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Hong Kong Physiotherapy Journal

Aims & Scope

The Hong Kong Physiotherapy Journal (HKPJ) is the official peer-reviewed, Open Access (OA) publication of the Hong Kong Physiotherapy Association.

HKPJ publishes papers related to all areas of physiotherapy (education, research, practice, policies) and is committed to facilitating communication among educators, researchers and practitioners in the field with the aim of promoting evidence-based practice.

We are particularly interested in publishing randomized controlled trials, systematic reviews and meta-analyses. Animal studies are also welcome if the study question and findings have important relevance to physiotherapy practice.

HKPJ welcomes submissions from all over the world in the form of original research papers, reviews, editorials, treatment reports, technical notes, and correspondence.

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Systematic Review and Meta-Analysis

Research Article

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A systematic review and meta-analysis on effect of spinal mobilization and manipulation on cardiovascular responses

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Background: Spinal pain or misalignment is a very common disorder affecting a significant number of populations resulting in substantial disability and economic burden. Various manual therapeutic techniques such as spinal manipulations and mobilizations can be used to treat and manage pain and movement dysfunctions such as spinal mal-alignments and associated complications. These manual therapeutic techniques can affect the cardiovascular parameters.
Objective: The objective of this systematic review and meta-analysis is to assess the effect of spinal manipulation and mobilization on cardiovascular parameters.
Methods: We conducted a systematic review and meta-analysis to assess the effects of spinal mobilization and manipulation on cardiovascular responses. Mean changes in Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Heart Rate (HR) were primary outcome measures. RevMan 5.3 software was used for the meta-analyses. Quality of the included studies was assessed by PEDro Rating scale. Risk of bias was assessed by Cochrane collaboration tool of risk of bias.
Results: Results of meta-analysis showed that there was statistically significant decrease in SBP (MD = −4.56, 95% CI = −9.20, 0.08; $p \leq 0.05$) with moderate heterogeneity (I2 = 75%, $p < 0.0002$) in experimental group as compared to control group. There was statistically non-significant decrease in DBP (MD = −1.96, 95% CI = −4.60, 0.69; $p = 0.15$) with high heterogeneity (I2 = 91%, $p < 0.00001$), Change HR was statistically non-significant (MD = −0.24, 95% CI = −3.59, 3.11; $p = 0.89$) with moderate

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heterogeneity (I2 = 60%, $p = 0.01$). Exclusion of short duration studies in sensitivity analysis revealed a statistically significant change in DBP (MD = −0.94, 95% CI = −1.85, −0.03; $p = 0.04$). However, the result was statistically non-significant for HR after sensitivity analysis.
Conclusion: Spinal manipulations and mobilizations may result in significant decrease of systolic as well as diastolic Blood Pressure.

Keywords: Spinal manipulations; spinal mobilizations; cardiovascular responses; blood pressure; heart rate.

Introduction

Manual therapy techniques, like spinal mobilizations, high-velocity, low-amplitude manipulations and mobilization with movement are frequently used by physiotherapists along with various therapeutic exercises to treat or manage spinal pain and movement dysfunction.[1–3] Spinal mobilizations are referred as "graded passive, oscillatory movements applied to the spine that moves it to the end of its available range".[3] These mobilizations are performed within the normal range of motion in such a way that it may be controlled by the patient, whereas manipulations are rapid movement at the end of the range of movement that cannot be controlled by the patient.[4] Although both the techniques are different in application, still the main emphasis of both techniques is continuous assessment and evaluation.[1] According to the findings of assessment and evaluation, spinal manipulative therapies are applied at varying speed and amplitude.[3]

Spinal manipulative therapies are mainly indicated to alleviate spinal pain and correct spinal malalignment.[1] Spinal pain is a very common disorder affecting a significant number of populations resulting in substantial disability and economic burden. It is estimated that approximately 54–80% population suffer from spinal pain at any stage of their life.[5] Research evidence suggests that workplace physical and psychosocial factors also contribute to the development of spinal pain. Gender, occupation, emotional problems, smoking, poor job satisfaction, awkward posture and poor work environment may also be associated with spinal pain.[6]

Spinal malalignments (such as scoliosis) are mainly caused by body's abnormal posture, asymmetries in bone growth and abnormalities of neuromuscular system. Asymmetrical load applied to vertebral axis is the main cause of development and progression of spinal deformity. Altered biomechanics, weakness of abdominal muscles, joint laxity and increased extensibility of soft tissues can be risk factors for the progression of spinal malalignments.[7] As a response, body progressively attains compensatory mechanism from other flexible parts of spine to preserve the spine posture. This puts additional stress over the musculoskeletal system and further leads to pain.[8] Literature suggests that psychosomatic symptoms such as stress, anxiety and depression are strongly associated with spinal pain and malalignment.[9] Spinal pain, mainly in cervical region, is strongly associated with migraine and severe headache with prevalence rate of 15.1%. Other associated symptoms are spine stiffness, headache, numbness, dizziness, sleeping difficulties, fatigue and memory as well as cognitive deficits.[6]

Evidence shows that spinal malalignment of cervical spine (especially C1 vertebra) can potentially injure, impair and compress brainstem neural pathways which is the regulatory centre of cardiovascular functions. Changes in the anatomical position of atlas [C1] and connected chain result in circulatory changes of vertebral artery. These circulatory abnormalities around the atlas vertebra and posterior fossa of brain have significant correlation with worsening of hypertension.[11] Involvement of thoracic spine alone or in combination with lumbar spine results in cardiovascular and respiratory complications.[10]

Therefore, it may be suggested that the spinal manipulations, especially of cervical region can affect heart rate and blood pressure. The primary mechanism of these benefits can be parasympathetic stimulation.[3] SMT of cervical spine may directly stimulate the parasympathetic flow via brain stem or indirectly through the stimulation of carotid sinus which further stimulates the brain stem via nucleus tractus solitaries (NTS).[11,12]

The existing research literature regarding effect of spinal manipulation and mobilization on

cardiovascular parameters is still ambiguous. Studies corroborate[11,13–18,21–23,26–28] as well as contradict[12,19,20,24,25] the effects of manual therapy on cardiovascular parameters. These studies also have various methodological flaws. Further, small sample size of these studies limits the generalizability of their results.

Till date, no systematic review and meta-analysis has been done to assess the effect of spinal manipulation and mobilization on these cardiovascular parameters. Therefore, the rationale of this systematic review and meta-analysis is to include good quality randomized control trial (RCT's), on this subject matter, so that a conclusion can be drawn on the basis of the collective inference of these RCTs.

Methodology

Search strategy and selection criteria

This systematic review and meta-analysis was developed according to the guidelines of the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA), 2015. The protocol of this systematic review and meta-analyses was registered under "The International Prospective Register of Systematic Reviews" (PROSPERO) with identification number **CRD42019124114.**

A comprehensive electronic database search for eligible trials (from inception to January 2019) was done in the Cochrane library (Cochrane Central Register of Controlled Trials) and PubMed. Reference lists were also examined to identify the articles not captured in the electronic database search. The research was restricted to RCT's, done on humans and reported in English language using keywords spinal manipulation, spinal mobilization, vertebral adjustment, Mulligan approach, Maitland approach, blood pressure, heart rate, pulse rate, pulse oximetry, electrocardiogram and cardiovascular responses as according to Participant Intervention Comparison Outcome (PICO) strategy. During the search, Medical subject Headings (MeSH) terms, related keywords and "Boolean operators ('OR' and 'AND') using 'Advanced' search options' were included. (*Search strategy as supplementary material 1*) RCTs that evaluated atleast one cardiovascular outcome such as BP or HR during or immediately following spinal manipulations and mobilizations were included. Reviews, systematic reviews, meta-analysis, case reports, editorials and letters were excluded. EndNote software (version X7.7) was used to remove the duplicate records of electronic databases. Two investigators (CG and MM) screened the titles and abstracts of the identified records. This was followed by full text screening performed independently by two investigators (CG, JK).

Inconsistencies were resolved by discussion among all the authors (CG, MM, JK and MS). If the study data was not available, corresponding researcher or the first researcher listed in the included articles was contacted to provide the missing data.

Data extraction and quality assessment

Two investigators (CG and JK) independently extracted the data as per study objectives. Extracted information was then compared and discrepancies such as unclear or missing data presentation were resolved by discussion among the authors.

To assess the efficacy of treatment, mean change in blood pressure (BP) and heart rate (HR) was considered as the primary outcome. Missing data of standard deviation were imputed using correlation coefficient for change from baseline. Chi (X^2) test and I^2-statistic (degree of heterogeneity) were used to assess the Heterogeneity of the studies. Heterogeneity of "0–25% was considered as low heterogeneity, 26–75% as moderate heterogeneity and 76–100% as substantial heterogeneity" in I^2 test. Sensitivity analysis was also done in case of moderate or substantial heterogeneity. Review Manager (RevMan, version 5.3) software was used to perform the meta-analysis.

The PEDro rating scale was used to assess methodological quality of each study. The PEDro rating scale is a eleven-point scale which is used to evaluate the internal quality and validity of the randomized control trials. A score of 6 or more is considered as high quality; while a score of 4–5 is considered as fair (4–5) and 3 or below as poor quality trial.

Risk of bias was evaluated using Cochrane Collaboration's modified tool. This assessment tool consists of seven primary sources for bias: "random sequence generation, allocation concealment, selective reporting, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data and other sources of bias".

These were evaluated independently by the authors to classify the risk of bias as a "high risk", "low risk" or "unclear risk".

Randomized controlled trials investigating the effect of spinal mobilizations and manipulations performed at any region of spine were grouped together for meta-analysis. Outcome measures were heart rate and systolic as well as diastolic blood pressure. Subgroup analysis of these outcome measures was performed on healthy individuals and patients of spinal pain or hypertension. The mean differences (MD) with standard deviations (SDs) of change in systolic blood pressure (SBP), diastolic blood pressure (DBP) and HR were calculated. Continuous variables were evaluated using confidence interval (CI) at 95% and weighted mean differences (WMD). Results of all eligible studies were considered as statistically significant at $p \leq 0.05$. The forest plots and funnel plots were generated using the Review Manager (RevMan, version 5.3) software. Further, sensitivity analysis was done in case of moderate or high heterogeneity. Sensitivity analysis was also performed by exclusion of short duration studies as well as studies with high weightage to evaluate the effect of these studies on outcome measures.

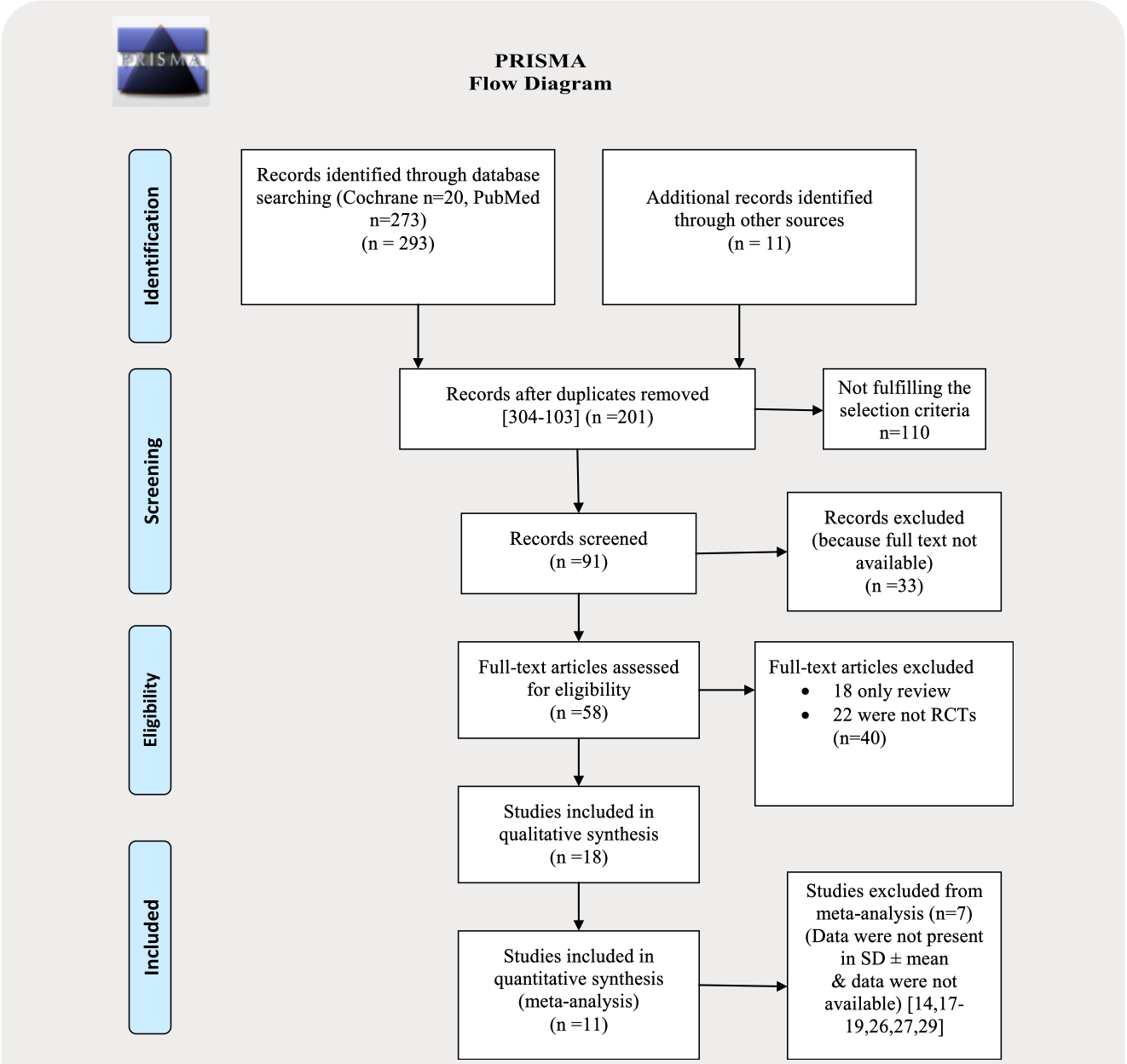

Fig. 1. Flow diagram showing selection of studies.

Table 1. Major characteristics of included studies.

