influence on the patient's QoL. The MDADI questions also contain both health-related quality of life (HRQOL) measuring, reflecting a patient's health perceptions, in addition to their functional health status (FHS) measuring, which reflects the influence of dysphagia on the patient's ability to perform tasks.[8, 19] In addition, this questionnaire has a small number of questions that are easy and quick to complete for use in clinical practice.[20] Therefore, the MDADI is considered a useful, standardized QoL instrument in clinical practice for reporting patient outcomes. However, there is no standardized dysphagia-specific QoL Thai instrument for measuring QoL in HNC patients.

The purposes of this study were to translate and validate The MDADI into the Thai language as well as to determine the reliability of the Thai version of the M.D. Anderson Dysphagia Inventory (MDADI-TH). Additionally, another purpose was to verify a correlation between dysphagia severity and quality of life in patients with HNC.

Materials and methods

MDADI

The original MDADI is a self-administered questionnaire developed by Chen et al.[18] This questionnaire consists of 20 questions to measure the effect of dysphagia on QoL in 4 domains, including: global (single question), emotional (6 questions), functional (5 questions) and physical (8 questions). Each question is scored on the 5-points Likert scale, consisting of a point value from 1 to 5 (strongly agree, agree, no opinion, disagree, strongly disagree) for all questions, except for 2 questions. These two questions; on the emotional domain (E7: I do not feel self-conscious when I eat) and functional domain (F2: I feel free to go out to eat with my friends, neighbors, and relatives), are reversely scored, as 5 points for strongly agree and 1 point for strongly disagree. The global question is scored individually, while the other questions, of each domain, are summed; and the mean score is multiplied by 20 to obtain a total score. Thus, higher scores indicate better day-to-day functioning and better QoL.

Translation Process

We performed the following six-step guidelines on the acceptable, internationally cross-cultural adaptation process.[21, 22]

Step 1: *Forward translation*, permission of the original MDADI was translated into Thai by two bilingual translators, who are proficient in both English and Thai languages; one translator having a medical background (both HNC and dysphagia) and the other with linguistic proficiency, but no medical background.

Step 2: *Synthesis*, the two translations were synthesized into one common translation by consensus between the two translators and authors.

Step 3: *Back translation*, the consensus version of the Thai translation was translated into English by two, additional bilingual translators, who were blinded from the original version. Neither of the two back-translators have a medical background, nor preliminary MDADI knowledge.

Step 4: *Expert committee review*, all translations were sent to an expert committee. The committee reviewed all translations and reached a consensus on the pre-testing version for cultural equivalence. The committee of bicultural experts consisted of two doctors who work with HNC patients, and another doctor who works with dysphagic patients. Discrepancies between the translations and the original MDADI were resolved by repeating the process as needed.

Step 5: *Pretesting*, the pre-testing version was tested on 10 HNC, patients who experienced dysphagia by cognitive interviews. Both the meaning and chosen response to each question without any clarification was verified. In depth interviews were conducted when there was misunderstanding, and ambiguity were found. All changes were in consensus within the research group.

Step 6: *Final proofreading*, typographic and other errors were corrected, and then the translated MDADI was completed.

Participants and Data collection

The cross-sectional study was conducted in the out-patient clinic at the Department of otolaryngology, Faculty of Medicine, Prince of Songkla University, Thailand. A total of 65 patients were enrolled. The inclusion criteria were patients diagnosed with HNC with dysphagia and who should undergo the video-fluoroscopic swallowing study (VFSS) by an otolaryngologist, age ≥18, with fluency in spoken and written Thai, who treated with radiotherapy, either alone or combination, should undergo treatment for at least 3 weeks, and able to complete the translated questionnaire. Patients who were diagnosed thyroid cancer and salivary gland cancer, who treated with total laryngectomy, who declined VFSS examination, who were pregnant, or unable to follow the procedure were excluded. Written informed consent was obtained from all participants.

All participants completed the pre-final version questionnaire and were examined with the swallowing function by VFSS upon enrollment. Two weeks later, the same questionnaire was performed again, to determine test-retest reliability.

Swallowing function

The swallowing function examination was conducted in radiographic imaging rooms, at the Department of Radiology, following routine clinical evaluation by a radiologist and an otolaryngologist; whom is an expert in evaluating and managing HNC and dysphagic patients.

The Penetration-Aspiration Scale (PAS) is the standard method to examine swallowing function that can indicate the severity of dysphagia, by describing airway invasion during swallowing. Airway invasion can define by the severity of penetration and aspiration, following the Rosenbek *et al*.[23] scale observed in VFSS.

For this study, dysphagia severity of patients was divided into 2 groups; according to the PAS are non-aspiration group (PAS level 1), and penetration and aspiration groups (PAS level 2-8) then the correlation between QoL and dysphagia severity was analyzed.

Data analysis

The content validation of MDADI-TH was determined by the cross-cultural adaptation process. The reliability was determined by internal consistency reliability and test-retest reliability to achieve the completed Thai version of MDADI (MDADI-TH). All analyses were conducted using Statistical Package for the Social Sciences version 16.0 (SPSS Inc., Chicago, IL, USA) for windows. Descriptive analysis was expressed as relative frequency distribution and arithmetic mean.

Internal consistency reliability was determined for each subscale, except the global subscale, by Cronbach's α coefficient (Cronbach's α). The acceptable level of Cronbach's α is 0.7 or greater, which indicates an adequate internal consistency reliability.[24]

Test-retest reliability was established by comparing scores between test (ass_1) and retest (ass_2) by calculating the mean difference, using paired sample t-test; with a statistical significance level of a two-tailed 0.05 level (p<0.05). Additionally, the stability coefficient was investigated by Spearman's rho correlation coefficient, which determined the relationship between test-retest calculating of each subscale score, with the statistical significance at a two-tailed 0.01 level: the higher the correlation between ass_1 and ass_2 the greater the stability coefficient of the questionnaire.[25] The intra-class correlation coefficient (ICC) was used as relative reliability. An ICC value of 0.75, or greater, is indicative of good reliability.[26] The correlation of each QoL aspect, evaluated by MDADI-TH with dysphagia severity assessed in VFSS, was verified by independent t-test with a significant level of p<0.05.

Results

Cross-Cultural Adaptation

The original MDADI was translated into the Thai language, by a cross-cultural adaptation process to achieve the equivalent, as comparing to the original, to establish the content validity. In a step of the synthesis, the consensus between the translators and authors was reached to add an explication (*The pronoun "I" in the first statement to the last one used to refer to the respondent*). An explication was considered to avoid confusing patients in using the pronoun or proposition, when the questionnaire was translated into Thai, when it was not clarifying any questions in this QoL instrument. When comparing between the Thai translation and the original, there were 19 items that were equivalent, except for one item in an emotional subscale; this was an E7 item. The most challenging aspect was the difficultly to translate the term self-conscious. The term self-conscious could be interpreted in different ways, and it was difficult to find in Thai a single word that could explain this term. One of the translators translated "self-conscious" as "*Pràːmàː* meaning lose self-confidence, lose courage, or nervous, while the other translators translated it as "*Ŕuːtua*", which means be aware. The consensus agreed with the term "*Pràːmàː*" as this best represented the word of self-conscious, and best captured a concept of emotional domain. The equivalent was checked by the expert committee review and back-translation process. The committee also agreed with the term *Pràːmàː* in the point of self-conscious representation, but this word may be incomprehensible for a target group, therefore the comprehensible word, which remained as a semantic equivalent, was substituted. However, the difference was found in an E7 item between the Thai translation and the original, in the point of a semantic proposition when back-translation was performed again. Furthermore, most of the interviewees did not noticed the negation in E7 and F2 items, leading to the giving of a wrong answer; thus, they were asked to read these questions again, so they could choose the correct answer. Hence, the two question items remained in the negation sentences, but changed typography involving typeface and letter-spacing for easier notice.

Psychometric Analyses

Sample Characteristics

In total, 65 HNC patients with dysphagia were included. However, five patients were excluded, because they could not follow the routine VFSS protocol; accordingly, sixty patients who met the selection criteria answered ass_1 and were

examined for swallowing function by VFSS, to verify the correlation. For reliability testing, a total of twenty-nine patients completed ass_2 by two weeks after first enrollment. Thirty-one patients were excluded because eighteen patients lost to follow up at the second assessment, five patients were unable to complete the questionnaire by two weeks after the first assessment, and eight changed feeding procedure in between ass_1 and ass_2 (Figure 1).

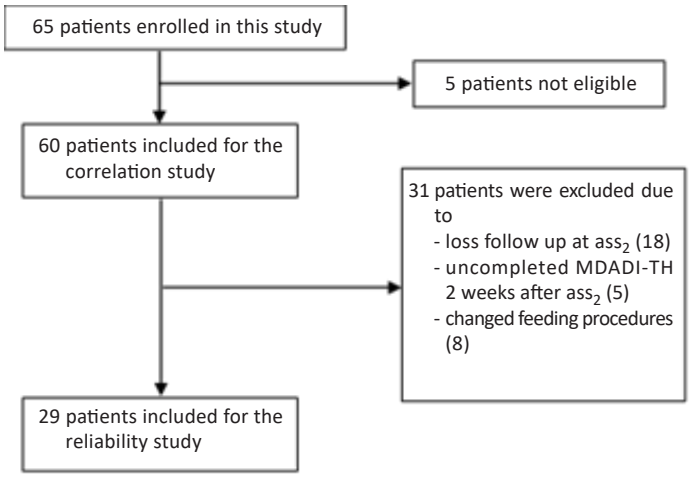

Figure 1. *Participants enrollment.*

Participants, consisting of 60 patients, are summarized characteristics in Table 1. Most patients were male (70%); with a mean age of 57 years, and the mean time since last treatment was 17.7 months. The oral cavity was the most frequent, primary tumor site, with 20 cases (33.33%). Most patients (76.67%) had clinical stage IV of the disease. Concurrent chemoradiotherapy (CCRT) was the highest prevalent treatment, with 29 cases (48.33%). The most common feeding procedure was a percutaneous endoscopic gastrostomy tube (PEG), consisting of 21 cases (35%). Twenty (33.33%), patients had a tracheostomy, which was the most common treatment for patients, who had penetration and aspiration.

Table 1 Demographic and clinical characteristics of 60 HNC patients with dysphagia.

Variable	No. of Patients	%	Mean
Gender			
Male	42	70	
Female	18	30	
Age (years)			
<60	25	41.67	57
≥60	35	58.33	
Primary tumor site			
Oral cavity	20	33.33	
Oropharynx	10	16.67	
Nasopharynx	16	26.67	
Hypopharynx	4	6.67	
Larynx	10	16.67	
Clinical stage			
I	4	6.67	
II	4	6.67	
III	5	8.83	
IV	46	76.67	
Information missing	1	1.67	

Table 1 Demographic and clinical characteristics of 60 HNC patients with dysphagia. (continues)

Variable	No. of Patients	%	Mean
Treatments regiments			
Surgery	1	1.67	
RT	9	15	
CCRT	29	48.33	
Surgery and RT	8	13.33	
Surgery and CCRT	13	21.67	
Feeding procedures			
Oral	12	20	
NG	10	16.67	
PEG	21	35	
Oral and NG	6	10	
Oral and PEG	11	18.33	
Tracheostomy			
Yes	20	33.33	
No	40	66.67	
Time from last treatment to study enrollment (month)			17.70

Note: *RT: radiotherapy, CCRT: concurrent chemoradiotherapy, NG: nasogastric tube, PEG: percutaneous endoscopic gastrostomy tube.*

Reliability

The internal consistency of the MDADI-TH was checked by Cronbach's α coefficient for each subscale, except the global subscale, because it only contains a single question. Cronbach's α were in the optimum range; 0.9 for emotional subscale, 0.88 for functional subscale, 0.71 for physical subscale and 0.94 for total score (Table 2).