Art.	Author	No. of participants	Characteristics of participants	Study location	Study duration	Treatment	Outcome measures	Findings
1	Bakris *et al.*[11]	$n = 50$, Treatment group ($n = 25$) and control group ($n = 25$).	Spinal (atlas vertebrae) malalignment with stage 1 hypertension	Barrington, USA	8 weeks	C1 correction	BP and pulse rate	Reduction in BP in treatment group. Pulse rate was not reduced.
2	Ward *et al.*[12]	$n = 48$, 12 each, left head turn control, no contact, left atlas, right atlas.	Healthy individuals	Pasadena, United States	2 consecutive days	C1 manipulation	BP,ECG and pulse oximetry	No significant difference between experimental and control group.
3	Touche *et al.*[13]	$n = 48$, experimental or placebo groups ($n = 24$ each).	Cervical spine pain and cranio-facial pain	Madrid, Spain	8 months	Upper cervical mobilization	Pain, breathing rate and HR.	Decrease pain and increase breathing rate and HR in experimental gp.
4	Yates *et al.*[14]	$n = 21$, active, placebo and no treatment control ($n = 7$ each).	Thoracic spine pain, hypertensive and anxiety	Toronto, Ontario, Canada	6 weeks	T1–T5 Adjustment	BP and anxiety.	Decrease BP and anxiety in experimental group.
5	Reis *et al.*[15]	Women with Fibromyalgia ($n = 10$) and healthy women ($n = 10$).	Thoracic spine pain	Brazil	10 weeks	PA and central thoracic Maitland mob.	Pain, HR and RR	Improve HR in experimental group. Pain was not reduced.
6	Younes *et al.*[16]	$n = 22$, Sham group ($n = 7$) and SMT ($n - 10$). Rest were left.	Mechanical Low back pain (lumbar spine pain)	France	6 months	HVLA thrust, lumber mobilization.	Pain, systolic BP and ECG.	Reduced HR and pain in SMT group. No effect on BP and ECG.
7	Vicenzino *et al.*[17]	$n = 24$, treatment, placebo and no treatment group.	Healthy individuals	Brisbane, Australia	2 months	Lateral cervical glide	BP, RR and HR	Increase BP, HR and RR in treatment group as compared toplacebo group.
8	Farthing *et al.*[18]	$n = 30$, rib raising, placebo and control treatment ($n = 10$ each).	Asymptomatic and healthy participants	Melbourne, Australia	8 weeks	slow rib raising	HR, RR, BP and pain pressure threshold (PPT)	Increase RR, DBP and PPT in rib raising treatment as compared to placebo and control group.
9	Goertz *et al.*[19]	$n = 51$, spinal manipulation ($n = 24$) and sham gp ($n = 27$).	Hypertensive patients	Davenport, Iowa, USA.	6 weeks	spinal manipulation of upper cervical	BP	No significant difference between SMT and Sham group.

Table 1. (*Continued*)

Art.	Author	No. of participants	Characteristics of participants	Study location	Study duration	Treatment	Outcome measures	Findings
10	Win *et al.*[20]	$n = 20$, normotensive and neck pain patient group ($n = 10$ each).	healthy volunteer and neck pain patients (cervical spine pain)	Malaysia	3 weeks	Spinal manipulation of upper and lower cervical spine.	Pain, BP and HR	Decrease in pain SBP in upperand lower cervical in treatment gp as compared to control.
11	Yung *et al.*[21]	$n = 39$, treatment and placebo gp.	Healthy participants	Los Angeles, USA	3 months	AP glide at C6	BP and HR.	Decrease in systolic BP and HR in treatment gp.
12	Ward *et al.*[22]	$n = 50$, SMT gp and control gp. ($n = 25$ each)	Hypertensive individuals	Pasadena, TX, USA	3 months	Upper thoracic T1-4 SMT	ECG, BP and pulse oximetry.	Lower left pulse oximetry in SMT. Slight decrease in BP in SMT gp.
13	Yung *et al.*[23]	$n = 44$, treatment and control group. (n=22 each).	Healthy, pain free participants	United States	2 years	PA mobilization at cervical region	BP, HR and pain	Decrease in SBP in treatment group and increase SBP in control group. No change in HR.
14	Valenzuela *et al.*[24]	$n = 37$, Sham ($n = 19$) & SMT (18) group.	Healthy individuals	Madrid, Spain	12 weeks	spinal manipulation therapy	HR, handgrip	Significant decrease in HR in SMT group than sham group.
15	Ward *et al.*[25]	$n = 36$, treatment, placebo and control group. ($n = 12$ each).	Thoracic spine pain participants	Pasadena, TX, USA.	3 months	T1-4 manipulation	ECG, BP and pulse oximetry.	No significant difference between treatment, placebo and control group.
16	Roy *et al.*[26]	$n = 51$, pain gp (sham, treatment, n=20) and pain free (sham, treatment and control) gp. ($n = 31$).	Spinal pain participants and Healthy individuals	Canada	4 months	spinal manipulation therapy at L5	Heart rate variability (HRV)	HRV decreased in sham and treatment group than control group
17	Roffers *et al.*[27]	Experimental group ($n = 99$), control ($n = 95$) and placebo (n=96).	Healthy participants and hypertensive participants	USA	8 weeks	T1-5 spinal manipulation	BP & pulse rate	BP and pulse rate was decreased in experimental group as compared to control and placebo group.
18	McMasters *et al.*[28]	$n = 24$, prehypertensive and hypertensive stage 1 group (n=12 each).	Spinal pain patients and prehypertensive and hypertensive patients	Spartanburg, SC, USA.	1 year	spinal manipulation	BP	BP was decreased in hypertensive stage 1 patient group.

Table 2. Assessment of quality of studies by PEDro scoring.

	1	2	3	4	5	6	7	8	9	10	11	Total
Articles	Specified eligibility criteria	Random allocation	Concealed allocation	Similar baseline	Subjects blinding	Therapists blinding	Assessors blinding	Measures of key outcomes from more than 85% of subjects	Intention to treat analysis of one key outcome	Statistical comparisons between-group of at least one key outcome	Variability for at least one key outcome	
1. Bakris *et al.*[11]	Yes	Yes	Unclear	Yes	Yes	Unclear	Unclear	Yes	Yes	Yes	Yes	8/11
2. Ward *et al.*[12]	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	9/11
3. Touche *et al.*[13]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
4. Yates *et al.*[14]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11/11
5. Reis *et al.*[15]	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	8/11
6. Younes *et al.*[16]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
7. Vicenzino *et al.*[17]	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	Yes	8/11
8. Farthing *et al.*[18]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
10. Goertz *et al.*[19]	Yes	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	9/11
11. Win *et al.*[20]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11/11
12. Yung *et al.*[21]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11/11
13. Ward *et al.*[22]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
14. Yung *et al.*[23]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11/11
15. Valenzuela *et al.*[24]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	11/11
17. Ward *et al.*[25]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
18. Roy *et al.*[26]	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	9/11
19. Roffers *et al.*[27]	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	10/11
20. McMasters *et al.*[28]	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	Yes	8/11

Results

Study Selection. A total of 304 articles were retrieved from the database searches, of which 18 met the selection criteria. Seven articles were excluded from the meta-analysis as required data couldn't be retrieved. The details of the study selection have been represented in Fig. 1. The remaining 8 out of 11 articles comprising 141 participants in treatment group and 134 participants in control/placebo group were included for the meta-analyses of blood pressure. 9 out of 11 articles comprising of 147 participants in treatment group and 143 participants in control/placebo group were included for the meta-analysis of heart rate.

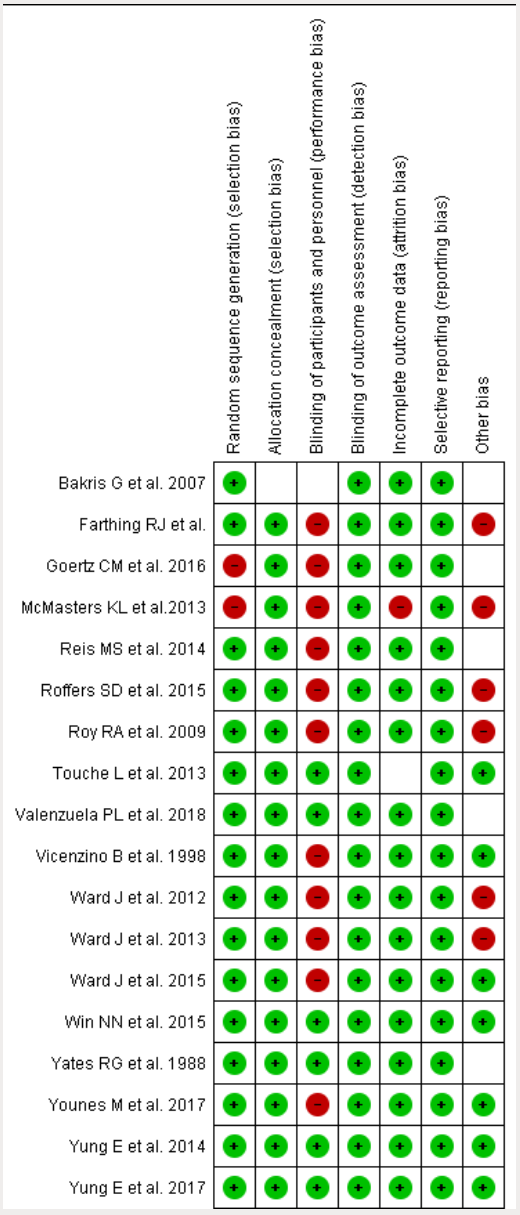

Fig. 2. Risk of bias summary. Studies in green or + are at low risk of bias. Studies in red or − are at high risk of bias. Studies in blank are at unclear risk of bias.

Study characteristics. Table 1 summarizes the characteristics of the included studies. Most of the studies were done in USA (nine)[11,12,19,21–23,25,27,28] followed by Australia (two),[17,18] Spain (two),[13,24] Canada (two).[14,16] One study each was conducted in Brazil,[15] France[16] and Malaysia.[20] Only randomized control trials, either on healthy population or symptomatic population (such as subjects with spinal pain or hypertension), that compared the intervention to either a placebo or a control group were included.

Eight out of the total 18 studies applied either spinal mobilization or manipulation to the cervical spine, six to the thoracic spine and two to the lumbar spine. One study applied manipulation to ribs while manipulation on whole spine was performed in two studies. All studies measured changes in cardiovascular responses (blood pressure and heart rate) during or immediately after the intervention.

Quality assessment. Table 2 summarizes the quality of the included studies. All the studies ranked high on PEDro rating scale. 5 out of 18 studies scored the highest score of 11.[14,20,21,24,25] 6 studies scored 10,[13,16,18,22,25,27] 3 studies scored 9[12,19,26] and 4 studies scored 8.[11,15,17,28] Therefore, it can be inferred that all the included studies were of good quality.

Risk of bias. Risk of bias of the included studies is summarized in Fig. 2. "Random sequence generation" was described adequately in 16 studies.[11–18,21–28] "Allocation concealment" was done in maximum number of studies.[12–28] "Blinding of participants and personnel" were described in six studies.[13,14,16,20,21,25] The overall risk of bias was low in all the included studies.

Meta-analysis. In primary outcome analysis of the studies, eight articles were included for the meta-analysis of BP. Spinal mobilization and manipulation resulted in a statistically significant reduction of SBP (MD = −4.56, 95% CI = −9.20, 0.08; $p = 0.05$). However, the heterogeneity of the data was moderate ($I^2 = 75\%$, $p < 0.0002$) (Fig. 3). Additionally, subgroup analysis revealed that the reduction in SBP was more in patients

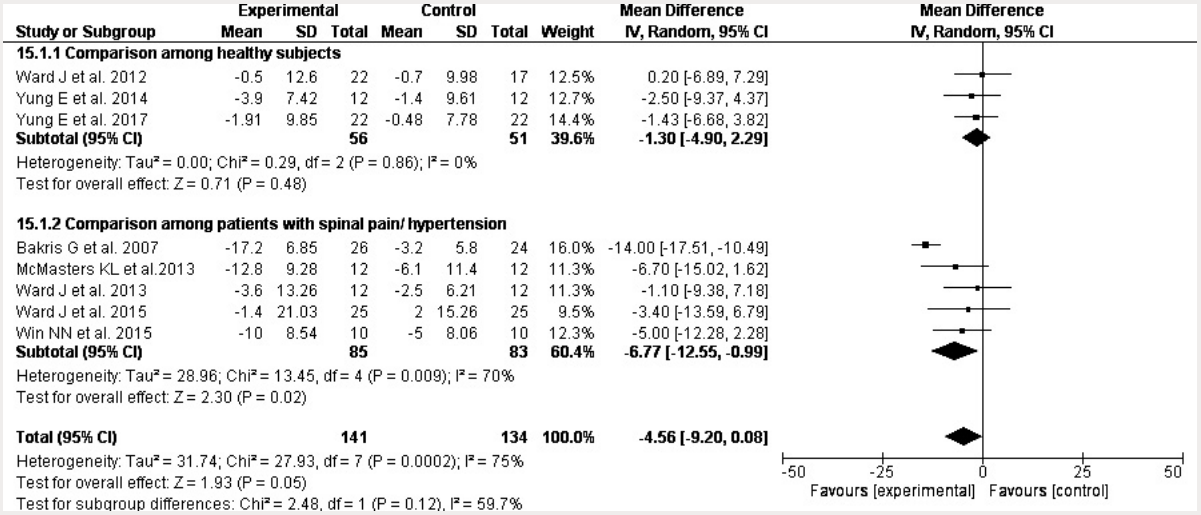

Fig. 3. Comparison of systolic blood pressure using forest plot and subgroup analysis.

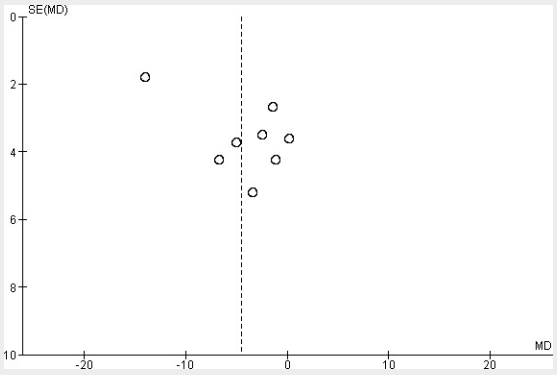

Fig. 4. Funnel plot showing no publication bias in systolic blood pressure.

with spinal pain and/or hypertension (MD = −6.77, 95% CI = −12.55, −0.99; $p = 0.02$). There was statistically non-significant decrease in diastolic blood pressure (DBP) of experimental group as compared to control and placebo group with (MD = −1.96, 95% CI = −4.60, 0.69; $p = 0.15$). However, the data was highly heterogeneous ($I^2 = 91\%$, $p < 0.00001$) (Fig. 5).

Nine articles were included for the meta-analysis of HR. There were statistically non-significant changes in heart rate with (MD = −0.24, 95% CI = −3.59, 3.11; $p = 0.89$) and moderate heterogeneity of $I^2 = 60\%$, $p = 0.01$ (Fig. 7).

Sensitivity analyses. Exclusion of studies with maximum weight has not affected the results for

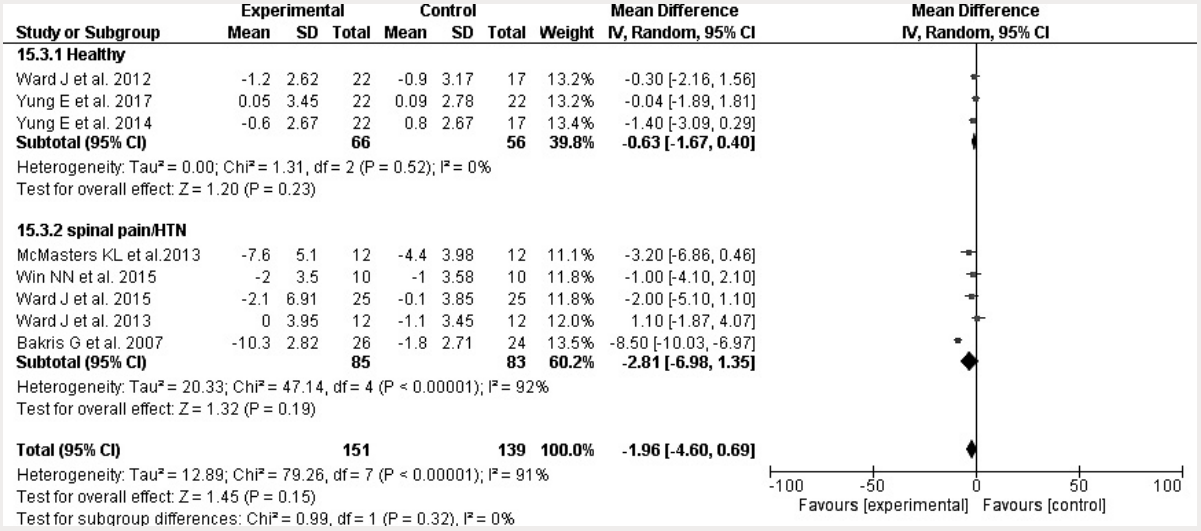

Fig. 5. Comparison of diastolic blood pressure using forest plot and subgroup analysis.

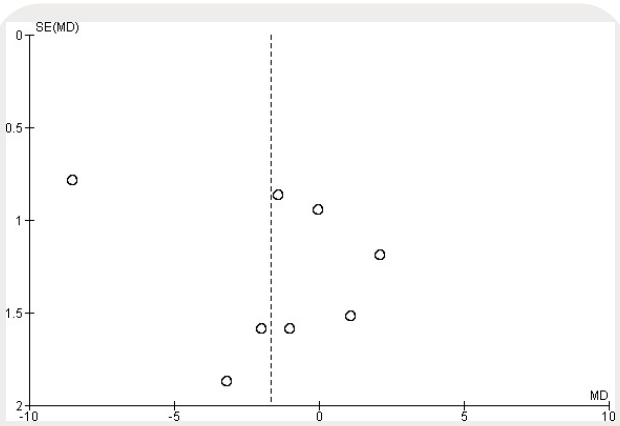

Fig. 6. Funnel plot showing no publication bias in diastolic blood pressure.

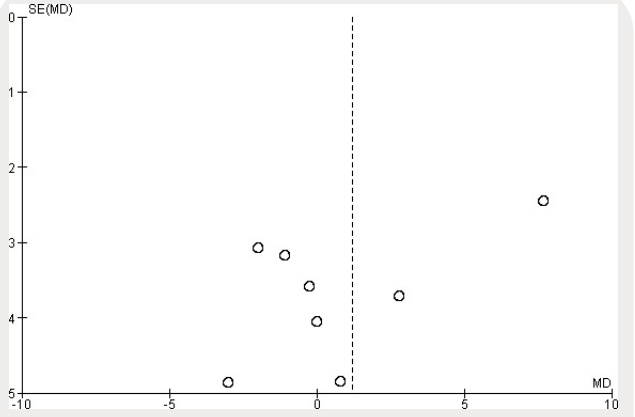

Fig. 8. Funnel plot showing no publication bias in heart rate.

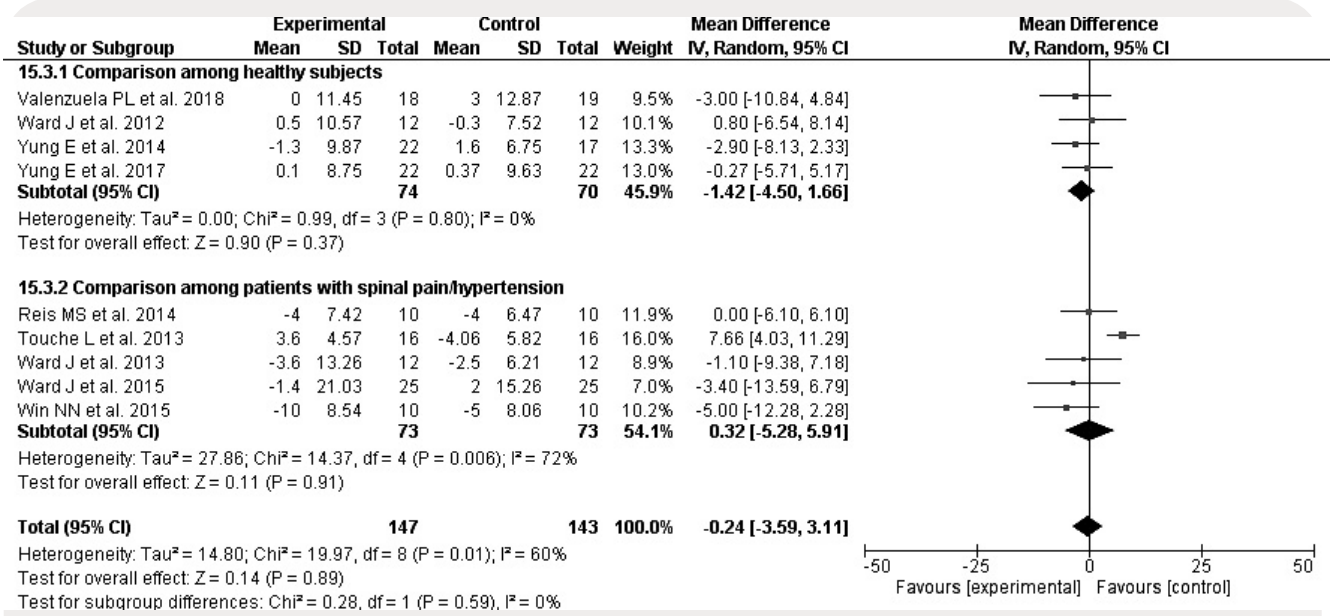

Fig. 7. Comparison of heart rate using forest plot and subgroup analysis.

DBP and HR. But exclusion of one study has reduced the heterogeneity to 0% for HR. However, the result was statistically non-significant. (*Fig. S1 available as supplementary material* 2). Further, the sensitivity analysis was also done by omitting short duration studies. This revealed that diastolic blood pressure reduced significantly in experimental group as compared to control/placebo group (*Fig. S2 as supplementary material* 3) for long duration studies with (MD = −0.94, 95% CI = −1.85, −0.03; $p = 0.04$). Exclusion of one study with maximum weight and another with smallest duration has reduced the heterogeneity to 0% and result was still significant for SBP. (*Fig. S3 available as supplementary material* 4).

Discussion

Spinal pain and malalignment mainly occur due to structure deterioration, altered biomechanics and abnormal posture.[7] Workplace physical and psychosocial factors, emotional problems, smoking, poor job satisfaction, awkward posture and poor work environment can be the possible risk factors for spinal pain and malalignment.[6] This leads to various musculoskeletal, psychosomatic, cardiovascular and respiratory dysfunctions which affect

the functional capacity of the patient as well as quality of life.[7,8,10]

In this meta-analysis, spinal manipulation and mobilization resulted in statistically significant reduction in SBP. Therefore, it can be used as an adjuvant therapy for the management of hypertension. These findings are supported by many previously published researches.[11,13–18,21–23,26,28] However, some of the previous researches are contradictory to our results.[12,19,20,24,25] Further, this meta-analysis also showed a statistically non-significant change in DBP and HR.

Sensitivity analysis was performed for diastolic blood pressure and heart rate. There was significant reduction in diastolic blood pressure after exclusion of short-term duration studies. Therefore, treatment duration and dosage may be attributed as an important factor. However, the results were statistically non-significant for HR.

Decrease in BP after application of spinal manipulative therapy and mobilization can be attributed to the influence on autonomic nervous system.[13,16] The physiological mechanism behind the reduction of blood pressure can be neural input of spinal mobilization via pontomedullary reticular formation (PMRF) and contralateral intromediolateral cell column (IML) which relaxes the whole vasculature.[27]

Changes in the cardiopulmonary parameters such as blood pressure, heart rate and respiratory rate may be due to stimulation of sympathetic fibers through spinal mobilizations and multi-system, centrally co-ordinated response.[3]

This meta-analysis and systematic review corroborates that spinal manipulations and mobilizations are effective in decreasing blood pressure. Manipulations and mobilizations may be helpful in managing hypertension and its associated complications.

Meta-analysis revealed that there were moderate amount of heterogeneity in case of systolic blood pressure and heart rate. There was a substantial heterogeneity in case of diastolic blood pressure. Sensitivity analysis was performed to see the various sources of heterogeneity. Heterogeneity was reduced after sensitivity analysis. This further increases the reliability of our results.

This systematic review and meta-analysis had a number of notable strengths. Firstly, as per our knowledge, it is the first review study that assessed the effect of spinal manipulation and mobilization on cardiovascular responses. Second, all included studies were of high quality and had low risk of bias. Third, we only included RCTs which are considered gold standard in experimental studies. Further, no publication bias was observed from funnel plots (Figs. 4, 6 and 8). Despite these strengths, this study had certain limitations. Although we have communicated the corresponding authors of many studies to retrieve the missing data, but we have to exclude seven studies because of insufficient data. Moreover, we did only two database searches. More database searches would have increased the number of studies. Inclusion of more good quality studies from other databases might have increased our sample size and possibly reduced heterogeneity of the data. Heterogeneity is high for diastolic blood pressure and moderate for systolic blood pressure and heart rate in our meta-analysis. Hence, the results would have been more conclusive without these limitations.

This systematic review and meta-analysis has a significant clinical implication. Spinal malalignments or spinal pain can be one of the most common causes of vertigo and secondary hypertension.[29] Hypertension is becoming a serious problem nowadays. The lifetime risk of developing hypertension is approximately 90%.[30] This may lead to serious complications such as coronary thrombosis, haemorrhage, stroke, heart attack, renal failure and so on. Patients with hypertension are prescribed antihypertensive drugs. There are a number of adverse effects of these antihypertensive drugs such as dizziness, hypotension, headache, flushing, nausea, peripheral edema, coughing, wheezing, pulmonary edema, acute lead to renal failure, dry cough, blurred vision, back pain, insomnia and many more. It may also produce muscle cramps and muscle weakness.[31]

Therefore, spinal manipulation and mobilization can be used as an adjuvant therapy in the treatment of patients suffering from hypertension with spinal malalignments. Manual therapy can reduce the drug dosage and dependency, thus preventing or decreasing drug-related adverse effects.

We have grouped together two different spinal manual therapy approaches that are spinal manipulations and mobilizations in our analysis. These techniques have different kinematics, biomechanics and mechanism of action. Therefore, the implications of our findings may not be ubiquitous. Results may vary depending on the type of technique and method of application. However, findings of the meta-analysis provide a preliminary

evidence to support that spinal manual therapy including spinal manipulations and mobilizations may have a significant influence on cardiovascular parameters.

Conclusion

Spinal manipulations and mobilizations showed significant reduction in SBP, but the heterogeneity was moderate. On sensitivity analysis, there was a significant decrease in both systolic as well as diastolic blood pressure and heterogeneity was also very low. Results were insignificant for heart rate. Therefore, within the limitations of the present systematic review and meta-analysis, it can be concluded that spinal manipulations and mobilizations may result in decrease of systolic as well as diastolic blood pressure. However, given the distinct kinematics, biomechanics and site of application of these techniques, more precise reviews can be performed to evaluate the efficacy of different types of manual therapy techniques applied at different regions of spine for progressing from generalized to specific conclusions.

Conflict of Interest

The authors report no conflict of interest.

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Author Contributions

Manoj Malik and Charu Gera contributed to study conceptualization and design, data extraction and drafting of submitted paper. Jaspreet Kaur and Minaxi Saini contributed to analysis and interpretation of data as well as critical revisions in draft for important intellectual content.

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Abdominal muscle activation: An EMG study of the Sahrmann five-level core stability test

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Background: Sahrmann five-level core stability test protocol has been used to evaluate the ability of the core muscles to stabilize the spine. However, validation studies on the Sahrmann protocol are limited.
Objective: The purpose of this study was to compare the different levels of Sahrmann five-level core stability (levels 1–5) on the muscle activity of rectus abdominis (RA), external oblique (EO), and transverse abdominis/internal oblique (TrA/IO).
Methods: Twenty-two asymptomatic male participants aged 21.36 ± 1.59 years were recruited. Participants were instructed to perform maximum voluntary contraction (MVC) and five levels of Sahrmann five-level core stability test guided with a pressure biofeedback unit (PBU). The surface electromyography (EMG) data of each muscle during five levels of Sahrmann five-level core stability test were normalized as a percentage of MVC.
Results: Results showed significant differences in the normalized EMGs of RA [$\chi^2(4) = 64.80$, $p < 0.001$], EO [$\chi^2(4) = 58.11$, $p < 0.001$], and TrA/IO [$\chi^2(4) = 56.00$, $p < 0.001$] between the five levels of Sahrmann five-level core stability test. Post-hoc analysis revealed Sahrmann levels 5 and 3 have significantly higher abdominal EMG signals than levels 4, 2, and 1 ($p < 0.001$).

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Conclusion: In conclusion, the Sahrmann five-level core stability test differs according to the level of Sahrmann tests. Significantly higher abdominal muscle activities were observed during levels 3 and 5. Therefore, the classification exchange in levels 3 and 4 of the Sahrmann five-level core stability test should be reconsidered in the future.