For test-retest reliability, mean differences of each subscale between test-retest were not statistically significant, with $p>0.05$; -5.52 for global subscale, 0.00 for emotional subscale, -1.79 for functional subscale, 0.95 for physical subscale and -0.07 for total score (Table 3). The Spearman's rho between each subscale showed a high correlation, ranging from 0.78 to 0.99, with statistical significance (Table 4). Similarly, all subscales presented with excellent ICC values, ranging from 0.86-0.99 (Table 4).

Table 2 Internal consistency of the MDADI-TH (N=29).

MDADI-TH Subscale	No. of questions	Cronbach's α coefficient
Global	1	-
Emotional	6	0.9
Functional	5	0.88
Physical	8	0.71
Total score	19	0.94

Table 3 Mean differences of overall scores, and the MDADI-TH subscale scores between test-retest (N=29).

MDADI-TH Subscale	Mean score±SD Ass_1	Mean score±SD Ass_2	Mean diff±SD (95% CI)	*p*-value
Global	46.90±28.92	52.41±27.99	- 5.52±7.47 (-11.91, 0.88)	0.09
Emotional	63.10±21.80	63.10±21.27	0.00±5.66 (-1.79, 1.79)	1.00
Functional	60.55±21.82	62.34±21.04	-1.79±5.63 (-3.81, - 0.22)	0.08
Physical	54.57±14.32	53.62±14.66	0.95±3.80 (-0.75, 2.64)	0.26
Total score	58.84±17.71	58.91±17.62	- 0.07±4.64 (-1.11, 0.96)	0.89

Note: *Ass1: first assessment, Ass2: second assessment, 95% CI: 95% confident interval, *p<0.05.*

Table 4 Correlation coefficient of overall scores, and the MDADI-TH subscale scores between test-retest; and intra-class correlation coefficient of the MDADI-TH (N=29).

	Global	Emotional	Functional	Physical	Total score	ICC (95%CI)
Global	0.78**	-	-	-	-	0.90 (0.78-0.95)
Emotional	-	0.97**	-	-	-	0.94 (0.90-0.97)
Functional	-	-	0.95**	-	-	0.94 (0.89-0.97)
Physical	-	-	-	0.95**	-	0.86 (0.77-0.92)
Total score	-	-	-	-	0.99**	0.99 (0.98-0.99)

Note: *ICC: intra-class correlation coefficient, **p<0.01*

Correlation between QoL and dysphagia severity

Dysphagia severity, by VFSS, showed non-penetration and aspiration (PAS level 1) had the most frequent severity of symptoms (51.67%). Penetrations (PAS level 2-5) were secondary presented (40%), and conversely, aspirations (PAS level 6-8) were rarely presented; with only 5 cases (8.33%). Furthermore, additional residue was observed that located at the base of the tongue, valleculae, and pyriform sinuses. This residue was most common in the non-penetration and aspiration group: approximately 50% (Figure 2).

According to dysphagia severity, they were divided into 2 groups consisting of a non-penetration and aspiration (npasp) and penetration and aspiration (pasp) group. The comparison of each subscale of MDADI-TH between the 2 groups showed statistically significant association with the mean total score, emotional subscale, and functional subscale: 8.69 for total score, 12.11 for emotional subscale, and 10.93 for functional subscale. In contrast, no significant association, with $p>0.05$, was demonstrated with global or physical subscales. The correlation between the severity groups and mean score of the MDADI-TH subscales is shown in Table 5.

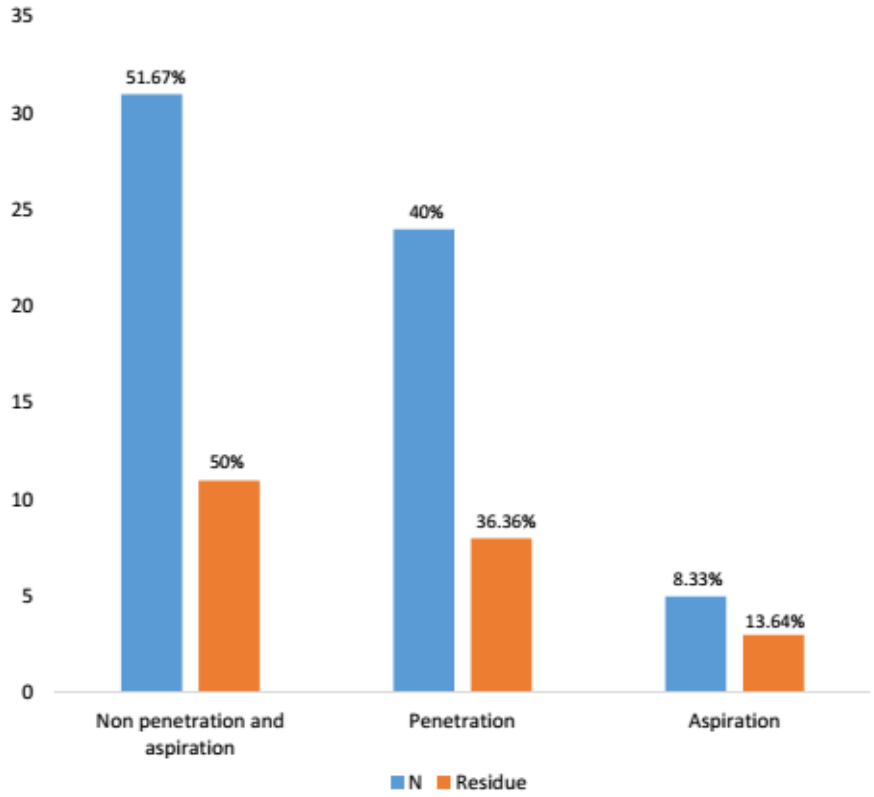

Figure 2. *Characterization of the results of VFSS for the presence of dysphagia severity and residue.*

Table 5 Correlation between the MDADI-TH subscales and dysphagia severity groups (N=60).

MDADI-TH Subscale	Mean (SD)		Range of scores		Mean diff (95% CI)	*p*-value
	Non pasp group[a]	Pasp group[b]	Non pasp group[a]	Pasp group[b]		
Global	46.45 (27.99)	38.62 (19.22)	80 (20-100)	60 (20-80)	7.83 (-4.66, 20.32)	0.21
Emotional	**64.41(20.35)**	**52.30 (18.54)**	**70 (26.7-96.7)**	**66.70 (23.3-90)**	**12.11 (2.03, 22.19)**	**0.02***
Functional	**59.48 (20.78)**	**48.55 (16.06)**	**72 (28-100)**	**60 (20-80)**	**10.93 (1.29, 20.58)**	**0.03***
Physical	54.03 (13.07)	49.31 (11.02)	47.5 (35-82.5)	50 (32.5-82.5)	4.72 (-1.55, 10.99)	0.14
Total score	**58.77 (15.90)**	**49.97 (12.51)**	**54.7 (35.8-90.5)**	**46.3 (31.6-77.9)**	**8.69 (1.25, 16.13)**	**0.02***

Note: *Non pasp group: non-penetration and aspiration group, Pasp group: penetration and aspiration group, *p<0.05, [a]N: 31, [b]N: 29.*

Discussion

The purpose of this study was to translate and validate the MDADI into Thai, and subsequently to verify reliability and correlation between QoL and dysphagia severity in HNC patients. The MDADI was translated into the Thai language by the cross-cultural process recommendation for translation and validation. According to the process, some questions of the MDADI-TH questionnaire were modified in a semantic proposition, to be explicitly and simply comprehension as well as suitable for the evaluators; but they retained the same meaning as compared with the original MDADI. This was in accordance to the semantic equivalence principle[21]; wherein, the difficulty of translation of grammatical structure, and vocabulary differences between the two languages may have to be modified, or replaced by a similar item. This was to reflect the same meaning with the source language and based on the same concept as the original measurement objective as well. Nevertheless, we found differences of semantic equivalence in E7 item. Therefore, the scoring of E7 item should be carefully considered when applying this in clinical practice.

The reliability of the MDADI-TH was satisfactory. The internal consistency reliability was established by Cronbach's α coefficient, with the value of Cronbach's α coefficient ranging from 0 to 1. The value approached closer to 1 as the questions within domain have greater internal consistency reliability.[26] In general, the minimum acceptable value of internal consistency is 0.7, suggesting that the questions within the domains are measuring via the same underlying concept.[24] In this study, Cronbach's α coefficient was within the optimum range (range from 0.71-0.94). As a result, the MDADI-TH demonstrated good internal consistency reliability.

Test-retest reliability was computed by comparing mean scores of each subscale between test-retest, stability coefficient and the intra-class correlation coefficient (ICC). Mean differences between test-retest demonstrated no difference of the MDADI-TH subscale scores; indicating that the MDADI -TH has consistent measuring. Stability coefficient was investigated by the correlation of subscale scores between test-retest. This relationship revealed a high correlation (range from 0.78-0.99); indicating that the MDADI-TH has great stability. Likewise, the relative reliability revealed the true ICC values as greater than 0.75 (range from 0.86-0.99). Considering a 95% confidence interval of estimated ICC values, these values were greater than 0.75 as well indicating good reliability. Hence, the MDAD-TH questionnaire is a precise measurement.

Considering the dysphagia severity, as related to HNC patient's QoL, it was expected that patients who present with worse airway invasion (penetration and aspiration) on VFSS will have an increased chance of reduced QoL. In this study, the results of comparison between the MDADI-TH subscale scores and dysphagia severity were significant in total scores, as demonstrated by HNC patients who had ineffective swallowing, causing penetration and aspiration. These presented as having a lesser QoL than those without penetration or aspiration. These results may indicate that patients with more severity of dysphagia showed obvious compromise on their QoL. Similar to previous studies,[27, 28] patients with severe dysphagia have a worse quality of life, compared to those without dysphagia or less severe dysphagia. Patients with moderate to severe dysphagia have worse QoL than those with mild dysphagia, or those without dysphagia.[12]

According to Timmerman *et al*.,[17] which shows the conceptual model of the possible impact of dysphagia on general health and QoL, supports our findings that an aspiration which is considered a significant symptom sign of dysphagia, leads to an inefficient or inability to eat and drink as a consequence of dehydration, malnutrition and aspiration pneumonia. Patients suffering from aspiration may have increased anxiety during their mealtimes and lose self-satisfaction, which causes a lack of willingness to eat and avoidance of eating with other people, this in turn may lead to weight loss and nutrition deficiency. Moreover, increasing aspiration severity is thought to decrease the patient's weight. These consequences limit the ability to perform daily activities resulting in diminished patient's

life quality.[9, 13]

Furthermore, the results obviously revealed that HNC patients who had more severe dysphagia had diminished QoL, especially in the emotional and functional subscales. These findings are rather like the study of Meyer *et al*.[29], wherein it was found that more severe dysphagia affects the ability to perform daily activities; especially the normalcy of diet and eating in public. However, other related studies found that the severity of dysphagia affects QoL in the physical subscale as well.[27, 28] In this study, we found not only aspiration, but also residue is one of the significant symptom signs of dysphagia.[29] HNC patients who were enrolled in the study also complained about food sticking, which corresponded to VFSS results showing that residue was found at the base of the tongue, valleculae and pyriform sinuses. When such residue occurs, the patient will have to make an effort of swallowing or gagging to get rid of said residue; reflecting impaired swallowing function.[30-32] In addition, the residue is also a risk factor that may lead to a post swallowing aspiration influence on efficient and safe swallowing.[30] Due to this fact, residue is another factor that affects QoL. Residue was mostly found in patients without penetration or aspiration, so it may be possible that residue may affect QoL in the physical subscale. As a result, QoL in this subscale of patients in both groups, were not different due to the residue reflecting the impairment of swallowing function as well as aspiration. Therefore, more severe dysphagia may affect QoL on both emotional functional and physical subscales.