Keywords: Abdominal muscles; muscle activity; surface EMG; core stability.

Introduction

Core stability is defined as the "ability of the lumbopelvic-hip complex to return to equilibrium following a perturbation without buckling of the vertebral column".[1] There are 29 muscles attached to the lumbopelvic-hip complex.[2] The muscles which were frequently mentioned in previous researches are the multifidus, which stabilizes the vertebral joints on each segmental level, and the transverse abdominis (TrA), which stabilizes the spine through the increment of intra-abdominal pressure.[3] Other superficial trunk muscles that contribute to spinal stability include abdominal muscles [rectus abdominis (RA), abdominal internal oblique (IO), and abdominal external oblique (EO)] and paraspinal muscles (erector spinae and quadratus lumborum). According to Barr *et al.*,[3] these superficial muscles are activated to provide additional stability during direction and load-specific activity to prevent unwanted spinal displacement. It is highlighted that the entire core muscles have to be co-activated from all angles and directions to enable all layers of core muscles, deep and superficial to be physically bound together enhancing spinal stability and stiffness to a higher degree.[4]

Lower extremity movement protocol with pressure biofeedback transducer has been widely used by researchers to evaluate core stability performance.[5–7] One of the commonly used lower extremity movement protocols to measure core stability is the Sahrmann five-level core stability test protocol.[7] Sahrmann[8] initially suggested a lower abdominal muscle progression grading which consists of nine different lower extremity movement protocol maneuvers (nine-level ordinal scale, scored on a scale of 0.10–5.00). However, previous researchers have utilized a modified version which only adapted five maneuvers from the original Sahrmann protocol.[9–12] The Sahrmann five-level core stability test consists of five different leg lowering maneuvers (levels 1–5) that progressively increase in difficulty.[7] Details of the Sahrmann five-level core stability test was explained in Sec. 2.

Aggarwal *et al.*[9] have examined the relationship of commonly used core stability tests; Sorensen test, prone plank test, side plank test, abdominal fatigue test, and Sahrmann five-level core stability test. Aggarwal *et al.*[9] discovered that the Sahrmann's test performance was only significantly correlated with the performance of prone plank test ($Rho = 0.408$; $p = 0.009$). It was highlighted that the significant correlation of Sahrmann five-level core stability test with the prone plank test indicates that both tests specifically evaluated the core stability performance in the sagittal plane.[9]

Although the Sahrmann protocol may indirectly evaluate the ability of the core muscles to stabilize the spine, studies on validation of the Sahrmann protocol are limited.[7] Therefore, there is a need to validate the Sahrmann five-level core stability test by comparing the muscle recruitment pattern amongst the different levels/maneuvers of Sahrmann five-level core stability test particularly the maximum voluntary contraction percentage (MVC %) of RA, EO, and TrA/IO.

Materials and Methods

Participants

Twenty-two asymptomatic male students from the Sports Centre took part in this study. The mean ± standard deviation of the age was 21.36 ± 1.59 years, of their weight was 65.83 ± 8.37 kg, of their height was 1.71 ± 0.06 cm, of their waist circumference was 74.39 ± 5.23 cm, of their hip circumference was 92.80 ± 4.59 cm, of their body mass index was 22.59 ± 2.2 kg/m^2, and of their waist–hip ratio was 0.80 ± 0.03. The participants were screened using the self-reported Nordic musculoskeletal questionnaire (NMQ). Individuals were excluded if they are having acute low back pain (LBP) (<7 days of LBP) or chronic low back pain

(>12 months of LBP). Individuals with a waist circumference greater than 94 cm were also excluded to reduce surface electromyography (EMG) artifact due to adipose tissue.[13] The University Malaya Research Ethics Committee (UMREC) granted ethical approval for this study (Reference No. UM. TNC2/UMREC-338) and all participants provided written informed consent before their participation.

Data acquisition

The wireless Trigno™ system (Trigno, Delsys Inc., USA) was used to record and process the EMG signals of RA, EO, and TrA/IO. Surface electrodes were attached to the muscle fibers on the right-hand sides of the body based on the guidelines from the previous studies[14–18] (see Fig. 1): (1) RA: 3 cm lateral to the umbilicus, (2) EO: 15 cm lateral to the umbilicus, and (3) TrA/IO: midway between the anterior iliac spine and symphysis pubis, above the inguinal ligament.

The raw EMG signals from the three muscle sites were amplified (common-mode rejection ratio (CMMR) of 130 dB, input impedance of 20,000 kΩ) using a differential amplifier (Trigno Wireless System, Delsys Inc., Boston, USA) and filtered using a Butterworth band-pass filter of bandwidth between 20 Hz and 450 Hz. The signals were converted from analog to digital at a sampling rate of 2,000 Hz for data processing and analysis (EMGworks 3.0, Delsys Analysis Software, Boston, USA). In order to minimize specific interfering frequency (i.e., electrical and radio frequencies), the EMG data acquisition was conducted in a controlled and contained laboratory.

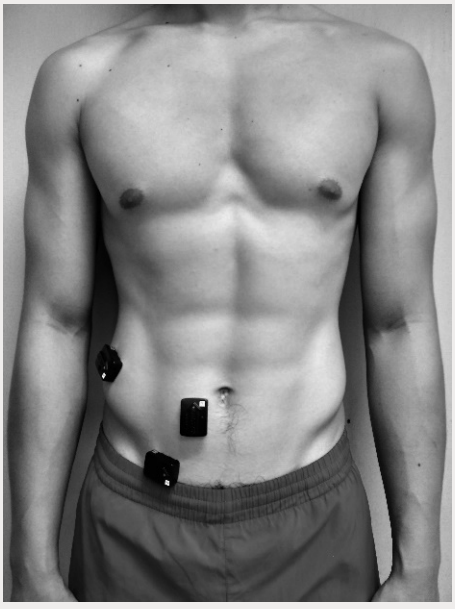

Fig. 1. Experimental setup for surface EMG: RA, EO, and TrA/IO.

Normalization exercises

To standardize the action potential of each of the three abdominal muscles, all participants performed three MVCs against manual resistance as suggested by Vera-Garcia *et al.*[19] The following are the MVC maneuvers for respective abdominal muscles:

(1) Rectus abdominis: Participants were in a sit-up posture positioned on a bench with the knees bent. They then attempted to flex the upper trunk in the sagittal plane while their thorax was manually braced by the experimenter.
(2) External oblique: Participants attempted to side bend the upper trunk in the frontal plane while they were in a side-lying position, with the knees bent, and thorax and arms were manually braced by the experimenter.
(3) Transverse abdominis/internal oblique: Participants maintained a right-side bridge position while a maximally resisted downward pressure on the pelvis was applied by the experimenter.

During the MVC testing, the participants were instructed to avoid any jerky contractions to decrease the chance of injury. To prevent muscle fatigue while the MVC was measured, each maneuver was performed in a random order, with each being held for 5 s and repeated twice with a 2-min rest between trials to prevent muscle fatigue.[13]

Sahrmann five-level core stability test

All participants were trained to perform the five levels of the standard protocol of the Sahrmann five-level core stability test as suggested by Aggarwal *et al.*[9] correctly before the measurement as described below. Each participant completed three trials at each of the five levels, with at least a 1-min rest between trials.

The inflatable pad of a stabilizer pressure biofeedback unit (PBU) (Chattanooga Group,

Inc., Hixson, TN) was placed under the lumbar spine at approximately L4–L5. While the participant was lying in a crook-supine position, the PBU was inflated to 40 mmHg. Participants were told to perform the Sahrmann five-level test while drawing-in their abdomen to avoid pressure deviation of more than 10 mmHg. A deviation of pressure more than 10 mmHg indicates that the stabilization action of stabilizer muscle has been lost.[9,10] After the familiarization phase, the participants performed random orders of Sahrmann five-level core stability test with abdominal muscle EMG testing and utilizing the PBU as their biofeedback. Participants were given a 2-min rest in between two test levels to reduce muscle post-activation potential carryover effects. Participants performed three trials for each level with at 1-min rest between trials. The average percentages of MVC derived from the three trials of each level were used in data analysis.

The five levels of Sahrmann test are described in Table 1 and illustrated in Fig. 2.

Data processing

The EMG signals generated during both MVCs testing and Sahrmann five-level core stability testing were analyzed and filtered using root-mean-square (RMS) technique (EMGworks 3.0, Delsys Analysis Software, Boston, USA). The MVC for each muscle was determined by calculating the peak EMG signal throughout the 5-s period of MVC. The starting and end of each EMG signal of the Sahrmann test were manually determined by assessing the muscle activities at baseline (rest periods), during the test, and at the end when the muscle activity returned to baseline.[20] Lastly, the EMG activity during Sahrmann five-level core stability test was normalized by the MVCs for each muscle.

Statistical analysis

Statistical analysis was carried out using IBM SPSS Statistics for Windows, version 25.0 (IBM, Armonk, NY). The normality of data was tested using the Shapiro–Wilk test. Categorical and continuous data were then analyzed using the most appropriate statistical tests based on data distribution. The Friedman two-way analysis of variance (ANOVA) by ranks was performed to test for the differences in EMG activities. Where a significant difference emerged, a multiple comparison procedure with the Wilcoxon signed-ranked test was used to test which pairwise differences were significant. A Bonferroni-adjusted alpha level was used to safeguard for the Type-1 error to be accepted as significant. The significance value for all was set at $p < 0.05$.

Sample size calculation

An *a priori* analysis was conducted for sample size calculation of repeated-measures ANOVA (within factors) using G∗Power for Windows, version 3.1.7.[21] The effect size from past-related used was from Ref. 22. The power analysis showed that F-test with an effect size of 0.328, alpha and statistical power equal to 0.05 and 0.95, respectively, with one group and five repeated measures yielded a sample size of 19 participants with an actual power of 0.96. A 15% sample size calculation adjustment for non-parametric Friedman test was added for the final sample size of this study to become 22 participants.[23]

Table 1. Five progressive levels of Sahrmann five-level core stability test.[9]

Level	Description
Level 1	The participant slowly raised one leg to a position of approximately 90° hip flexion with 90° knee flexion. The participant then attempted to bring the opposite leg also to the same position in the same manner.
Level 2	From the final position of the previous level, the participant slowly lowered one leg such that the heel contacted the ground/plinth. Then the leg slid out to fully extend the knee.
Level 3	From the end position of level 1, the participant slowly lowered one leg such that the heel reached approximate 12 cm above the ground. Then the leg slid out to fully extend the knee.
Level 4	From the final position of level 1, the participant slowly lowered both legs together such that the heels contacted the plinth. Then the legs slid out to fully extend the knees.
Level 5	From the final position of level 1, the participant slowly lowered both legs simultaneously such that the heels reached 12 cm above the ground. The legs then slid out to fully extend the knees.

Fig. 2. Illustration of the five levels of Sahrmann five-level core stability test.

Results

Comparison of EMG activity within five levels of Sahrmann five-level core stability test

Table 2 summarizes the data for the electromyographic activities of three abdominal muscles (MVC %) during the Sahrmann five-level core stability test. Statistically significant differences in the normalized EMGs of RA [$\chi^2(4) = 64.80, p < 0.001$], EO [$\chi^2(4) = 58.11, p < 0.001$], and TrA/IO [$\chi^2(4) = 56.00, p < 0.001$] were observed between the five levels of Sahrmann five-level core stability test.

Post-hoc analysis using the Wilcoxon signed-rank tests with Bonferroni correction revealed that Sahrmann level-5 test elicits significantly greater EMG signals from all three abdominal muscles as compared to levels 1, 2, and 4 ($p < 0.001$). No significant difference in all three abdominal muscle EMG signals was noted between Sahrmann levels 3 and 5. Sahrmann level-3 test yields significantly higher RA and TrA/IO muscle EMG signals compared to Sahrmann levels 1, 2, and 4. Sahrmann level-3 test demonstrated significantly higher EO muscle EMG signal than Sahrmann levels 1 and 4. No difference was noted in the EO muscle EMG signals between Sahrmann levels 3 and 2. The graphical representations of RA, EO, and TrA/IO muscle EMG signals are shown in Figs. 3(a)–3(c).

Table 2. Descriptive statistics of electromyographic activities of three abdominal muscles (MVC %) during Sahrmann five-level core stability test ($N = 22$).

		Abdominal muscle activity (MVC %)		
Sahrmann	Muscles	Q1	Median	Q3
Level 1	RA	11.30	13.49	21.63
	EO	8.95	14.87	20.35
	TrA/IO	9.28	12.74	23.58
Level 2	RA	12.01	17.20	26.25
	EO	13.04	18.78	23.56
	TrA/IO	11.97	14.81	21.85
Level 3	RA	20.97	26.40	38.84
	EO	14.37	25.47	33.55
	TrA/IO	15.05	25.15	39.95
Level 4	RA	11.62	18.19	27.08
	EO	11.37	17.56	22.53
	TrA/IO	11.68	14.93	22.57
Level 5	RA	24.96	35.69	45.90
	EO	20.33	27.46	37.54
	TrA/IO	17.50	27.24	41.41

Note: RA: Rectus abdominis; EO: external oblique; TrA/IO: transversus abdominis/internal abdominal oblique; and MVC: maximum voluntary contraction.

Comparison of EMG activity within muscles

This study also compared EMG activities within abdominal muscles (RA, EO, and TrA/IO) during each level of Sahrmann five-level core stability tests. No significant difference was found between RA, EO, and TrA/IO EMG activities during each level of Sahrmann five-level core stability test ($p > 0.05$).

Discussion

The purpose of this study was to evaluate the abdominal muscle activity (RA, EO, and TrA/IO) during different levels/maneuvers of Sahrmann five-level core stability test. The Sahrmann five-level core stability test was assumed to evaluate the abdominal muscle function as they act by isometrically contracting into flexion to maintain lumbar spine flexion by posteriorly tilting the pelvis against an assumed increasing resistance. The abdominal muscle activity levels are supposed to increase from Sahrmann levels 1 to 5.

The results of this study suggest that the abdominal muscle activity varies between the five different maneuvers of Sahrmann core stability test, with the highest abdominal muscle activities recorded during level 5, followed by level 3, level 4, level 2, and level 1. To our best knowledge, this is one of the few studies which explore abdominal muscle activity during non-heel contact and heel contact during leg lowering maneuvers. This study showed that the abdominal muscle activity was higher when heels do not contact the ground as noted in levels 3 and 5. A similar study by Gilleard and Brown[24] showed that thigh unsupported leg lowering yields greater abdominal muscle activity than thigh supported with hands leg lowering. This shows less recruitment of abdominal muscles may be needed during supported lowering (levels 2 and 4) as compared to unsupported lowering (levels 3 and 5) because participants may have utilized the lower limb muscles to support the abdominal muscles to maintain the neutral lumbar curvature.

Our study also reveals similar abdominal muscle synergy pattern in unilateral leg lowering (level 3) and bilateral leg lowering (level 5). Our findings in this study are supported by those of Richardson *et al.*[25] who also reported no significant difference in abdominal muscle activity between pelvic tilt with unilateral leg lowering and pelvic tilt with bilateral leg lowering. However, this study contradicts with the findings from Ref. 24 which observed lower RA activity but higher IO and EO muscle activities in bilateral leg lowering as compared to unilateral leg lowering. Shields and Heiss[26] proposed two muscle synergy patterns during bilateral leg lowering. The first pattern included high RA, high EO, and low IO muscle activations, while the second pattern includes low RA, high EO, and low IO muscle activations. The Sahrmann level-5 bilateral leg lowering test differs from the conventional leg lowering test as the leg lowering maneuvers are started from 90° hip and knee flexion compared to conventional leg lowering test which started in a 90° hip flexion with knees extended, therefore different muscle synergy patterns may occur. During conventional leg lowering, when legs are lowered from a vertical position to a horizontal position, high external torque is created by the mass of the limbs (about 30% of the body weight) resulting in a great challenge to the abdominal muscles.[22,27]

This study has several limitations that needed to be addressed. First, the cross-talks between surface electrodes are minimized in this study by using standardized surface EMG electrode

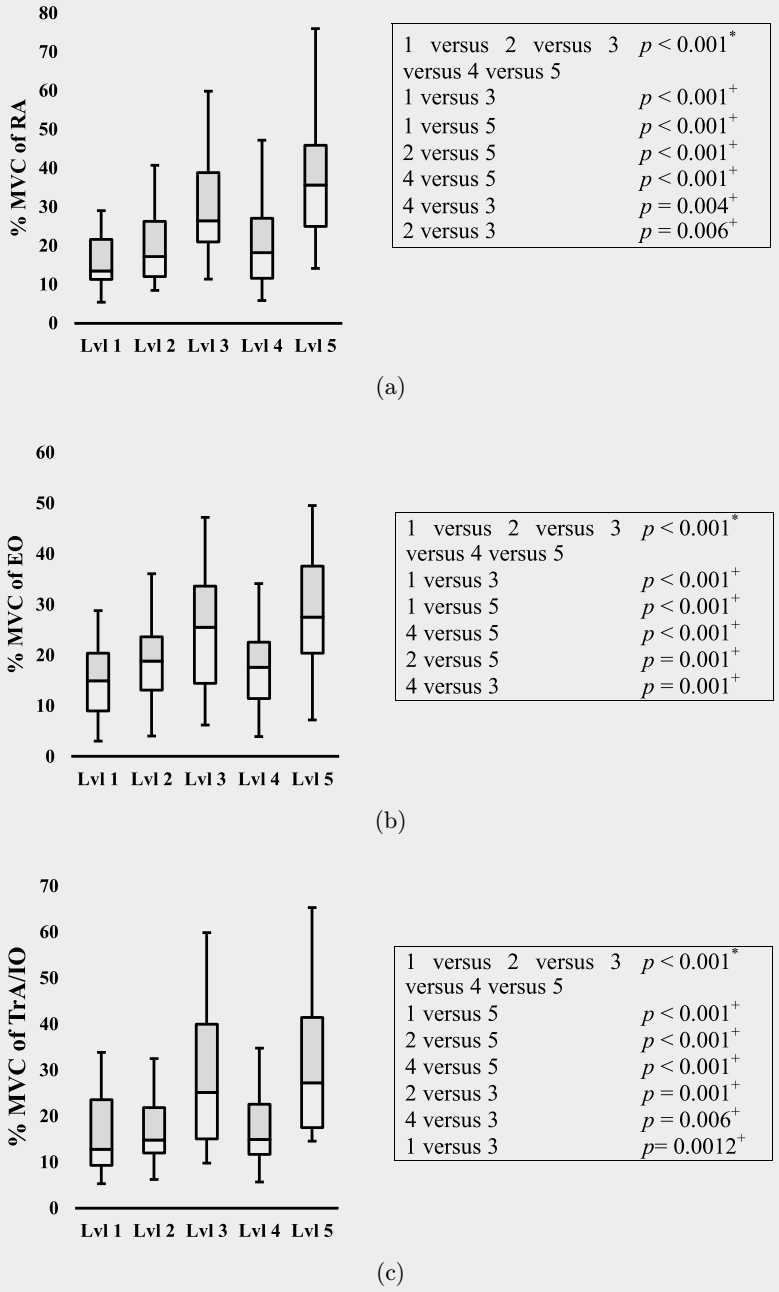

Fig. 3. (a) Boxplot for MVC % of RA muscle between level (Lvl) 1 and level 5 of Sahrmann five-level core stability test; *Friedman test and +Wilcoxon signed-rank tests with Bonferroni correction. (b) Boxplot for MVC % of EO muscle between Lvl 1 and Lvl 5 of Sahrmann five-level core stability test; *Friedman test and +Wilcoxon signed-rank tests with Bonferroni correction. (c) Boxplot for MVC % of TrA/IO muscle between Lvl 1 and Lvl 5 of Sahrmann five-level core stability test; *Friedman test and +Wilcoxon signed-rank tests with Bonferroni correction.

position as described by previous researchers.[14–18] McGill *et al.*[15] proposed the location of surface TrA/IO electrodes which accurately reflects the muscle activity of deep abdominals. However, the TrA/IO electrodes are still susceptible to cross-talk as they lie underneath superficial muscles.[20] Furthermore, the recorded EMG signal from the TrA/IO electrode would come largely from IO rather than TrA because IO is more superficial than the TrA.[28] Second, all participants in this study were healthy young men. The abdominal muscle activity pattern may differ between gender and among individuals with musculoskeletal conditions. Previous studies have reported significantly

higher RA and EO muscle activities among women compared to their male counterparts.[29] Additionally, higher RA and EO with lower IO muscle activities were reported among patients with low back pain compared to healthy individuals.[30] Further exploration of abdominal muscle activity pattern during the Sahrmann core stability test among women and individuals with musculoskeletal conditions is warranted. Recommendations for future research include: (1) examining the abdominal muscle activity pattern of Sahrmann five-level core stability test in different populations, i.e., females and individuals with musculoskeletal conditions; and (2) investigating the effects of adding upper limb movements during performing Sahrmann five-level core stability test.

Conclusion

To our best knowledge, this is one of the few studies which investigated the Sahrmann five-level core stability test on abdominal muscle activity. The results of this study showed that the abdominal muscle responds differently in supported (levels 2 and 4) or unsupported (levels 3 and 5) positions. Therefore, consideration should be taken in the future for the classification exchange in levels 3 and 4 of the Sahrmann five-level core stability test. Correspondingly, classification of the Sahrmann five-level core stability test into two smaller subcategories can also be considered, i.e., Poor (levels 1, 2, and 4) and Good (levels 3 and 5). As all the abdominal muscle sites were recruited below 40% of maximal isometric contraction, endurance benefit could be obtained with an appropriate number of repetitions. This may indicate that the Sahrmann five-level core stability test can be used as a screening tool and an abdominal endurance training regime.

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Conflict of Interest

The author(s) have no conflicts of interest relevant to this paper.

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Author Contributions

The concept and designing of paper was carried out by all authors. Ebby Waqqash Mohamad Chan prepared the manuscript along with data collection and analysis. Eliza Hafiz and Mohamad Shariff A. Hamid helped in research design planning, results validation and interpretation. Ali Md. Nadzalan helped in data collection and research team training.

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Effectiveness of hamstring stretching using a pressure biofeedback unit for 4 weeks: A randomized controlled trial

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Background: Stretching and length test of hamstring muscles have been performed commonly to manage lower back pain (LBP) in sports rehabilitation. Previous literatures addressed that stretching techniques and length test of hamstring muscles should be performed with the pelvic maintained in an anterior tilt position. However, there is no study to determine the effectiveness of pressure biofeedback unit (PBU) to maintain in anterior pelvic tilting (APT) on length test and stretching of hamstring muscles.
Objective: To determine the effectiveness of hamstring muscles stretching using a PBU.
Methods: Forty participants with shortness of hamstrings randomized into two groups. Participants performed the active knee extension (AKE) stretching without (control group) or with PBU (intervention group) for four weeks. AKE tests without and with PBU were administered three times before and after hamstrings stretching by each group.

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Results: The AKE test without PBU showed a significant main effect of time ($p < 0.01$) but not of group ($p = 0.55$) on the AKE angle. The AKE test with PBU showed a significant increase in the AKE angle in the post-intervention compared to the pre-intervention assessments in both groups ($p < 0.01$). The difference of AKE angle between the pre- and post-intervention results was significantly greater in the intervention group than in the control group ($p < 0.01$).
Conclusion: We recommend the use of a PBU to maintain the pelvic anterior tilting position when performing the AKE test or AKE stretching.

Keywords: Stretching; hamstrings; pressure biofeedback unit; active knee extension test.

Introduction

A short hamstring is a common risk factor for lower back pain (LBP).[1–4] Because hamstrings cross the hip, attaching proximally to the ischial tuberosity, the shortness of the hamstring muscles influences the pelvis posture.[5] Indeed, a short hamstring may limit hip flexion, leading to compensation by tilting the pelvis in a posterior direction, which causes excessive lumbar motion during dynamic activities such as forward bending, consequently induces the LBP.[6,7] Thus, lengthening the hamstrings may allow for greater motion in the hips and change the lumbopelvic rhythm to reduce the load on the lumbar spine.

In clinical and sports-related settings, many stretching techniques, such as static stretching, ballistic stretching, and proprioceptive neuromuscular facilitation (PNF) techniques are commonly used to improve the flexibility of the hamstring muscles in patients with LBP.[8–11] PNF stretching uses the theories of autogenic and reciprocal inhibition to "relax" the muscle before the stretch. The hamstrings anatomically originate at the ischial tuberosity and is then inserted into the proximal tibial and fibular head.[12,13] Because of this proximal attachment, a posterior pelvic tilt (PPT) can be used during stretching to compensate for a short hamstring.[14] Then, it is also important to stabilize the pelvis not to increase the load of lumbar spine during stretching regardless of the stretching technique applied.

Previous researches suggested that stretching techniques for the hamstring muscles should be performed not to tilt the pelvis posteriorly.[15,16] Sullivan *et al.* reported that although there was no significant difference in hamstrings flexibility between static and PNF stretching groups, the anterior pelvic tilting (APT) group was significantly more effective in increasing the length of their hamstring muscles than the PPT group.[16] Then, they suggested that the APT position had a more pronounced influence than the stretching technique on the increase in the flexibility of the hamstring muscles. In this experiment, verbal instructions were provided and all stretching sessions were performed under direct supervision to maintain the pelvic tilting posture of each group. To control lumbopelvic motion during lower limb movements, clinicians commonly use several feedback tools such as tactile feedback involving touch, verbal corrections, visual feedback, and a pressure biofeedback unit (PBU).[17] PBUs have used in clinical practice for self-monitoring lumbopelvic movement during lower limb movements. However, although many studies have demonstrated the effectiveness of a PBU for specific muscle contraction or lumbopelvic stabilization exercises, no study has investigated the effectiveness of this device for maintaining the APT position during hamstrings stretching.

Also, the pelvic position should be considered when measuring the length of the hamstring muscles. Herrington assessed the effect of the two extreme pelvic positions (maximal APT and PPT using a PBU) on the active knee extension (AKE) angle during an AKE test.[6] The results showed that the AKE angle in the PPT position was significantly greater than that in the APT position. However, no study has assessed the length test of hamstrings with APT position using the PBU after hamstrings stretching. In this study, AKE test with PBU was performed using the PBU for maintaining the anterior pelvic tilt position. Therefore, the purpose of this study was to compare the lengths of the hamstring muscles in AKE

test without and with PBU between control (AKE stretching without PBU) and intervention (AKE stretching with PBU) groups in participants with short hamstrings.

Methods

A repeated-measures, single-blinded randomized study was conducted to determine the effect of AKE stretching with PBU on the length of hamstring muscles through the AKE test. This study was reported according to the CONSORT 2010 checklist. The purpose and protocol of this study were explained to each participant, and a signed informed consent form was obtained prior to participation. This study was approved by the Institute Review Board (IRB) of 0000000 University (JIRB-2016082401-02-160908).

Participants

Sixty individuals volunteered to participate in this study. Forty-eight volunteers with hamstrings shorter than 70° bilaterally, as measured by the AKE test, met criteria for participation and began the study.[6] Previous studies reported significant changes between group in length of hamstrings with sample sizes of 20 or less in each group.[18–20] Based on the previous studies, a sample size of 20 in each group will yield adequate power. To allow for possible dropout, 24 participants were assigned for each group. Forty (20 males, 20 females) participants completed the study, and eight participants did not, due to pain or discomfort during stretching (Fig. 1). The following exclusion criteria were applied: (1) current or recent (last 3 months) LBP (2) history of lower limb pain or previous hamstrings injury or (3) current or recent (last 3 months) participation in a specific program designed to lengthen the hamstrings.

Each participant was randomly assigned to one of the two groups: hamstrings stretching without a PBU (control group: age 22.5 ± 3.4 years, height 168.6 ± 7.9 cm, weight 64.3 ± 10.4 kg) and with a PBU (intervention group: age 26.7 ± 3.6 years, height 168.9 ± 7.6 cm, weight 62.4 ± 9.6 kg). A randomized allocation list was created with a random number generator using eight blocks of six participants by a non-involved person. Allocations were sequentially numbered and placed in opaque envelopes to ensure concealed allocation. After participant enrollment was completed, the envelope was opened by the physical therapist. Participants were blinded to avoid watching the other stretching program.

Instrumentations

The AKE test was used to determine the length of the hamstring muscles using an electrical inclinometer (Dualer IQ, J-Tech Medical, Midvale, UT, USA) as this test showed high reliability in some previous researches.[21–23] A PBU (Chattanooga Group, Inc, Hixson, TN, USA) was used to maintain the anterior pelvic tilt position during AKE test or stretching, by monitoring the pressure of airbag. In this study, the AKE test was performed without and with PBU both before and after the intervention.