In addition to aspiration and residue factors influencing QoL, there are other factors that also affect the QoL of patients. A feeding tube is one of the factors that strongly affect QoL.[34, 35] The presence of the feeding tube has negatively affected the patient's QoL. Also, it restricted their daily and social activities, which impact on emotional and functional subscales.[35] In this study, the presence of the feeding tube was mostly found. The main feeding via NG or PEG alone is most frequent, which was mostly found in the patients presenting with penetration and aspiration. Feeding tube dependence decreases the use of swallowing muscles causing disused atrophy of pharyngeal muscles and possibly increases the risk of formation stricture of muscles, which diminished the patient's QoL.[36, 37] Thus, this may possibly be a contributing factor that made HNC patients with penetration and aspiration has more deteriorated QoL than those without penetration and aspiration. Radiotherapy and/or chemotherapy treatments and tracheostomy are secondary factors that also significantly affect QoL.[34,35] Radiotherapy and/or chemotherapy treatments cause a complication that affects the patient's ability to perform activities of daily living, especially xerostomia, which is a complication caused by radiotherapy. It has an effect on swallowing efficiency, resulting in a worse QoL related to the limitation of the functional domain.[38, 39] Our study founded that the vast majority of HNC patients were treated with radiotherapy, either alone or combined with other treatments. This was a contributing factor that may possibly worsen QoL in the patient with penetration and aspiration. These was another a contributing factor, namely tracheostomy, that may possibly worsen QoL in the patient with penetration and aspiration. HNC patients who underwent the tracheotomy have limitation in social and daily activities that impact on emotional and functional subscales.[35] In our study, we founded that the tracheostomy was seen in the patients with penetration and aspiration that might diminish QoL. Thus, the patients with penetration and aspiration have lesser QoL than those without penetration and aspiration. These factors could contribute to the diminishing QoL in the patients who present penetration and aspiration, particularly in emotional and functional subscales.

Limitation

Several limitations were presented in our study. Firstly, the construct validity could not be established by discrimination between the groups of subjects. We expected to discriminate between the groups by comparing the MDADI-TH scores between patients, with grouping in different severity of clinical stage; but it was limited in characteristics of subjects. Thus, further research would be needed to establish the construct validity of the MDADI-TH with a proper method. Second, the concurrent validity could not be established, due to the lack of another Thai version of a dysphagia-specific QoL instrument. Third, the sample size was too small for the correlation study. We expected to divide the subjects into 3 groups, following PAS, consisting of a non-penetration and aspiration group, a penetration group, and an aspiration group, but the aspiration group was rarely present. Therefore, a large sample size would be required for further studies. Fourth, the residue is also a significant factor influencing QoL as is described, and hereby further research is warranted to inspect the residue in a correlation study. Fifth, scoring of the E7 item in the MDADI-TH should be considered carefully, because inequivalent in semantic proposition was found.

Conclusion

The MDADI-TH is a useful dysphagia-specific QoL instrument in clinical practice, for Thai HNC patients to evaluate QoL influenced by dysphagia symptoms. Patients with more severity of dysphagia showed compromise on their quality of life, especially in the emotional and functional domains.

Conflicts of interests

The authors declare that they have no conflict of interest.

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แบบสอบถามกลืนลำบาก The M.D. Anderson Dysphagia Inventory ฉบับภาษาไทย (MDADI-TH)

แบบสอบถามฉบับนี้สอบถามความเห็นเกี่ยวกับความสามารถในการกลืนของท่าน ข้อมูลที่ได้จะช่วยให้เราเข้าใจว่าท่านรู้สึกอย่างไรเกี่ยวกับการกลืน
ข้อความต่อไปนี้ทำขึ้นโดยผู้ที่มีปัญหาเกี่ยวกับการกลืน บางข้อความอาจใช้ได้กับท่าน
กรุณาอ่านข้อความแต่ละข้อและวงกลมรอบคำตอบที่สะท้อนถึงประสบการณ์ที่ตรงที่สุดของท่านในสัปดาห์ที่ผ่านมา

** โดยจะใช้คำสรรพนามว่า " ข้าพเจ้า " แทนตัวท่านตั้งแต่ข้อแรกจนถึงข้อสุดท้าย **

G. ความสามารถในการกลืนของข้าพเจ้าได้จำกัดกิจวัตรประจำวันของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E2. ข้าพเจ้ารู้สึกอายในพฤติกรรมการกินอาหารของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

F1. คนอื่นมีความลำบากในการทำอาหารให้ข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P2. การกลืนจะลำบากมากขึ้นในช่วงท้ายของวัน

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E7. ข้าพเจ้า **ไม่รู้สึก** กังวลใจเมื่อกินอาหาร

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E4. ข้าพเจ้ารู้สึกแย่ในปัญหาการกลืนของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P6. ข้าพเจ้าต้องใช้ความพยายามอย่างมากในการกลืน

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E5. ข้าพเจ้าไม่ออกไปข้างนอกเนื่องจากปัญหาการกลืน

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

F5. การกลืนลำบากของข้าพเจ้าทำให้สูญเสียรายได้

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P7. ข้าพเจ้าใช้เวลานานขึ้นในการกินอาหารเนื่องจากปัญหาการกลืน

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P3. คนอื่นถามข้าพเจ้าว่า "ทำไมไม่สามารถกินสิ่งนั้น"

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E3. คนอื่นมักหงุดหงิดเกี่ยวกับปัญหาการกินอาหารของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P8. ข้าพเจ้าไอเมื่อพยายามดื่มของเหลว

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

F3. ปัญหาการกลืน**จำกัด**การเข้าสังคมและชีวิตส่วนตัวของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

F2. ข้าพเจ้า **รู้สึกสบายใจ** ที่จะออกไปกินอาหารกับเพื่อน เพื่อนบ้าน และญาติ

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P5. ข้าพเจ้าจำกัดการกินอาหารเนื่องจากการกลืนลำบาก

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P1. ข้าพเจ้าไม่สามารถรักษาน้ำหนักตัวไว้ได้เนื่องจากปัญหาการกลืนของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

E6. ข้าพเจ้ารู้สึกด้อยค่าเนื่องจากปัญหาการกลืนของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

P4. ข้าพเจ้ารู้สึกว่ากำลังกลืนอาหารได้ทีละมากๆ

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

F4. ข้าพเจ้ารู้สึกแปลกแยกเนื่องจากพฤติกรรมการกินอาหารของข้าพเจ้า

เห็นด้วยอย่างยิ่ง เห็นด้วย ไม่มีความเห็น ไม่เห็นด้วย ไม่เห็นด้วยอย่างยิ่ง

ขอขอบคุณสำหรับการตอบแบบสอบถามนี้

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Impact of inspiratory muscle training and early mobilization program during the peri-weaning period on body composition in critically ill surgical patients: A pilot randomized controlled trial

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ABSTRACT

Background: A long period of mechanical ventilation and bed rest cause alterations in body composition which are associated with higher mortality. In particular there is an association with loss in muscle mass. Inspiratory muscle training (IMT) and early mobilization (EM) have been used to increase muscle activity, which leads to improvement in muscle mass and strength. IMT and EM have been shown to prevent intensive care unit-acquired weakness in critically ill patients. However, it is still not known whether they have any effect on body composition in critically ill patients.

Objectives: To evaluate the effects of IMT and EM on body composition in critically ill surgical patients.

Materials and methods: Surgical patients at a single center in whom there had been failure at the first attempt of short weaning were randomized into two groups, a control group (n=12) and an experimental group (n=15). Usual care, IMT, and EM were provided in the experimental group, and only usual care was provided for the control group. Both groups were treated twice a day until 48 hours after extubation. The body composition was measured by bioelectrical impedance analysis before and after the treatment.

Results: After treatment, there were significant decreases from baseline in skeletal muscle mass (SMM), segmental lean of right arm (SLRA), segmental lean of left arm (SLLA), and segmental lean of trunk (SLTR) in the experimental group. In the control group, SLRA and SLTR showed significant decreases from baseline. However, there were no significant changes in segmental lean of right leg (SLRL), and segmental lean of left leg (SLLL), fat mass, and percent of body fat (PBF) in either group from baseline to after treatment. The multivariate regression analysis with adjustment for confounding factors showed no significant differences between the groups as regards body composition.

Conclusion: Inspiratory muscle training and early mobilization in conjunction with usual care did not improve body composition when compared to solely usual care in critically ill surgical patients.

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Introduction

In the intensive care unit (ICU), alterations in body composition including respiratory and limb muscle loss[1, 2] and increased adiposity[3] are substantial due to prolonged bed rest and mechanical ventilation (MV). In addition, prolonged MV also subsequently leads to prolonged bed rest which causes alterations in body composition.[1] Alteration of body composition in mechanically ventilated critically ill patients, in particular muscle mass loss which is the critical contributor of ICU-acquired weakness (ICUAW) is associated with longer bed rest[1] and higher mortality.[4, 5] Muscle loss in critically ill patients is the result of the occurrence of the disease itself and also a rapid increased in muscle protein breakdown.[6-8] During intensive care, a reduction in muscle mass is noticeable within 3 days and progressively declines.[9] Prolonged bed rest in critically ill patients decreases limb muscle mass by 13-21% within a week of admission.[10] Furthermore, prolonged bed rest causes a decrease in the cross-sectional area of diaphragm fibers[11] and in the thickness of diaphragm muscle[12], which leads to long duration of MV.[1, 2]

Inspiratory muscle training (IMT) and early mobilization program (EM) have been provided for critically ill patients. IMT in mechanically ventilated patients increases inspiratory muscle activity[13] which leads to improved inspiratory muscle strength.[14-16] In a similar way, EM increases skeletal muscle activity[17, 18] which results in prevention or reduction of the occurrence of ICUAW[19] and improvement in muscle strength after discharge from ICU.[20] In elderly chronic obstructive pulmonary disease (COPD) patients, EM has been shown to improve thigh lean mass and strength.[21] It has also been shown to restore muscle mass after bed rest in healthy elderly[22] and after immobilization in healthy adults.[23]

It is widely accepted that physical therapy including IMT or EM prevents ICUAW and improves physical function in critically ill patients.[19, 24-26] Importantly, these treatments are safe and feasible in critically ill patients.[14, 27] The early mobilization program involves substantial treatment which is recommended for assisting improvement of functional outcomes and respiratory conditions resulting from prolonged bed rest.[28, 29] Inspiratory muscle training has been shown to reduce MV duration[14-16] which may lead to a shorter periods of bed rest. Taken together, the combined treatments of IMT and EM may further promote MV weaning, prevent prolonged bed rest, and subsequently prevent muscle loss in critically ill patients. To date, there have been no studies which evaluate the combined effects of IMT and EM on the body composition in critically ill surgical patients.