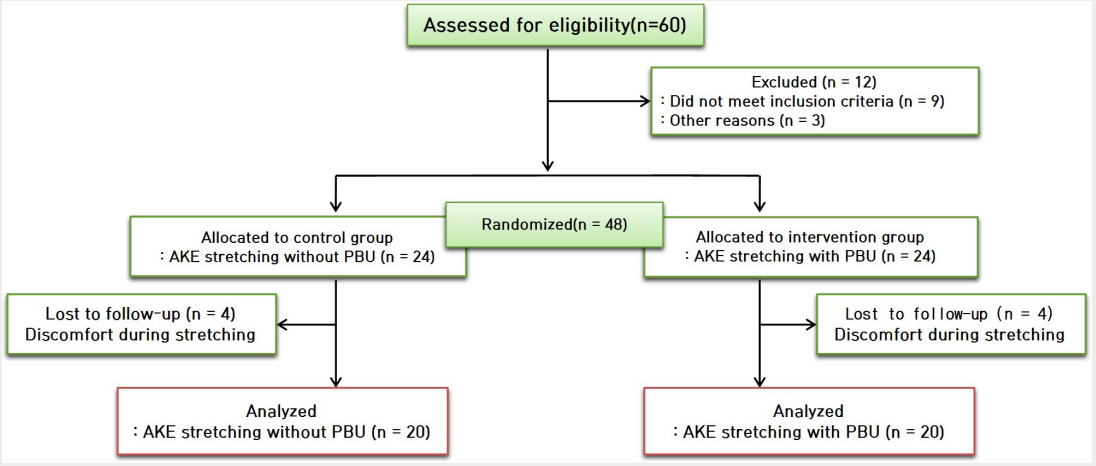


Fig. 1. CONSORT flow diagram.

Outcome measures

Both experimenters were physical therapists. An experimenter trained and supervised the participants, who had nine years of experience in orthopedic physical therapy and had used to asses lumbopelvic movement during the lower limb movement test using a PBU. Another experimenter recorded the AKE angle while performing the AKE test, who was blinded to group allocation of participants. Data collection took place at research laboratory of university and private physiotherapy clinic from January to April 2017.

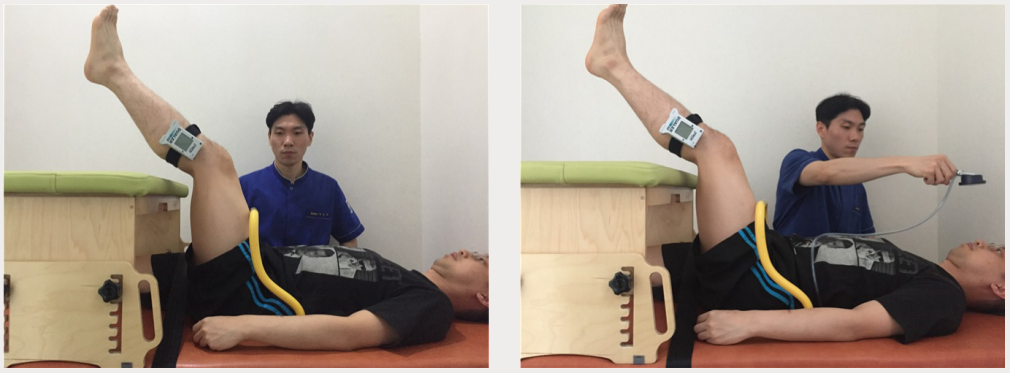
Measurements were taken with participants in a supine position on a standard treatment table with their hip and knee flexed at 90° and their anterior thigh touching the cross-bar to maintain the flexed hip. For comfort, participants placed their left leg on a wooden table to maintain the flexion in the knee at 90° before measurement. The inclinometer was attached below the fibular head by a strap. The 90° knee flexion in horizontal position was reset as 0° at the starting position (Fig. 2). Participants kept their feet relaxed without ankle dorsiflexion during the AKE test. To perform the AKE test without PBU, participants were instructed to extend their leg as much as possible, regardless of pelvic movement, while keeping their thigh against the bar; the end position was then held for 5 s. During the hold time, an experimenter recorded the AKE angle (Fig. 2(a)).

To perform the AKE test with PBU, an airbag of PBU was placed under the lumbar spine (L1–S1) centered at L3 spinous process above L4, which was palpated in middle from tops of left and right iliac crests. Each participant was asked to maximally anterior tilt the pelvis with their left hip and knee flexed at 90° and straightened right leg, "Hollow the lower back off the table as much as possible and hold it." Then the airbag was inflated to a base pressure of 40 mmHg until it filled the available lordotic space.[17] Keeping the hip bent and the pelvic anterior tilting (no pressure change), the participants actively extended the testing leg as far as possible while keeping their thigh against the bar; the end position was then held for 5 s. During the hold time, an experimenter recorded the AKE angle (Fig. 2(b)).

If the participant moved away from the bar, he/she was instructed to flex the knee until his/her thigh touched the bar again, and the AKE angle was determined. To eliminate the stretch effect, the participants rested for 5 min between AKE tests without and with PBU. The order of testing was carried out in block fashion with even-numbered participants starting the AKE test without PBU and odd-numbered participants the AKE test with PBU. The AKE tests without and with PBU were administered three times in each group before and after four weeks of the study period.

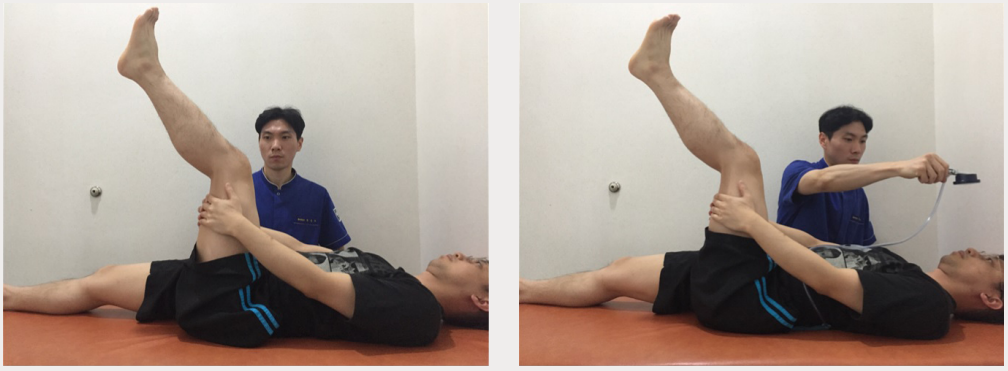
Interventions

Participants assumed a supine position to perform the static AKE stretching to increase the flexibility of their hamstring muscles (Fig. 3). All participants actively stretched five days per week for four weeks while they were supervised by a physical therapist trained to stretch the hamstring muscles using a PBU. Each group stretched for a total of 100 s in each session and held the stretch for 10 s, for 10 repetitions, with a 10 s rest between sets. The training session lasted approximately 4 min.



(a) (b)

Fig. 2. AKE test without PBU (a) and with PBU (b).



(a) (b)

Fig. 3. AKE stretching without PBU (a) and with PBU (b).

Participants in the control group (AKE stretching without PBU) assumed a supine position with their hip and knee in 90–90 degrees of flexion and their foot in a relaxed position as the starting position; they then slowly extended their knee until maximum resistance was encountered. During the relaxation periods, participants were returned to the starting position. The physical therapist ensured that the stretch did not cause any pain (Fig. 3(a)).

In intervention group (AKE stretching with PBU), prior to stretching, the airbag of the PBU was placed under the lumbar spine of participants in supine position with their hip and knee in 90–90 degrees of flexion. As mentioned in outcome measure section, the airbag was then inflated to 40 mmHg in maximal anterior pelvic tilting, and participants slowly extended their knee until maximum resistance was encountered. During the stretching maneuvers, the participants were asked to maintain the pressure at 40 mmHg by viewing the pressure gage (Fig. 3(b)). On the first day of the experiment, participants in each group were familiarized with AKE stretching without or with PBU for approximately 5 min. We asked participants to complete a weekly log of the adherence to the stretching intervention.

Statistical analysis

Independent-sample t tests were used to compare the baseline of AKE angles between the control and intervention groups. Intra-class correlation coefficients (ICCs) were used to determine the intra-rater reliability for AKE tests without and with PBU using an electronic inclinometer. The $ICC_{3,1}$ model was computed to test the intra-rater reliability from the three repeated measurements of the AKE angle of AKE tests without and with PBU for all the participants at baseline before the intervention.

We used the averaged data from three repeated measurements of the AKE angle made by the AKE tests without and with PBU before and after the interventions. A two-way mixed-model analysis of variance (ANOVA) was used to determine the effect of time and group on the AKE angle in the AKE tests without and with PBU. When a significant time by group interaction was found, *post hoc* paired t tests were performed. Independent-sample t tests were used to compare the mean differences in the AKE angles of the control and intervention groups. To reduce the type I error rate, statistical significance for the *post hoc* paired t tests was set at $\alpha = 0.01$. SPSS Ver. 15.0 for Windows (SPSS, Inc., Chicago, IL, USA) was used for data analysis.

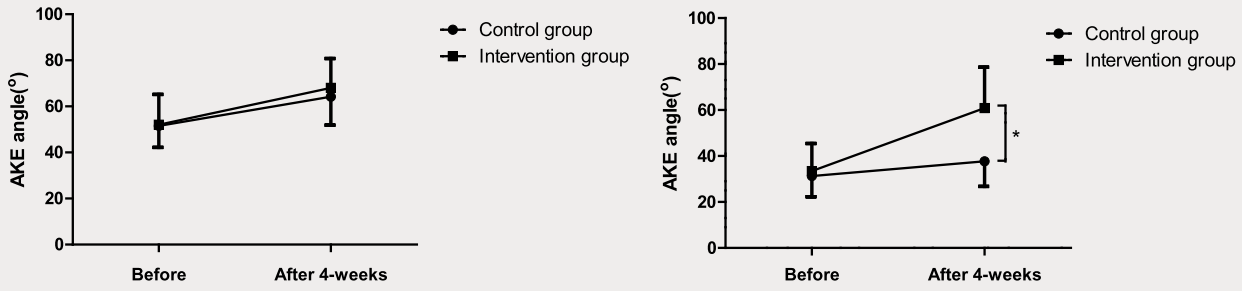
Results

The control and intervention group did not differ significantly in baseline of the AKE angle in the AKE tests without and with PBU ($p > 0.05$). We found good intra-rater reliability for the AKE angle (AKE test without PBU: $ICC_{3,1} = 0.97$, 95% CI: 0.95–0.98; AKE test with PBU: $ICC_{3,1} = 0.96$, 95% CI: 0.93–0.98). The two-way mixed ANOVA showed a significant main effect of time in the AKE test without PBU ($F_{1,38} = 196.5$, $p < 0.01$); however, there was no significant main effect of group ($F_{1,38} = 0.4$, $p = 0.55$) on the AKE angle (Table 1) (Fig. 4).

Table 1. AKE angle of AKE test without PBU variations of Groups and Time.

Group	Intervention		Within-group difference[b] (95%CI)	Between-group difference (95%CI)	p*
	Before	After 4-weeks			
Control	51.56 ± 9.40[a]	64.21 ± 12.32	12.65 (11.55–14.94)	3.27 (0.86–7.40)	0.117
Intervention	52.12 ± 13.22	68.04 ± 12.74	15.92 (3.66–19.51)		

Notes: [a]Mean ± SD; [b]Within-group differences are calculated by subtracting value in post-intervention from value in post-intervention. *The p value refers to the between-group difference in angle of AKE between control and intervention groups.



(a) AKE test without PBU (b) AKE test with PBU

Note: *$p < 0.01$ significance of difference in the pre- and post-intervention measurements between control and intervention groups.

Fig. 4. AKE angles in AKE tests without (a) and with PBU (b) before and after interventions.

In the AKE test with PBU, significant time by group interactions was found for the AKE angle ($F_{1,38} = 57.7$, $p < 0.01$). The results of the *post hoc* paired t test showed that the post-intervention AKE angle was significantly increased compared to that of the pre-intervention angle in the control (difference: 6.4°, 95% CI: 3.7–9.2°, $p < 0.01$) and intervention (difference: 27.4°, 95% CI: 22.3–32.5°, $p < 0.01$) groups (Table 2) (Fig. 4). An independent t test indicated that the difference between the pre- and post-intervention measurements was significantly greater in the intervention group than in the control group (between-group difference = 21.0°, $p < 0.01$) (Table 2).

Discussion

In this study, we performed the AKE test to assess the length of the hamstring muscles. The intra-rater reliability for the measurement of the AKE angle was very good. Herrington reported that the mean difference in the AKE angle between the APT and PPT positions was 13.4° and noted that

Table 2. AKE angle of AKE test with PBU of Groups and Time.

Group	Intervention		Within-group difference[b] (95%CI)	Between-group difference (95%CI)	p*
	Before	After 4-weeks			
Control	31.26 ± 8.95[a]	37.68 ± 10.91	6.42.(3.66–9.18)	21.00 (15.34–26.59)	0.000
Intervention	33.49 ± 12.21	60.90 ± 17.70	27.42(22.33–32.50)		

Notes: [a]Mean ± SD; [b]Within-group differences are calculated by subtracting value in post-intervention from value in post-intervention; *The p value refers to the between-group difference in angle of AKE between control and intervention groups.

the position of the pelvis should be taken into consideration when measuring the length of the hamstrings because the length of this muscle influences the position of the pelvis.[6] Thus, after four weeks of hamstrings stretching, we initially employed the AKE test using a PBU to maintain the pelvic anterior tilting. Compared to the results of a previous study,[6] our data showed that the mean differences in the AKE angle between the AKE tests without and with PBU were 20.3° and 17.7° greater in the control group and intervention groups, respectively.[6] In a previous study, a PBU inflated slightly was placed under the lumbar spine in the presence of a maximum PPT in the 90° hip position.[6] Then, the knee was extended while the pressure gauge of the PBU was monitored to maintain the pressure. In contrast, the participants in our study were instructed to extend their leg as far as possible, regardless of their pelvic movement, during the AKE test without PBU. We inferred that the AKE angle in our study was greater than that in the previous study owing to greater compensatory PPT movement for a short hamstring during the AKE test without PBU.

In the AKE test with PBU, the AKE stretching using the PBU was more effective in increasing the AKE angle, as compared to the AKE stretching performed without a PBU (mean difference = 6.4°). However, this study also found no significant difference between the groups in the AKE angles in the AKE test without PBU (mean difference = 3.3°). These results indicate that the AKE test without PBU did not detect the different changes in the lengths of the hamstring muscles in the control and intervention groups after hamstrings stretching. Therefore, we recommend maintaining the pelvic anterior tilting position using a PBU when performing the AKE test or AKE stretching for length test and stretching of the hamstring muscles.

In the AKE test without PBU, the average AKE angle in the post-intervention assessment was significantly increased, by 12.7° in the control group and by 15.9° in the intervention group, compared to the comparable figures in the pre-intervention assessment. Four previous studies examining the effect of static hamstrings stretching using the AKE test without PBU reported improvements of 8.8°,[24] 9.1°,[25] 7.2°,[26] and 9.2°[16] in the AKE angle. Because both positions during the length test and the stretching maneuver were the same in our study, the increase in the AKE angle after AKE stretching would be expected to be greater in our study than in previous studies. Indeed, two previous studies confirmed the functional effect on hamstrings stretching. Yoon *et al.* reported that forward-bending using a stick was effective for preventing excessive lumbar flexion and more helpful for improving hip flexion than that without stick during forward bending.[27] However, Li *et al.* found no change in lumbar motion during forward bending after three weeks of AKE stretching.[28] Nonetheless, no study has compared functional movement patterns between the non-functional and functional stretching. Additional research is needed to compare the effect of AKE stretching and forward-bending stretching on forward-bending movement patterns.

Of the extant research, the study performed by Sullivan *et al.* is the one most similar to this work.[16] They reported that the mean difference of AKE angle was significantly greater in the APT group than the PPT group after two-week hamstrings stretching. However, in our study, there was no significant difference between the groups in the AKE angle of the AKE test without PBU. This inconsistency can be explained by differences in the stretching force used. In the previous study, participants stood facing a table with one heel resting on the edge of the table at approximately 90° of hip flexion; members of both groups were then instructed to anteriorly bend their trunk while maintaining the APT or PPT position. On the other hand, participants in our study were asked to assume a supine position and extend their leg with their hip in a 90° flexed position during AKE stretching. Although participants stretched until they perceived tightness but not pain in both the previous and our research, stretching in an open versus a closed kinetic chain are associated with different stretching forces. We inferred that the greater stretching force led to the greater difference in the lengths of the hamstrings between stretching in APT and PPT positions. Further research is needed to determine the effect of stretching force (open versus closed kinetic chain) combined with pelvic position (PPT versus APT) on flexibility of hamstring muscles.

In the control group, the difference in the AKE angle in the AKE tests without and with PBU was greater after, compared with before, stretching (before stretching: 20.0° versus after stretching: 26.5°). However, in the intervention group, the difference in the AKE angles between the AKE tests without and with PBU was smaller after than

before stretching (before stretching: 18.6° versus after stretching: 7.1°). These results reflect uncontrolled lumbopelvic movement as a result of the greater lumbar flexion and PPT movement during the conventional as opposed to during the AKE test with PBU in the control group. However, in the intervention group, the difference in the AKE angles between AKE tests without and with PBU was smaller, compared with before stretching (before stretching: 18.6° versus after stretching: 7.1°). This result reflects uncontrolled lumbopelvic movement as a result of the greater lumbar flexion and PPT movements during AKE test without PBU, as opposed to during AKE test with PBU in the control group. One possible explanation for this result is that an alternative movement strategy was employed during the AKE test without PBU, which was administered to the intervention group after the AKE stretching using the PBU. Park *et al.* reported that a group who engaged in active prone knee flexion with an abdominal drawing maneuver using a PBU showed a greater reduction in their compensatory pelvic motion and LBP symptoms than did a group who stretched their rectus femoris while standing.[29] Although we did not determine the difference in the lumbopelvic movement during the AKE tests without and with PBU, we would expect that less lumbar flexion and PPT would occur in the intervention group than control group, as a result of the altered movement pattern during the AKE test without PBU. Therefore, we postulated that AKE stretching using a PBU improved the flexibility of the hamstring muscles as well as the motor control involved in lumbopelvic stabilization.

This study has several limitations. First, although participants were blind to the experimental protocol, the investigator was aware of the identities of the control and intervention groups. The use of single blinding can lead to observation bias. Second, limitation is the lack of symptomatic individuals with LBP. Future studies should recruit patients with LBP to evaluate the effect of two different stretching approaches on the pain and function of patients. Third, we did not analyze the data using intention-to-treat. In our study, eight participants did not complete due to pain or discomfort during stretching and they were not included in data analysis. The on-protocol analysis will tend to bias results in favor of intervention effect, as those who succeed at intervention are most likely to stick with it. Finally, we did not determine the effect of a PBU on the maintenance of a pelvic position in other stretching positions. Thus, caution is needed when stretching a hamstring muscle using a PBU in either a sitting or a standing position.

Conclusion

The difference between the pre- and post-intervention results in the AKE test with PBU was significantly greater in the group performing AKE stretching with a PBU than in the group performing AKE stretching without a PBU. We recommend the use of a PBU to maintain the pelvic anterior tilting position when performing the AKE test or AKE stretching for length test and stretching of the hamstring muscles.

Conflict of Interest

The authors declare that there is no conflict of interest.

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Author Contributions

Jin-Oh Ahn and Do-young Jung were responsible for research conception and design of the study. Data collection and preparation for the first draft of the paper were carried by Jin-Oh Ahn and Do-young Jung. Analysis/interpretation of data, and critical revision of the paper for important intellectual content were contributed by Jonghyuck Weon and Eun-kyung Koh. All authors read and approved the final version of the paper.

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Immediate effects of muscle energy technique and stabilization exercise in patients with chronic low back pain with suspected facet joint origin: A pilot study

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Background: Facet joint is a potential structure to be the source of chronic low back pain (LBP) affecting lumbar motion, pain, and disability. Other than the recommended treatment of lumbar stabilization exercise (LSE), several manual procedures including muscle energy technique (MET) are commonly used in physical therapy clinic. However, little evidences of the effects of MET have been reported.
Objective: This study aimed to compare the immediate effects of MET and LSE in patients with chronic LBP with suspected facet joint origin.
Methods: Twenty-one patients with low back pain were recruited and randomly assigned to receive treatment either MET or LSE. The outcomes were kinematic changes, pain intensity, and disability level. Lumbar active range of motion (ROM) of flexion, extension, left and right lateral flexion, and left and right rotation were evaluated using the three-dimension motion analysis system at baseline and immediately after treatment. Pain intensity was evaluated using visual analogue scale (VAS) at baseline, immediately after, and two days after treatment. Thai version of the modified Oswestry disability questionnaire (ODQ) was utilized at baseline and two days after treatment. The mixed model analysis of variance was used to analyze all outcomes.
Results: The results showed that all outcomes were not different between groups after treatments. Although there were statistically significant improvements after the treatments when collapsing the groups, the minimal clinically important change was found only for pain but not for lumbar movements and disabilities scores.
Conclusion: The effect of MET and LSE alone in single session might not be intensive enough to improve movements and decrease disability in patients with chronic LBP with suspected facet joint origin.

Keywords: Chronic low back pain; facet joint; lumbar stabilization; muscle energy technique.

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Introduction

Facet joint has been implicated as the cause of chronic pain in the lower back due to the possible pathoanatomical mechanism.[1] The prevalence of facet joint pain was estimated as high as 75% among people reporting low back pain (LBP).[2] In a community-based survey, the prevalence of lumbar facet osteoarthritis reportedly increased with age i.e., 89.2% in persons age more than 60 years, although the association between LBP and osteoarthritis identified by computed tomography was not apparent.[3] The assumed characteristics of acute facet joint pain include local, unilateral, decreased motions in extension and rotation, occasionally pain extending to thigh, no neurologic signs, and aggravation of pain in flexion, sitting, coughing or sneezing, and no antalgic posture.[4] The clinical indicators of LBP with facet joint origin have been consensus by an expert panel and suggested to make the patients more homogeneous and appropriate for investigating effect of specific interventions.[5]

Decreased lumbar motions, as well as an increased pain and disability are the main impairments in patients with chronic LBP including ones with facet joint origin. The possible mechanism is the forces on articular facets which could stretch the joint capsules and the sinu-vertebral capsular nerve might be irritated and provoking muscular guarding.[6] Joint inflammation, degeneration and trauma are then associated with pain during movement, and lead to movement and functional limitation.[7] A variety of manual and exercise techniques are used in clinics to solve these complaints with little evidences on movement improvement. A study was conducted previously to test the effect on the kinematic of osteopathic manipulative treatment combined with specific exercise in patients with chronic LBP.[8] However, the study only measured the forward flexion in sagittal plane.

The Muscle Energy Technique (MET) has been suggested for treating patients with LBP especially ones with facet joint dysfunction.[9] However, the reports of the MET effectiveness were mostly based on asymptomatic subjects[10,11] or cases with heterogeneous clinical pictures.[12] Studies using MET showed its effectiveness to improve disability and functional level in patients with acute LBP[13] and a short-term positive effect in patients with lumbopelvic pain.[14] For chronic cases, the evidences of MET effectiveness are still very limited. A study of MET compared with Maitland's mobilization presented moderately better outcomes of function and range of motion (ROM) in the subjects with chronic LBP due to sacroiliac joint dysfunction.[15] The six-day intervention of MET compared with conventional physical therapy also showed that the MET could restore functional leg length difference to nearly normal. However, both groups presented similar results for pain and disability.[16]

From a physiological perspective, MET serves the treatment goals of patients with chronic LBP with facet joint origin in restoring motion and eliminating muscle spasm.[6] MET procedures focus on identifying the restriction and mobilizing joints and tissues through the local muscle effort.[17] The proposed treatment mechanisms involve the neurological and biomechanical responses, including hypoalgesia, proprioception, motor control, and changes of tissue fluid.[18–20] The pain alleviated mechanisms involve central and peripheral modulations such as activation of muscle and joint mechanoreceptors and centrally neural mediated pathways.[21] Localized mobilization using MET might also inhibit the motor neuron activity which effectively relaxes the motion segment as well as normalizes the proprioceptive and motor coordination of the involved region.[22,23]

The lumbar spinal stabilization exercise is a common intervention used in physical therapy clinic for treating LBP patients.[24] A systematic review supported the evidence that lumbar stabilization exercise (LSE) could reduce pain and disability level in patients with chronic LBP.[25] The main focus of this treatment is also to improve the neuromuscular control of lumbar spine by the trunk muscles,[24,25] therefore it was chosen to be the control intervention in this study.

The evidence to support the results of MET for symptomatic subjects was limited. Therefore, this study aimed to compare the immediate effects of MET and LSE for patients with chronic LBP with clinical symptoms of suspected facet joint origin on active ROM, pain intensity and disability level.

Methods

This pilot study was compared between two groups of LBP patients who were treated with two different treatments i.e., the MET and the LSE. Randomized group allocation and blinded assessor

procedure were applied. The outcomes were the kinematic changes, pain intensity, and disability level. This study was conducted after the protocol was approved by the Ethics Committee Mahidol University Institutional Review Board (MU-IRB, COA. No. 2014. 033.2103, Protocol No. MU-IRB 2014/006.0901). This study was registered with the ISRCTN, trial registration code ISRCTN 18528219.

The subjects were the patients with chronic LBP with the clinical symptoms of facet joint origin from the Physical Therapy Center, Mahidol University. All subjects who participated in this study signed the informed consent before commencing the study. The inclusion criteria were the age range of 18–60 years, recurrent or chronic LBP for at least three months, and pain severity from mild to moderate (21–69 mm on Visual Analogue Scale (VAS)). Nine out of 11 diagnostic criteria of facet joint pain origin according to Wilde *et al.* were used since they were applicable and routinely used in physical therapy clinic.[5] The criteria consisted of (1) localized unilateral back pain, (2) referred pain not exceeding the knee level, (3) no sign of a nerve root irritation (dermatomal pain and paraesthesia) and nerve root compression (dermatomal sensory loss, myotomal weakness, and loss of reflex), (4) pain aggravated by pressure over lumbar facet joint, (5) pain aggravated in extension, (6) pain aggravated in three plane movements (extension, lateral flexion, and rotation) to the ipsilateral side, (7) pain eased in flexion, (8) increased stiffness of the facet joint during passive accessory movement, and (9) unilateral muscle spasm over the affected lumbar facet joint. The interrater reliability of this examination scheme in patients with LBP was reported to be acceptable (86.7%), with percent agreements for items ranging from 73.3% to 91.1%, and overall Kappa coefficient of 0.492 ($p = 0.001$).[26]

The three dimension motion analysis system (Vicon Motion Systems Ltd., Oxford, UK) was used to assess the lumbar ROM. The reflective markers were attached on the 12th thoracic segment, the left and right anterior superior iliac spines, and the midpoint between the left and right posterior superior iliac spines.[8,27] To prevent random errors from raw data that might contain additive noises from many sources during data collection, harmonic or frequency analysis was conducted. Residual analysis to choose cut-off frequency and filter technique with Butterworth was used. The cut-off frequency in this study was 5 hertz. The movements measured included flexion, extension, right and left lateral flexion and rotation. All movements were repeated three times, and the average value was used in the analyses. The measurement errors of this system were 7.39°, 6.75°, 2.25°, and 2.05° for flexion, extension, lateral flexion, and rotation, respectively.[28]

To assess pain intensity, the horizontal 100 mm VAS with two ends labeled as 'no pain' and 'pain as bad as it could be' was used.[29] The subjects were asked to put a mark on the line to represent their level of pain intensity. The Thai version of modified Oswestry Disability Questionnaire (ODQ) was applied to assess the level of disability related to LBP. The test–retest reliability of this questionnaire was reportedly excellent (ICC = 0.98).[30] The assessor was a therapist who was blinded to the information of the group allocation. After screening the patients to confirm the eligibility, the assessor performed all pre-treatment measurements. The subjects were then asked to move to the separated treatment area.

To assign the group allocation, another staff drew a label of group from an opaque box. The treatments according to the predetermined protocol for each group were then applied. The treatments for both groups were provided by the same physical therapist with 21 years of experience in the musculoskeletal field. After treatments, the patients went back to the evaluation section and all lumbar active ROMs were re-evaluated immediately after the treatments by the same assessors. The pain intensity was recorded immediately post-treatments and on the next visit which for our research setting was normally two days after the first treatment. The disability level measurement was also conducted during the following visit.