Objective

To study the changes in body composition in critically ill surgical patients who have received IMT with EM and usual care.

Materials and methods

Study design

A pilot randomized controlled trial was conducted at the surgical ICU and critical care unit (CCU) of Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand. The Research Ethics Committee, Faculty of Medicine, Chiang Mai University (SUR-2561-05554) approved this study. A physical therapist (PT), specializing in critical care, visited daily to identify and recruit eligible patients, and obtain informed consent from the patients. Patients were allocated to either control group or experimental group (1:1 ratio) using thick opaque sealed envelopes in random block sizes of six within each stratum. A system involving a list of computer-generated random numbers, and preparation and sequential numbering of the envelopes was used by a researcher who was not involved in the data collection or treatment. Usual care alone was provided for the control group. Usual care with IMT and EM were provided for the experimental group. Both groups were treated twice a day until 48 hours after extubation by the same PT who recruited eligible patients. The physicians who were blinded to the allocation made a decision regarding extubation according to the standardized weaning protocol.[30] The body composition was measured before and after the treatment periods by a single assessor blinded to the grouping of the patients. This study was presented in accordance with the CONSORT guidelines.

Participants

Adults surgical patients (aged≥18 years) who were on an endotracheal tube (ETT) and whom there had been failure at the first attempt of short weaning from MV (Weaning according to a New Definition (WIND) classification). Short weaning is defined as termination of weaning after the first attempt within 24 hours.[31] Additional criteria were patients had to be alert with good cooperation (-1 to +1 of the Richmond Agitation–Sedation Scale (RASS)), did not have active sepsis or hyperthermia, were in a stable respiratory condition (FiO_2<0.60, oxygen saturation>92%, no use of respiratory-depressant drugs), were hemodynamically stable (no hypotension, systolic blood pressure (SBP) 90-170 mmHg, mean arterial pressure (MAP) not varying by>10 mmHg, had no need for vasopressors or were using very low levels (dopamine<5 μg/kg/min or levophed 0.01-0.1 mg/kg/min), had no significant chronic congestive heart failure, and no life-threatening cardiac arrhythmia. In addition, patients were eligible for inclusion when their causes for respiratory failure were resolved, when the underlying disease was stable, and when the patients remained psychologically steady.

Patients with neurological diseases and those in the end stage of lung cancer were excluded. Patients with the following conditions were also excluded: musculoskeletal pathology impacting chest wall movement, severe orthopedic problems (unstable spine, severe scoliosis, ribs fracture, hip fracture); hypothyroidism; malnutrition; ascites; obesity (BMI≥40 kg/m^2); pregnancy; significant pain or distress impacting breathing capacity; and palliation. Additionally, exclusion criteria included an inability to walk without assistance (except using a cane or walker) before admission to ICU, cardiopulmonary resuscitation (CPR) at admission, and readmission to the ICU within the current hospitalization.

Usual care

Usual care included a combination of secretion clearing techniques, breathing exercises, chest mobilization, bed mobility training, upper and lower limb exercises without external weight in Fowler's position (5-10 repetitions),

ankle pump exercises, and sitting balance training. Usual care was provided twice a day until 48 hours after extubation. The vital signs including heart rate (HR), blood pressure (BP), respiratory rate (RR), oxygen saturation, and rate perceived exertion (RPE) were recorded before and after training.

Inspiratory muscle training

An electric inspiratory training device (POWERbreathe KH2, POWERbreathe International Ltd, UK) was used in the training procedure. The IMT was carried out with patients in Fowler's position. The intensity of training was set at 40-60% of the daily maximal inspiratory pressure (MIP). The measurement of MIP was repeated three times (differences between values<10%), and the most negative value was recorded.[32]

Patients were encouraged to inhale quickly and forcefully against the device with full exhalation for every breath. The program consisted of 30 breaths per session which was divided into 10 breaths per set with a one-minute rest between each set, and each session was repeated twice a day. During each resting period, MV was permitted. The termination of training included presentation of any of the following: RR>35 breaths per min, oxygen saturation<90%, HR>140 beats per min or >20% at the start, SBP>180 mmHg or <80 mmHg, paradoxical breathing, agitation, hemoptysis, depression, or sweating.[33] The vital signs were recorded before and after training.

Table 1 Early mobilization program.

Levels of EM	Testing	Training
Level I	• Alert	• AAROM exercise or AROM exercise of UE&LE 5-10 reps, twice a day
	• Follow simple command for upright position	• Sitting balance training
Level II	• Elbow flexors and extensors grade >3/5 (MRC scale)	• UE: resistance exercise (weight ≤500 g) 5-10 reps, twice a day
	• At least fair grade of sitting balance testing for sitting over the edge of the bed	• LE: active exercise 5-10 reps, twice a day
		• Gross motor function training (supine to side lying, side lying to sitting)
Level III	• At least antigravity of bridging on bed	• Standing balance training
	• Knee extensors grade >3/5	• Less than 40% of HRR or Borg scale <3 (10-point scale) of aerobic exercise while standing 10-15 minutes, twice a day
	• At least fair grade of standing balance testing for actively sit to stand beside the bed	

Note: *AAROM: active-assisted range of motion, AROM: active range of motion, EM: early mobilization, UE: upper extremity, LE: lower extremity, reps: repetitions, MRC: Medical Research Council, g: grams, HRR: heart rate reserve.*

Early mobilization program

The EM program was modified from Morris et al. [34] and divided into three levels (Table 1). Before the training, manual muscle testing (MMT) using the Medical Research Council (MRC) scale[35] and balance assessment were performed. Balance was assessed when the MRC scale was >3/5. Each patient received a level of EM according to their grade of MMT and balance. Patients were progressed to the next level when their grade of MMT and balance improved. The criteria used to determine termination of training included the following conditions: hypoxia with oxygen saturation<88%, hypotension (MAP<65 mmHg), new vasopressor administration, new documented myocardial infarction, requirement of administration of a new antiarrhythmic agent, needing a change of MV mode into assist control mode or an increase in the positive end-expiratory pressure (PEEP) (no absolute limit regarding PEEP and FiO_2 to terminate the training). Re-assessment was performed the next day if the EM was terminated. The training was initiated again when patients were in a stable clinical.[34] During training, other events such as falling or ETT dislocation were also documented. The vital signs were recorded before and after training.

Body composition

The bioelectrical impedance analysis (BIA) (InBody S10®, InBody Co., Ltd, Seoul, South Korea) was used for measurement the body composition. In critically ill patients, the BIA has been successfully used for body composition assessment and monitoring.[36, 37] Before each measurement, manual inputs of patient information including age, height, weight, and sex were recorded.[38] The arms were separated naturally from the trunk at approximately 15 degrees, and the legs were separated approximately shoulder width apart. Touch-type electrodes were placed in contact with the patient's thumbs and middle fingers. The foot electrodes were placed between the patient's ankle bones and heels. The procedure was performed for 10-15 minutes in a supine position.

Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (SPSS) Version 17 (IBM Inc., Armonk, NY, USA). The Shapiro-Wilk test was used to analyze the normality of distribution. An unpaired t-test or the Mann-Whitney U test was used to examine differences between groups in the case of continuous variables. The chi-square test was used for analysis of categorical variables. Multivariate regression analysis was used for analysis of possible confounding factors of the outcomes. Significance level was set at $p<0.05$.

Results

Characteristics of the patients

The period of recruitment and follow-up was from December 2018 to July 2019. Thirty patients were enrolled onto study. Three were excluded after the initial enrolment and the remainder were randomized into the control (n=12) and the experimental group (n=15) (Figure 1). There was no loss to follow-up. Body composition was measured before and after treatment. The three patients excluded after enrolment was in the control group were not measured for the following reasons: had a metal implant (n=1) and had skin lesions at site where the electrodes were placed (n=2). The MV duration in the control and the experimental groups were 5.00±2.70 and 3.93±1.49 days, respectively. Upon admission, primary diagnoses of patients in both groups were gastrointestinal surgery (59.26%), thoracic surgery (25.93%), urinary tract surgery (3.70%), and vascular surgery (11.11%). The mean values and standard deviations of pain visual analog scale (VAS) in the control and experimental groups were 0.00±1.56 and -0.40±1.45, respectively. There was no significant difference between the groups. The percentages of patients in the control and experimental groups that completed total sessions of the treatment were 91.42% and 89.89%, respectively. Incompletion of the treatment sessions included unstable clinical conditions and other events not related to the treatment, such as bedside bronchial suctioning. The minimum and maximum treatment days of the EM program were three and five. The percentages of patients at each training were as follows: 1) Day 1: 33.33% of level II and 66.67% of level III; 2) Day 2: 20% of level II and 80% of level III; 3) Day 3: 20% of level II and 80% of level III; 4) Day 4: 6.67% of level II and III; and 5) Day 5: 6.67% of level III. None of the patients started EM at level I. The mean intensity of IMT (cmH_2O) on each day of treatment was as follows: 16.57 (Day 1); 19.09 (Day 2); 18.67 (Day 3); 21.76 (Day 4); and 21.31 (Day 5). There were no adverse effects from the treatments in this study. There were no significant differences in baseline characteristics between the groups of the patients apart from the BMI which was significantly different (p=0.04) (Table 2).

The MIP at baseline, after treatment, and mean changes are presented in Table 2. After treatment, the mean changes in MIP showed an increasing trend in the experimental group. Although the MIP in the experimental group was higher than the control group, there was significant difference between groups at baseline. Therefore, a multivariate regression analysis adjusted with potentially confounding variables was performed, including Model 1 (MIP at baseline) and Model 2 (MIP at baseline, age, and BMI). Both models of the multivariate regression analysis showed that the treatments significantly increased MIP by 12.83 cmH_2O p=0.01) and 13.12 cmH_2O (p=0.02) in the experimental group when compared to the control group.

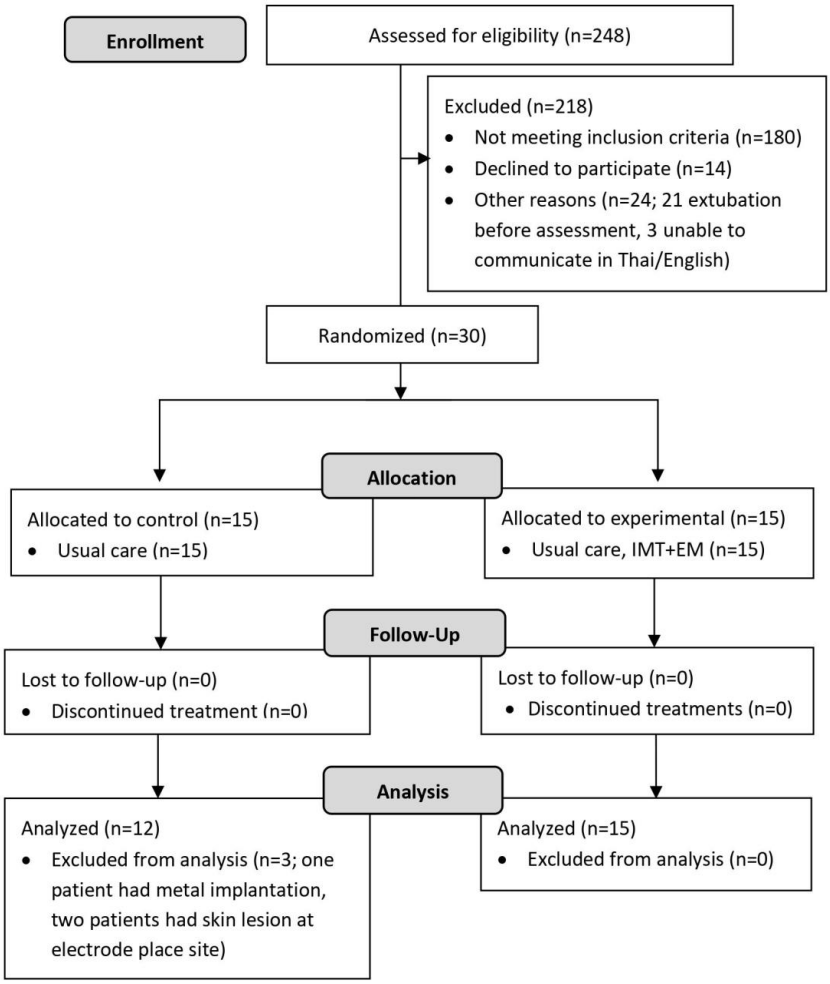

Figure 1. *Flow diagram of the procedure (CONSORT). IMT=inspiratory muscle training; EM=early mobilization.*

Table 2 Characteristics of the patients.

Parameters	Control (n=12)	Experimental (n=15)	*p* value
Sex, male, n (%)	5 (41.67)	7 (46.67)	0.55†
Age, years‡	65.75±12.90	61.27±5.95	0.28
Height, m‡	1.56±7.14	1.59±9.52	0.52
Weight, kg‡	50.58±12.57	57.80±13.40	0.22
BMI, kg/m²‡	19.90±3.72	23.29±5.17	0.04*
Primary diagnosis category at admission, n (%)			
Gastrointestinal surgery	9 (75.00)	7 (46.67)	0.25
Thoracic surgery	3 (25.00)	4 (26.66)	
Urinary tract surgery	0 (0.00)	1 (6.67)	
Vascular surgery	0 (0.00)	3 (20.00)	
MV mode, n (%)			
PCV	0 (0.00)	1 (6.67)	0.36†
PSV	12 (100.00)	14 (93.33)	
MV duration, days‡	5.00±2.70	3.93±1.49	0.52
Treatment day, days‡	4.25±2.42	3.20±0.56	0.52
MIP, cmH_2O			
Baseline‡	23.00±10.24	34.23±13.78	0.03ϕ
After treatment‡	19.54±8.80#	39.18±15.83	<0.01ϕ
Mean changes‡	-3.47±4.98	4.95±15.29	0.06
Regression models of MIP	**Coefficient (95% CI)**		***P***
Model 1: MIP at baseline	12.83 (3.03 to 22.63)		0.01Ж
Model 2: MIP at baseline, age, BMI	13.12 (2.44 to 23.80)		0.02Ж

Note: *‡Data are presented as the mean±SD. m=meters, kg=kilograms, BMI=body mass index, MV=mechanical ventilation, PSV=pressure-support ventilation, PCV=pressure-control ventilation, MIP=maximal inspiratory pressure. †P by chi-square test of control versus experimental groups, *P<0.05 by Mann-Whitney U test of control versus experimental groups, ϕP<0.05 by T-test of control versus experimental groups, #P<0.05 by T-test of baseline versus after treatment in the control group, ЖP<0.05 by multivariate regression analysis.*

Effects of IMT and EM on the body composition

The changes in body composition are presented in Table 3. After treatment, no significant changes of the segmental lean of right leg (SLRL), segmental lean of left leg (SLLL), fat mass, and percent of body fat (PBF) were found in either group. However, decreases in skeletal muscle mass (SMM), segmental lean of right arm (SLRA), segmental lean of left arm (SLLA), and segmental lean of trunk (SLTR) were found in the experimental group after treatment. In the control group, decreases in SLRA and SLTR were found. Baseline values of SMM, SLRA, SLLA, and SLTR in the experimental group were significantly higher than the control group. Therefore, multivariate regression analysis with adjusted confounding factors (Model 1 and 2), was performed. The body composition at baseline was used for adjusting in Model 1 and the body composition at baseline, age, and BMI were used in Model 2. The results showed that no significant differences between the groups (Table 4).

Table 3 Body composition at baseline and after treatment, and mean changes between baseline and after treatment in the control and experimental groups.

Parameters	Control (n=12)			Experimental (n=15)			#*p* value
	Baseline	After treatment	Mean changes	Baseline	After treatment	Mean changes	
Fat mass, kg	10.13±8.66	10.53±9.54	0.41±4.53	10.97±9.87	12.21±9.61	1.24±2.56	0.55
PBF, %	17.89±13.05	19.01±14.82	1.12±8.35	17.50±10.74	19.80±10.93	2.30±4.27	0.64
SMM, kg	20.91±4.20	20.39±5.39	-0.52±2.67	24.87±3.91ϕ	23.92±4.04†	-0.95±1.32	0.59
SLRA, kg	2.26±0.72	1.91±0.72†	-0.35±0.39	3.07±0.71ϕ	2.68±0.60*	-0.38±0.25	0.77
SLLA, kg	2.21±0.86	1.91±0.90	-0.30±0.48	2.96±0.74ϕ	2.52±0.49*	-0.44±0.34	0.38
SLTR, kg	18.37±4.59	16.65±4.58†	-1.72±2.29	22.73±3.99ϕ	20.57±2.96*	-2.16±1.43	0.54
SLRL, kg	5.43±1.22	5.91±2.21	0.48±1.64	6.22±1.64	6.47±1.20	0.24±0.76	0.91
SLLL, kg	5.36±1.23	5.92±2.36	0.55±1.70	6.33±1.68	6.56±2.09	0.23±0.86	0.98

Note: *Data are presented as coefficients with 95% CIs of multivariate regression analysis with adjusted confounding factors of body composition. BMI: body mass index, CI: confidence interval, PBF: percentage of body fat, SMM: skeletal muscle mass, SLRA: segmental lean of right arm, SLLA: segmental lean of left arm, SLTR: segmental lean of trunk, SLRL: segmental lean of right leg, SLLL: segmental lean of left leg. ϕP<0.05 by T-test of control versus experimental groups at baseline, †P<0.05 by T-test of baseline versus after treatment in the experimental and control groups, *P<0.01 by T-test of baseline versus after treatment in the experimental group, #P by T-test of mean changes of control versus experimental groups.*

Table 4 Correlation coefficient of overall scores, and the MDADI-TH subscale scores between test-retest; and intra-class correlation coefficient of the MDADI-TH (N=29).

Parameters	Regression models of body composition	Coefficient (95% CI)	*p value*
Fat mass	Model 1: Fat mass at baseline	0.87 (-2.02 to 3.76)	0.54
	Model 2: Fat mass at baseline, age, BMI	0.78 (-2.68 to 4.23)	0.65
PBF	Model 1: PBF at baseline	1.16 (-4.03 to 6.35)	0.65
	Model 2: PBF at baseline, age, BMI	0.88 (-5.26 to 7.03)	0.77
SMM	Model 1: SMM at baseline	-0.61 (-2.46 to 1.24)	0.50
	Model 2: SMM at baseline, age, BMI	-0.59 (-2.57 to 1.39)	0.54
SLRA	Model 1: SLRA at baseline	0.11 (-0.16 to 0.39)	0.41
	Model 2: SLRA at baseline, age, BMI	0.13 (-0.16 to 0.42)	0.37
SLLA	Model 1: SLLA at baseline	0.41 (-0.09 to 0.92)	0.10
	Model 2: SLLA at baseline, age, BMI	0.35 (-0.21 to 0.91)	0.21
SLTR	Model 1: SLTR at baseline	0.45 (-1.06 to 1.97)	0.54
	Model 2: SLTR at baseline, age, BMI	0.54 (-1.09 to 2.17)	0.50
SLRL	Model 1: SLRL at baseline	-0.87 (-2.18 to 0.43)	0.18
	Model 2: SLRL at baseline, age, BMI	-1.03 (-2.35 to 0.29)	0.12
SLLL	Model 1: SLLL at baseline	-0.53 (-1.61 to 0.56)	0.33
	Model 2: SLLL at baseline, age, BMI	-0.76 (-1.91 to 0.39)	0.19

Note: *Data are presented as coefficients with 95% CIs of multivariate regression analysis with adjusted confounding factors of body composition. BMI: body mass index, CI: confidence interval, PBF: percentage of body fat, SMM: skeletal muscle mass, SLRA: segmental lean of right arm, SLLA: segmental lean of left arm, SLTR: segmental lean of trunk, SLRL: segmental lean of right leg, SLLL: segmental lean of left leg.*

Discussion

This study aimed to investigate the differences in body composition between critically ill surgical patients with either usual care alone or IMT with EM in addition to usual care. Although this study found significant decreases in muscle mass or lean mass in the control and experimental groups, the multivariate regression analysis showed no significant differences in body composition between the groups.

Significant decreases in SMM, SLRA, SLLA, and SLTR were found in the experimental group after treatment. Significant decreases in the SLRA and SLTR were observed in the control group. These results were similar to the findings published in a study by Puthucheary *et al*.[9] which stated that a reduction in muscle mass noticeably starts within 3 days and progressively declines during intensive care. However, the multivariate regression analysis in the present study showed that there were no significant differences in SMM, SLRA, SLLA, SLTR, SLRL, and SLLL between the groups. These results could be explained by the short weaning period (the mean was only 3 days) which consequently shortens the study period.

According to American College of Sports Medicine (ACSM), several weeks of resistance training are needed for the enhancement of muscle mass in healthy individuals.[39] However, the effects of EM on muscle mass after bed rest and immobilization in healthy subjects, COPD patients, and breast cancer patients have been reported.[21-23, 40] EM restores and increases lean muscle mass or cross-sectional area of thigh muscle after 6 or 8 or 15 weeks of training. Additionally, type and intensity of EM training between previous studies and this study were not similar. In the experimental group in our study, 80% of patients reached the highest level of EM (level III) which was focused on the aerobic training while standing with low intensity. COPD patients[21, 41] and healthy subjects[22, 23] underwent the training with maximal intensity isokinetic resistance, once a day for 3 sessions per week. Breast cancer patients underwent combined aerobic and resistance training with intensity at 40-60% of maximal HR, once a day, 2 days per week.[40] Inspiratory muscle training led to significantly increased MIP in the experimental group when compared to the control group after treatment. Increased MIP may involve the improvement of diaphragm muscle thickness.[42-44] Although diaphragm muscle is the essential skeletal muscle for respiration, the muscles are thin and may not affect body composition, especially as regards the SMM. This might explain why the muscle mass was unaffected.

This pilot study did not find significant differences in fat mass and PBF between groups. These might be also because of the short training period. Similar to enhancement of muscle mass, several weeks of aerobic training or active physical activity are required to reduce body fat.[39] In active adults, endurance types of physical activities have been shown to limit fat mass gain when compared with sedentary adults. The physical activities, such as jogging, tennis, gymnastics, skiing, and swimming were performed for >2 months at moderate- or high-intensity level at least 3 hours a week to show results regarding reduction in body fat.[45] Early

mobilization has also been shown to decrease fat mass and PBF after 20 weeks of training in older women, again over a longer period than this study. The program comprised 5 minutes of warm-up, 30 minutes of resistance training, 30 minutes of moderate-intensity aerobic training, and 5 minutes of stretching at the end. The training took place for approximately 70 minutes a day, twice a week.[46] Liao *et al*.[47] demonstrated that resistance training decreased fat mass and PBF in older women with sarcopenic obesity after 12 weeks of training. Subjects were trained using progressive elastic bands for 30-45 minutes per session, 3 sessions a week. In addition, home-based physical training decreased visceral abdominal fat in patients with coronary artery disease after 8 weeks of training. That training comprised 13 minutes of warm-up, 15-20 minutes of strength training, 35-45 minutes of endurance training, and 6 minutes of stretching. The patients were trained with 60-70% of maximal HR, once a day, 3 times a week.[48] In comparison, this pilot study involved only a short training period, and in addition the experimental group seemed to have lower level of physical activity and lighter intensity of training than the previous studies. This might explain why the fat mass and PBF were no different between groups.

Limitations

One limitation of this study was that the population was too small to achieve any statistically significant differences in body composition. A larger population may result in a significant difference in the outcomes. Incision pain in critically ill patients is a factor that limits physical activity and voluntary force generation during inspiratory muscle training and measurement. Therefore, pain management has been provided in patients who underwent the surgery[49], this would limit the ability of the patient to generate muscle force in the same way as a non-critically ill surgical patient. However, pain did not affect the measurement and training in the present study. This study did not match fluid balance between patients as it is difficult to control fluid levels in critically ill patients. However, this study did not find differences in fluid balance between the groups. Early nutritional support plays an important role in the physical and functional recovery of critically ill patients and would need to be included in a further study as the nutrition was not controlled in patients in this study.[50] This might be another reason why no improvement in body composition was found.

Conclusion

The conclusion of this pilot study is that a combination of inspiratory muscle training and early mobilization in conjunction with usual care did not improve body composition when compared to the usual care alone in critically ill surgical patients. After treatment, a decrease in segmental lean of arm and segmental lean of trunk were found in both groups. The multivariate regression analysis adjusted for confounding factors showed no significant differences in body composition between the groups.

Conflicts of interests

The authors declare that there is no conflict of interest

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Analysis of patient radiation dose and angiographic techniques during intracranial aneurysmal diagnosis: a 5-year experience of interventional neuroradiology unit in Srinagarind Hospital.

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ABSTRACT

Background: Intracranial aneurysmal diagnosis (IAD) with an angiographic procedure is the gold standard diagnosis that provides more benefit than other techniques. Moreover, IAD has been the most common diagnostic procedure in the Interventional Neuroradiology unit (INR) in Srinagarind Hospital. However, the angiographic techniques and radiation dose from IAD had never been determined. Therefore, a review of the IAD procedure was considered.

Objectives: This study was set up to obtain a baseline data of IAD radiation dose and angiographic techniques, to compare the radiation dose and angiographic techniques during 5 years of experience and to set up the local DRLs for IAD.

Materials and methods: A retrospective study from January 2014 to December 2018 of IAD patients using bi-plane digital subtraction angiography (DSA) was conducted. Patient's data was reviewed as follows: age, gender, cerebral angiography techniques including kV, mAs, acquisition time of 2-dimensional angiography (2DA) and 3-dimensional rotational angiography (3DRA), total number of angiographic frames, fluoroscopic time, number of 2DA exposure, number of 3DRA exposure, and radiation dose (dose area product; DAP in µGy.m^2 and air kerma; Kar in mGy).

Results: A total of 795 cases (338 male and 457 female), including adult and pediatric patients at the age of 1-91 years old, were recruited into this study. The results showed significant differences in radiation dose, kV, mAs, number of 2DA exposures, 2DA acquisition time, fluoroscopic time, and angiographic frames (p<0.05) throughout 5 years. The 3rd quartile of DAP and Kar have significantly increased from 15,636.30 µGy.m^2 and 939.70 mGy in 2014 to 20,006.36 µGy.m^2 and 1,050.53 mGy in 2018 (p<0.001), respectively. The pediatric DAP and Kar (16,375.54 µGy.m^2 and 816.70 mGy) are slightly lower than the total patient's dose.

Conclusion: Alteration of angiographic techniques during IAD procedure over 5 years might mainly contribute to factors influencing the elevation of radiation dose. The DRLs of IAD procedure in this study is much higher than in other studies. The finding of strategies to reduce radiation dose, particularly pediatric radiation dose, must be further performed.

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Introduction

The diagnosis of cerebrovascular diseases can be performed using several radiological imaging procedures, including computed tomography angiography (CTA), magnetic resonance angiography (MRA), and cerebral angiography. Cerebral angiography is an invasive diagnostic technique. However, it has greater advantages over CTA and MRA, and has been recommended as the gold standard for subarachnoid hemorrhage diagnosis.[1] It has been previously reported that 3-dimensional rotational angiography (3DRA) technique in cerebral angiography increases the detection of intracranial aneurysms, particularly in aneurysms smaller than 3 mm.

Moreover, the planar projection also provides an accurate aneurysm measurement for surgical or endovascular treatment planning.[1] However, the effective dose obtained from cerebral angiography is 5-7 times higher than those in CTA.[2] The higher radiation dose causes greater deterministic injury such as skin erythema, desquamation, and radiation-induced cataract as well as stochastic effect.[3-4] Therefore, the concern of radiation dose from DSA has been considered. The Interventional Neuroradiology (INR) unit in Srinagarind Hospital, Khon Kaen University, is the only institute responsible for the diagnosis and intervention of neurovascular diseases in the Northeastern region of Thailand. At our center, the bi-plane DSA system (Artis zee, Siemens, Germany) has been established since late 2013 and has been used until now. The angiographic techniques, fluoroscopic time, and radiation dose parameters[5] including dose area product (DAP; μGy.m^2) and air kerma (Kar; mGy) can be recorded and kept in the picture achieving communication system (PACS). Several lines of reported evidence revealed that changes of angiographic technique play a crucial role in the alteration of patient radiation dose.[6-9] The changes of angiographic technique had been performed several times at our institute. Unfortunately, the patient radiation dose has never been recorded. In addition, with concerns of patient radiation dose, setting up of dose reference levels (DRLs) in interventional neuroradiology and optimization of radiation dose has gained much attention worldwide.[10-15] Therefore, reviewing of radiation dose and angiographic techniques during INR procedure in our institute had been focused. Intracranial aneurysmal diagnosis (IAD) is the most common procedure used at Srinagarind Hospital[16] and has been conducted with standard angiographic protocols, which include 2-dimensional angiography (2DA), 3-dimensional rotational angiography (3DRA), and fluoroscopy. Therefore, the changes of angiographic technique and the alteration of radiation dose during IAD procedure can be easily observed. The purposes of this study were 1) to obtain a baseline data of IAD radiation dose and angiographic techniques, 2) to compare radiation dose and angiographic techniques during 5 years of experience, 3) to set the local DRLs for IAD at Srinagarind Hospital.

Materials and methods

This study was approved by the Khon Kaen University Ethics Committee in Human Research (HE621359). The retrospective reviews were conducted from January 2014 to December 2018 using the INR unit database and picture archiving and communication system (PACs) at the Faculty of Medicine, Khon Kaen University. All angiograms were performed using a bi-plane DSA system (Artis zee, Siemens, Germany), where angiographic imaging was controlled by using an automatic exposure control system. The quality control of the DSA machine was annually performed by a medical physicist of the Department of Medical Sciences, Ministry of Public Health, following the standard guideline. In addition, preventive maintenance was also quarterly performed by Siemens Limited Thailand. The inclusion criteria involved patients undergoing IAD from January 2014 to December 2018, which angiographic techniques and radiation dose were able to be reviewed, while patients who were unable to be reviewed had been excluded from the study.

Cerebral angiography protocol and parameters for intracranial aneurysm

The standard protocol for intracranial aneurysmal diagnosis at our institute includes fluoroscopy, 2-dimensional angiography (2DA), and 3-dimensional rotational angiography (3DRA) of 3 main cerebral vessels with left and right internal carotid artery and left vertebral artery. The protocol of cerebral angiography is shown in Tables 1 and 2, while the images obtained from these protocols are shown in Figure 1.

Data reviews and collection

The radiation dose indicators, including total DAP (μGy.m^2), total Kar (mGy), DAP, and Kar from 2DA, 3DRA, and fluoroscopy, were recorded. In order to evaluate the factors influencing radiation dose, the cerebral angiography techniques including 2DA techniques (kV, mAs and acquisition time) of the posteroanterior (PA) plane and lateral (Lat) plane, 3DRA techniques (kV, mAs, rotational duration) of pre-contrast and post-contrast, total number of angiographic frames, fluoroscopic time, number of 2DA exposure, and number of 3DRA exposure were also reviewed. Any patient under 18 years old was identified as a pediatric patient.

Statistical analysis

The data was expressed as mean±S.D., median, 3rd quartile, and range. Statistical analysis was performed using SPSS Statistics 19.0 for Windows. The Shapiro–Wilk test was used to identify the normality of data. Comparison of data with normal distribution was performed with a one-way ANOVA test, while Kruskal–Wallis test was used to analyze data with abnormal distribution. ANCOVA and Non-parametric (Quade's) ANCOVA were also applied to analyze radiation dose. *P*-value<0.05 was regarded as a significant difference.

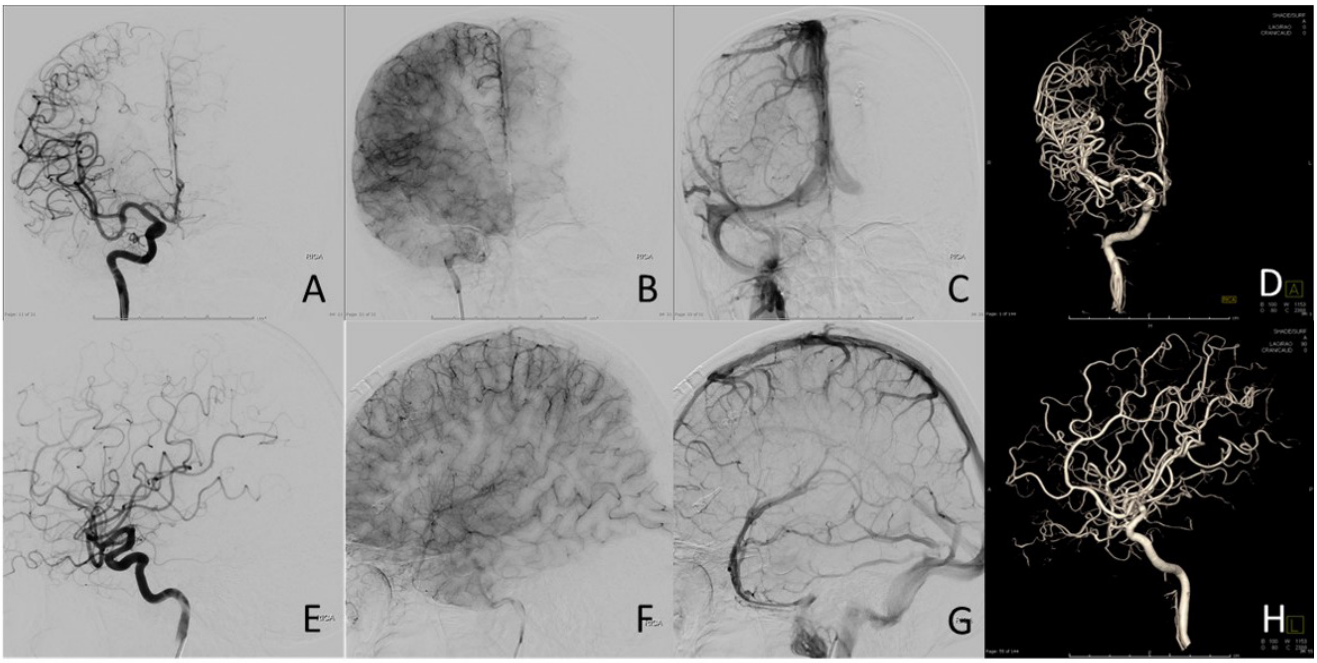

Figure 1. *The angiographic images obtained from 2DA and 3DRA protocol. A-C: arterial phase, capillaries phase and venous phase of RICA in PA view from 2DA protocol, respectively; D: 3DRA image in PA view; E-G: arterial phase, capillaries phase and venous phase of RICA in lateral view form 2DA protocol, respectively; H: 3DRA image lateral view.*

Table 1 The angiographic protocol for 2DA.

Angiographic protocol for 2DA	Value
Field size (PA/Lat)	32/25 cm
Projection of x-ray tube	
Right Internal carotid artery (RICA)	PA view Lateral view
Left internal carotid artery (LICA)	PA view Lateral view
Left vertebral artery (LVA)	PA view Lateral view
Frame rate	
Arterial phase	4 f/s
Venous phase	2 f/s
Delay phase	1 f/s
Contrast media injection	
Flow rate	4 mL/s
Volume	8-13 mL
Pressure	300 PSI

f/s: frames/second, ml/s: milliliter per second, cm: centimeter, PSI: pounds per square inch.

Table 2 The angiographic protocol for 3DRA.

Angiographic protocol for 3DRA	Value
Field size	42 cm
Rotational arc	200 degree
Number of frame/rotation	133
Time	5 sec
Contrast media injection	
Flow rate	2.5 mL/s
Volume	16 mL
Pressure	300 PSI

f/s: frames/second, ml/s: milliliter per second, cm: centimeter, PSI: pounds per square inch.

Results

Patient demographic data

Inclusive of adult and pediatric patients between 1-91 years old who underwent intracranial aneurysmal diagnosis from 2014 to 2018, a total of 795 cases (338 males and 457 females) were reviewed in this study as shown in Table 3. The number of patients in 2014 was 73 (35 males, 38 females), which had sharply increased to 178 (6 males, 112 females) in 2015, and later decreased to 165 (78 males, 87 females) in 2016. The number of patients in 2017 had slightly escalated to 199 (87 males, 112 female) and, then, dropped to 180 (72 males, 108 females) in 2018. There were 13 pediatric patients (12 boys and 1 girl) who had undergone intracranial aneurysmal diagnosis during these 5 years of experience.

Table 3 The demographic data of IAD patient during 5 years of experience.

Year	Gender		Total patient	Age (years old)	
	Male	Female		Mean±SD	Range
2014	35	38	73	53.21±1.84	16-83
2015	66	112	178	53.74±0.99	1-84
2016	78	87	165	53.51±0.98	11-91
2017	87	112	199	52.93±0.97	10-83
2018	72	108	180	55.62±0.91	14-80
Total	338	457	795	53.83±13.50	1-91

Angiographic techniques

kV and mAs

The data of kV and mAs is shown in Table 4. There was a significant difference in kV and mAs in 2DA PA plane and 2DA Lat plane during 5 years of experience (p<0.001). The median kV in 2DA PA plane had decreased from 94 in 2014 to 77 in 2015 and was kept relatively constant until 2018, while the median kV in 2DA Lat plane in 2015-2018 had slightly dropped from 2014. The mAs in both 2DA PA and 2DA Lat planes in 2015-2018 had elevated almost 2-time higher than that in 2014. Although the mAs of 3DRA in both pre-contrast and post-contrast conditions had slightly changed throughout 5 years, significant differences among 5 years were also observed (p<0.001) with the lowest mAs in 2015 and 2016.

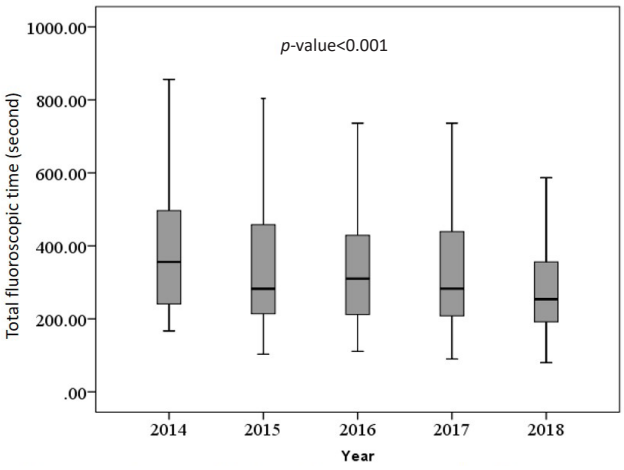

Figure 2. *Total fluoroscopic time from the intracranial aneurysm diagnosis under bi-plane DSA during 5 years of experience.*

Table 4 The angiographic techniques including kV and mAs of 2DA PA plane, 2DA Lat plane, 3DRA pre-contrast and 3DRA post-contrast during 5 years of experience.

Year		2DA PA Plane		2DA Lat Plane		3DRA Pre-contrast		3DRA Post-contrast	
		kV	mAs	kV	mAs	kV	mAs	kV	mAs
2014	Median	94	10.01	74	11.00	70	2.10	70	2.07
	Range	74-96	9.09-20.84	68-80	8.98-21.18	70-71	1.49-2.88	70-71	1.38-2.64
2015	Median	77	19.99	70	18.08	70	2.01	70	2.00
	Range	73-88	17.28-21.70	68-75	13.13-21.69	70-72	1.09-2.76	70-72	1.07-2.72
2016	Median	75	19.80	72	17.88	70	2.01	70	2.00
	Range	70-86	16.25-21.15	68-76	11.67-21.25	70-71	1.20-2.65	70-71	1.15-2.64
2017	Median	76	19.45	73	18.19	70	2.11	70	2.10
	Range	70-87	15.69-23.52	68-77	13.19-25.14	70-71	1.20-3.08	70-71	1.17-3.10
2018	Median	76	19.73	73	16.24	70	2.12	70	2.11
	Range	73-82	13.12-21.49	68-76	10.05-22.25	70-71	1.20-2.97	70-71	1.21-2.87
	p value	<0.001	<0.001	<0.001	<0.001	1.000	<0.001	0.686	<0.001

Number of exposures, acquisition time, angiographic frames

The data on number of exposure and angiographic frames from intracranial aneurysmal diagnosis is shown in Table 5. The median number of 2DA exposure was 6 in the years 2014-2016 and 2018. This parameter had slightly increased to 7 exposures in 2017. However, there was no significant difference among 5 years. The range of 2DA exposure varied from 2 to 28 exposures during the years of experience. Number of 3DRA exposure varied between 2 to 12 exposures with a significant difference among 5 years (p=0.012), where the highest range was observed in 2018 (2-12 exposure). The 2DA acquisition time was a significant difference among 5 years of experience (p<0.001) with the highest median acquisition time in 2018 (15.00 sec, a range of 7.00-29.33 sec). Moreover, in the years 2016 and 2017, the 2DA acquisition time was 14 sec with a range of 8.00-23.00 and 8.67-21.00 sec, respectively. However, the 3DRA acquisition time did not show any significant difference (p=1.00). The number of frames was depending on the number of exposure and the acquisition time from each exposure. The total angiographic frames were also collected and had shown a significant difference among 5 years (p<0.001). The median value of this parameter had slightly increased from 979 to 1,006 frames during the period of 2014-2018.

Table 5 Number of 2DA and 3DRA exposure, 2DA and 3DRA acquisition time and total angiographic frames during 5 years of experience.

Year		No. of 2DA Exposure	No. of 3DRA Exposure	2DA acquisition time (sec)	3DRA acquisition time (sec)	Total angiographic frames
2014	Median	6	6	13.00	5.00	979
	Range	4-12	2-8	8.00-20.00		334-1,594
2015	Median	6	6	12.00	5.00	987
	Range	2-16	2-8	7.80-19.33		322-1,766
2016	Median	6	6	14.00	5.00	992
	Range	2-19	2-9	8.00-23.00		322-1,614
2017	Median	7	6	14.00	5.00	1,004
	Range	4-16	2-9	8.67-21.00		382-1,560
2018	Median	6	6	15.00	5.00	1,006
	Range	2-28	2-12	7.00-29.33		322-2,022
	p value	0.304	0.012	<0.001	1.00	<0.001

Fluoroscopic time

The fluoroscopic time from IAD under bi-plane DSA is shown in Figure 2. The data revealed that the fluoroscopic time has a significant difference throughout 5 years of experience (p<0.001). It was found that the median fluoroscopic time was lowest in 2018 (251.5 sec). While, between the years 2014-2017, the values of this parameter were 354, 281, 310 and 283 second, respectively. There was 41% reduction of fluoroscopic time from 2014 to 2018.

Radiation dose

Standard protocols for IAD in our institute include 2D angiography, 3D rotational angiography, and fluoroscopy. The total radiation dose is the summation dose from these protocols and presented as DAP (µGy.m^2) and Kar (mGy). The results of DAP and Kar from 2014-2018 are shown in Table 6 and 7. The results showed that there is a significant difference of DAP and Kar from 2DA, 3DRA, fluoroscopy, and total DAP during 5 years of experience (p<0.001 all). The lowest median DAP of 2DA was found in 2014 (5,792.24 µGy.m^2) and significantly raised to 8,898.79, 10,085.45, and 10,790.30 µGy.m^2 in 2015, 2016, and 2017, respectively. This value had slightly decreased in 2018 (10,172.55 µGy.m^2). Median Kar of 2DA showed the same trend as median DAP with the values of 441.25, 511.90, 583.80, 621.00, and 595.70 mGy in the years between 2014-2018, respectively. The 2DA DAP had increased in 2018 almost double from 2014, while Kar had increased for around 35% in the same period.

Medians for DAP and Kar of 3DRA were fluctuating during 5 years of experience. The lowest median values of DAP and Kar of 3DRA were found in 2015 (5,425.06 µGy.m^2; 216.30 mGy), while the highest values were found in 2017 (6,355.50 µGy.m^2, 258.00 mGy). Since the mAs during 2015 and 2016 were lower than the others, mAs might play a crucial role in the reduction of DAP and Kar in these years. Interestingly, the median fluoroscopic DAP and Kar had gradually decreased from 1,102.80 µGy.m^2 and 71.90 mGy in 2014 to 548.05 µGy.m^2 and 30.20 mGy in 2018, respectively. Median for total DAP was 13,732.57 µGy.m^2 in 2014 and had slightly elevated to 18,146.25 µGy.m^2 in 2017. This number had dropped to 16,755.16 µGy.m^2 in 2018. The median for total Kar value showed the same trend as the median for total DAP with the value of 782.25, 788.80, 885.30, 927.00, and 859.50 mGy between the years 2014-2018, respectively.

The 3rd quartile of radiation dose parameters, including DAP and Kar, which may be set as local DRLs (LDRLs) for IAD were also evaluated. The 3rd quartile values of DAP were 15,636.30, 18,807.37, 20,546.41, 20,914.66, and 20,006.36 µGy.m^2, while those of Kar were 939.70, 979.60, 1,085.65, 1,090.05, and 1,050.53 mGy, in the respective years.

Since pediatric radiation dose is an important issue, the data of 13 pediatric patients' radiation dose was separated, analyzed, and is shown in Table 8. Median 2DA DAP and Kar were 8,945.69 µGy.m^2 and 513.30 mGy, while median 3DRA was 4,777.23 µGy.m^2 and 189.30 mGy. Median fluoroscopy DAP and Kar was 595.03 µGy.m^2 and 30.40 mGy. Median and 3rd quartile of total DAP were 14,398.39 and 16,375.54 µGy.m^2, while Kar value was 768.20 mGy. Pediatric dose was approximately 17% lower than the overall radiation dose.

Table 6 DAP value during 5 years of experience.

Year		2DA DAP (µGy.m^2)	3DRA DAP (µGy.m^2)	Fluoroscopic DAP (µGy.m^2)	Total DAP (µGy.m^2)
2014	Median	5,792.24	6,321.80	1,102.80	14,036.85
	3rd Quartile	7,788.33	7,362.25	1,794.11	15,636.30
	range	1,608.13-19,009.30	911-18,337	383.01-8,334.12	3,884.4-27,906.51
2015	Median	8,898.79	5,425.06	985.43	15,486.47
	3rd Quartile	11,181.28	6,559.60	1,557.7	18,807.37
	range	2,423.34-21,837.90	1,356.87-11,349.00	338.32-7,388.60	4,556.84-34,870.51
2016	Median	10,085.45	5,520.80	1,068.4	17,154.83
	3rd Quartile	12,882.95	7,185.80	1,609.42	20,546.41
	range	2,232.20-26,815.50	1,619.30-16,013.00	303.55-7,946.34	4,458.75-44,954.23
2017	Median	10,790.30	6,355.50	910.86	18,146.25
	3rd Quartile	12,594.44	7,371.03	1,480.835	20,914.66
	range	4,485.59-34,738.70	1,861.89-17,622.00	147.61-4,849.23	9,189.5-41,592.47
2018	Median	10,172.55	6,175.96	548.05	16,755.16
	3rd Quartile	11,974.69	7,197.18	800.695	20,006.36
	range	1,413.75-38,868.60	1,787.10-10,807.00	170.39-4,188.69	2,078.07-47,050.92
	p value	<0.001	<0.001	<0.001	<0.001

Discussion

This is the first report of radiation dose and angiographic techniques from intracranial aneurysmal diagnosis using bi-plane DSA in Northeastern Thailand. Data from this study is beneficial for further study optimization, radiation dose reduction, and effect minimization of stochastic injury in both patient and INR staff. Epidemiology and meta-analysis of aneurysms reported that aneurysms could occur in all ages, and the number of female patients is 2-time higher than male at age above 50 years.[17] Data from this study showed that patients in our institute were found in all age ranges, with the mean age of 53.83±13.50 years old, and the number of female patients was 1.35-time higher than male. The prevalence of the disease in Northeastern region showed a similar trend as presented in the previous report. Moreover, the increasing number of patients was in concordance with the increasing number of radiologists. In 2014, there was only one radiologist responsible for the INR unit. The number of radiologists increased to 2 in 2015-2016, then there were 3 radiologists in 2017, which eventually decreased to 2 radiologists in 2018. In addition, the increase of IAD cases might be due to high effectiveness of INR procedures as well as improvement of healthcare network and patient referral system in the region.

The angiographic techniques, including kV, mAs, number of exposures, acquisition time, number of frames, and fluoroscopic time during 5 years of experience, were collected. Changes in kV, mAs were observed in the second year of experience. Since the exposure of bi-plane DSA in our institute was controlled by AEC, kV can be set while mAs is automatically controlled by AEC.[18] Reduction of kV in 2DA was the main factor of mAs elevation, following the relationship between kV and mAs of previous reports.[18-19] However, other explanations of rising mAs should be further explored. Total angiographic frames in each patient depend on the number of exposures, acquisition time on each exposure, and number of frame rates in each protocol. The elevation of 2DA acquisition time might be resulted from the variety in experience of radiologists and the difficulty of IAD procedure in recent years of this study. Since 3DRA technique provides 133 frames per exposure, it is the main source that produces total angiographic frames from IAD in our institute. Moreover, the range of 3DRA exposure in this study was between 2-12 exposure/session, while that reported in previously published study was between 0-4 exposure/session.[10] Therefore, the total angiographic frames from the IAD in our institute was higher than those reported in the other institutes.[10,12] It has been reported that reduction of pulse fluoroscopy significantly decreases the fluoroscopic dose.[20] In our institute, reduction of fluoroscopic pulse from 15 frames per second (f/s) to 10 f/s was performed since August 2017 with the constant of kV and mA. In addition, the fluoroscopic time showed a good trend of reduction from the year 2014 to 2018. Hence, the reduction of fluoroscopic time and pulse fluoroscopy resulted in a sharp decrease of fluoroscopic dose for approximately 50% from previous years. However, fluoroscopic dose has less influence on total DAP and Kar dose with approximately 6-8% of the total dose. Therefore, this reduction did not affect the total radiation dose mainly obtained from 2DA and 3DA exposure. The radiation dose from 2DA protocol of IAD had sharply escalated in 2016 and 2017, following the reduction of kV, which increased mAs in 2DA, 2DA acquisition time, and angiographic frames. Moreover, a possible explanation for the reduction of 3DRA radiation dose in 2016 and 2017 might be the effect of mAs reduction. Several studies have evaluated the radiation dose from neurointerventional radiology procedure and set up the DRLs. The comparison of IAD DRLs with other studies is shown in Table 9. The 3rd quartile of DAP in our institute during 2014 was lower than the study of Brambilla and coworker in 2004[14] and the study of D'Ercole and cowoker.[13] While DAP radiation dose of 2014 was equivalent to the study of Chun and coworker,[12] but higher than the study of Inh *et al*. and Aroua *et al*.[10-11] The 3rd quartile of DAP dose in 2015 was approximately equal to the study of D'Ercole and cowoker,[13] while higher than that of other studies from 2016 until 2018. Since most studies did not record Kar dose, this parameter was not compared in this study. In addition to the 3rd quartile comparison, the comparison of median total DAP of this study with the National DRLs (NDRLs) of Korea,[10] which studied similar bi-plane DSA technology, was also performed. The median total DAP of this study from 2015-2018 was higher than that of NDRLs of Korea. Therefore, the optimization process must be implemented in our institute.

Subgroup analysis of pediatric radiation dose was also performed. Since the number of pediatric patients in each year was very small, the summation of data from all pediatric patients was done for 5 years. The pediatric radiation dose was lower than the total patient's radiation dose. However, these parameters were 2 times higher than that of previous study.[15]

The study revealed that alteration of angiographic techniques, including reduction of kV, elevation of mAs in 2DA, 2D image acquisition time, and number of angiographic images, might be the main factors for the increase of radiation dose from IAD procedure in our institute. Moreover, the median total DAP from IAD procedure of our institute was also greater than that of NDRLs reported. Therefore, the optimization by modifying angiographic techniques is important and should be performed. Since this study was a retrospective study, the other important factors influencing radiation dose, such as magnification and source image distance (SID), cannot be recorded and might miss some important factors. Therefore, a further prospective study in which all parameters that have influence on radiation dose can be recorded should be performed.

Table 7 The Kar value during 5 years of experience.

Year		2DA Kar (mGy)	3DRA Kar (mGy)	Fluoroscopic Kar (mGy)	Total Kar (mGy)
2014	Median	441.25	247.10	71.90	782.25
	3rd Quartile	549.60	290.40	120.20	939.70
	range	93.5-1,182.9	35.4-887.5	23.9-323.0	239.2-1,516.0
2015	Median	511.90	216.30	56.00	788.80
	3rd Quartile	645.40	261.35	83.15	979.60
	range	158.6-1,596.4	45-533.9	16.9-1,066.5	247-2,191.50
2016	Median	583.80	220.00	59.00	885.30
	3rd Quartile	745.05	286.25	89.00	1,085.64
	range	124.2-1,624.5	64.5-637.9	15.9-404.0	213.6-2,164.1
2017	Median	621.00	258.00	47.40	927.00
	3rd Quartile	712.95	296.85	75.90	1,090.05
	range	244.4-1,381.8	73.4-654.6	7.5-889.7	464.1-1,864.9
2018	Median	595.70	246.85	30.20	859.50
	3rd Quartile	711.00	286.38	42.83	1,050.53
	range	31.1-4,371.1	70.8-4,345.3	9.0-410.4	46.2-4,939.9
	p value	<0.001	<0.001	<0.001	<0.001

Table 8 Pediatric radiation dose from 5 years of experience.

Pediatric radiation dose		2DA	3DRA	Fluoroscopy	Total radiation dose
DAP ($\mu Gy.m^2$)	Median	8,945.69	4,777.23	595.03	14,398.39
	3rd Quartile	10,631.30	6,062.31	787.15	16,375.54
	range	4,920.77-20,067.35	2,217.40-7,719.10	267.27-7,388.60	10,296.57-24,556.98
Kar (mGy)	Median	513.30	189.30	30.40	768.20
	3rd Quartile	603.80	241.60	49.88	816.70
	range	373.00-1,036.00	73.40-297.90	14.00-1,066.50	542.00-1,767.50

Table 9 The comparison of 3rd quartile of DAP with previous studies.

References	DAP (3rd Quartile)
Inh et al.,2016	14,420 $\mu Gy.m^2$
D'Ercole et al., 2012	18,041.50 $\mu Gy.m^2$
Chun et al., 2014	15,420 $\mu Gy.m^2$
Aroua et al., 2007	12,500 $\mu Gy.m^2$
Brambilla et al.2004	19,800 $\mu Gy.m^2$
This study (2014)	15,636.30 $\mu Gy.m^2$
This study (2015)	18,807.37 $\mu Gy.m^2$
This study (2016)	20,546.41 $\mu Gy.m^2$
This study (2017)	20,914.66 $\mu Gy.m^2$
This study (2018)	20,006.36 $\mu Gy.m^2$

Conclusion

The result from this study revealed that alteration of angiographic techniques, particularly in 2DA during the IAD procedure, might be the factors that influence elevation of radiation dose. Moreover, LDRLs of IAD procedure in our institute were higher than the others. Therefore, finding strategies to reduce radiation dose, particularly pediatric radiation dose, should be further conducted.

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Conflicts of interest

The authors declare no conflict of interest in this research.

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