For the MET group, the selection of technique was based on the symptoms and diagnosis of the direction of the dysfunction according to the textbook "Greenman's principles of manual medicine".[31] The dysfunction diagnostic procedure included the assessment of the paired transverse processes in neutral, extended and flexed positions. Started with spinous processes palpation to mark the lumbar vertebra level, the transverse processes of both sides were then identified. The levels of transverse processes were first assessed in the neutral, and extended with prone position on the bed. The fully flexed position was also assessed with the patient seated on a stool with the feet on the floor. If transverse process of one side was more

posterior in the flexed position and symmetric in the extended position, the restriction with extension, rotation, and side bend (ERS) dysfunction was posited. If one transverse process was more prominent in the extended position and symmetric in the fully flexed position, the restriction with flexion, rotation, and side bend (FRS) was posited. A neutral dysfunction was suspected if three or more transverse processes were prominent in all positions. The direction for treatment was the same with movement barrier and opposite with positional diagnosis. Prior to the treatment, the therapist arranged the appropriate position and assessed the pain or resistance barrier of the subject. The physical therapist used palpation to monitor the dysfunction segment and muscle contraction at that specific level during treatment.[31] Since the pain was chronic, a light to moderate active contraction force was applied. After the contraction effort, the subject was instructed to completely relax the back, and the therapist reengaged movement limitation. Before repositioning to a new barrier resistance, the subject was relaxed and his/her muscles could be stretched to a new resting length. These procedures were repeated for about three to five times.[9]

For the LSE group, the procedure of exercise to relearn a precise co-contraction pattern of the deep trunk muscles including the transversus abdominis and lumbar multifidus muscles was conducted.[32] Before the exercise, the abdominal breathing and abdominal hollowing were practiced as training. The exercises were performed in supine position including abdominal hollowing, unilateral knee abduction, extension and knee raise, and bilateral knee raise. The levels of exercise and progressions were customized for each subject, depending on the ability to learn to perform the co-contracting of the lumbar stabilizers. Approximately, 25 min was taken to complete the session for both MET and LSE treatments.

Since there was no previous study on the immediate effect of MET on the kinematic data, the sample size calculation was based on the most resembling of specific exercise and osteopathic manipulative therapy (OMT).[8] The authors compared the kinematic data, pain, and disability from two groups of treatments: the group which was treated with specific exercises (SE) plus OMT, and the other group with the SE alone. The calculation with criteria of 80% power and $\alpha = 0.05$ indicated that 18 subjects of each group was required.[8]

To analyze the data, all results gained in this study were computed with the IBM SPSS Statistics for Windows, Version 19.0 (Armonk, NY: IBM Corp). Besides, the mixed model analysis of variance was applied for the analysis of all outcomes. Also, the independent sample t-test was used to compare the personal characteristics between two groups of subjects.

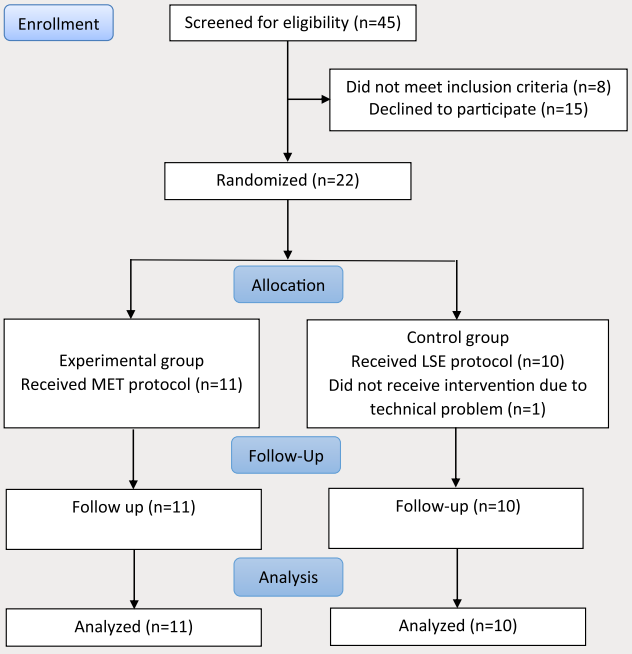


Fig. 1. CONSORT flow chart of participant recruitment.

Results

As shown in Fig. 1, 45 patients with chronic LBP were eligible but 37 subjects met the inclusion criteria. Twenty-two patients agreed to participate and were randomly allocated into two groups. Fifteen patients denied joining the study due to the considerably lengthy period of measurement and treatment sessions. The dataset of one subject was excluded due to the technical error during the data collection process. The characteristics of the subjects are shown in Table 1. All demographics data of both groups were normally distributed except the distribution of gender and pain location.

Table 2 shows the active ROM of lumbar spine at pre- and post-treatment, pain intensities at pre-, post-, and 2-days follow up, and the disability scores at pre and 2-day follow up of both groups. The average changes of VAS at immediately and 2-day post-treatments were 20.5 and 26.8 mm for the MET group and 17.8 and 21.6 mm for the LSE group. For ODQ, the average changes of disability scores at 2-day post-treatment were 6.0 and 8.8 for MET and LSE, respectively. The results also graphically presented in Figs. 2–4.

There were no significant differences of all kinematic variables (flexion, extension, right lateral flexion, left lateral flexion, right rotation, and left rotation), VAS, and ODQ scores for both MET and LSE groups at the baseline. No significant interaction effects of all kinematic variables, pain intensity, and disability level were found. The main effect analysis showed significant differences between times for right lateral flexion, VAS, and ODQ scores ($p < 0.001$). The post-hoc analysis of VAS showed significant difference between pre-treatment with 2-day post-treatment, with p value $= 0.006$ for MET group and < 0.001 for LSE group.

Discussion

This study was the first one to compare the immediate effects of the MET and the LSE in patients with chronic LBP with suspected facet joint origin. There was a trend of an increased active ROM for all directions after treatments in both groups except the extension in LSE group. No significant differences between groups were presented and the effect sizes of all movements were minimal, except for the right lateral flexion which had a medium effect size.[33] These results might be influenced by the reflexive relaxation on spasm muscle, as most of the subjects had pain on left, especially the MET group. However, the change was not clinically meaningful according to a previous study.[30] This finding was similar to a previous report which studied the MET effects on lumbar movements in which significant increases (5–10.5°) of ROM were observed in all directions.[34] However, there were no significant differences of movements gained between two groups who were treated with the MET and myofascial release techniques.[34]

The results of treatment on pain were not different between two groups, and the effect size was also minimal. However, there was a significant main effect of time. The decrease in pain at immediate and two days after treatments was found when the data of both groups were combined. This implied that active exercise treatments either MET or LSE had an effect on pain in patients with

Table 1. Characteristics of subjects.

Characteristics	MET group ($n = 11$)	LSE group ($n = 10$)	p-value[a]
Age (years)	28.82 ± 9.26	27.70 ± 4.80	0.357
Height (cm)	160.47 ± 7.04	162.41 ± 5.98	0.508
Weight (kg)	59.00 ± 11.00	58.69 ± 12.00	0.950
BMI (kg/m^2)	23.00 ± 4.36	22.29 ± 4.01	0.745
Duration of symptom (months)	14.27 ± 16.99	11.60 ± 7.27	0.108
Gender (F/M) (n)	8/3	8/2	
Pain location	Number (%)	Number (%)	
Right lumbar	3 (27.3%)	7 (70%)	—
Left lumbar	8 (72.7%)	3 (30%)	—

Notes: [a]p-value from the independent sample t-test.
The values show as $\bar{x}$ ± SD or number (n).

Table 2. Outcomes for MET and LSE group.

		MET		LSE			
Outcome	Evaluation	Mean score	Mean change from baseline	Mean score	Mean change from baseline	Mean difference between groups in change from baseline[a]	*P* value
AROM Flexion	Baseline	47.8 (20.65 to 76.39)		44.7 (13.66 to 82.16)			
	Immediately after	48.8 (20.55 to 70.49)	9.21 (−10.93 to 20.15)	45.8 (7.44 to 77.97)	1.11 (−6.22 to 9.32)	−1.88 (−6.38 to 6.00)	0.95
	2-days						
AROM Extension	Baseline	39.3 (11.39 to 46.67)		41.3 (33.71 to 54.25)			
	Immediately after	40.8 (23.31 to 61.14)	1.50 (−21.10 to 11.92)	37.3 22.23 to 47.86	−4.00 (−14.74 to 4.08)	5.51 (−1.55 to 12.58)	0.119
	2-days						
AROM Right Lateral Flexion	Baseline	23.4 (18.16 to 31.49)		26.8 (17.98 to 39.46)			
	Immediately after	27.6 (21.99 to 36.61)	4.11 (−1.02 to 9.39)	30.8 (23.32 to 38.73)	4.01 (−4.36 to 12.99)	0.10 (−3.73 to 3.95)	0.954
	2-days						
AROM Left Lateral Flexion	Baseline	23.2 (14.52 to 37.45)		24.3 (17.90 to 49.22)			
	Immediately after	24.7 (13.82 to 35.29)	1.48 (−3.69 to 6.78)	26.9 (10.83 to 47.86)	2.58 (−7.07 to 10.03)	−1.10 (−5.43 to 3.23)	0.601
	2-days						
AROM Right Rotation	Baseline	13.2 (6.23 to 32.23)		11.0 (6.55 to 17.49)			
	Immediately after	14.6 (6.32 to 26.19)	1.38 (−12.09 to 12.95)	12.7 (6.72 to 20.43)	1.70 (−2.11 to 7.08)	−0.31 (−5.35 to 4.72)	0.897

Table 2. (*Continued*)

Outcome	Evaluation	MET		LSE		Mean difference between groups in change from baseline[a]	*P* value
		Mean score	Mean change from baseline	Mean score	Mean change from baseline		
	2-days						
AROM Left Rotation	Baseline	13.0 (6.49 to 22.35)		13.0 (5.34 to 21.04)			
	Immediately after	13.9 (3.77 to 30.77)	0.60 (−8.84 to 15.45)	13.0 (6.47 to 22.02)	0.46 (−4.95 to 6.26)	0.56 (−4.47 to 5.59)	0.818
	2-days			—			
VAS scores	Baseline	43.6 (21 to 67)		48.3 (21 to 78)			
	Immediately after	23.0 (3 to 62)	−20.55 (−67 to 20)	30.5 (8 to 71)	−17.80 (−49 to 20)	−2.74 (−24.24 to 18.75)	0.7.92
	2-days	16.8 (5 to 62)	−26.82 (−64 to 9)	26.7 (5 to 55)	−16.80 (−42 to 17)	−10.01 (−29.17 to 9.13)	0.287
ODQ scores	Baseline	12.7 (6 to 30)		19.4 (6 to 60)			
	Immediately after 2-days	6.7 (2 to 16)	−6.0 (−16 to 0)	10.6 (2 to 34)	−8.80 (−26 to 2)	2.80 (−3.05 to 8.65)	0.329

Note:[a] Mean differences are adjusted for baseline scores of outcome variable.

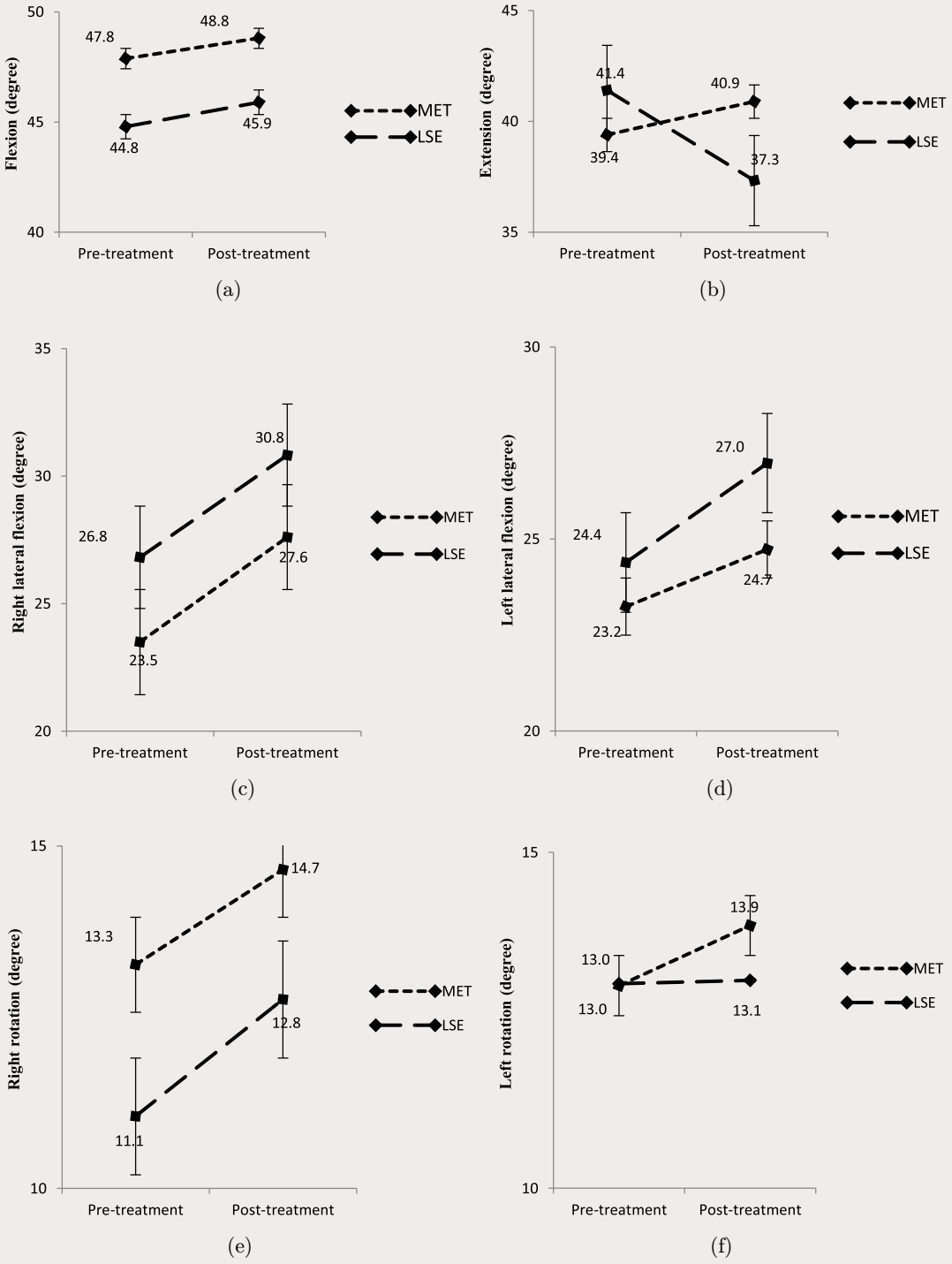
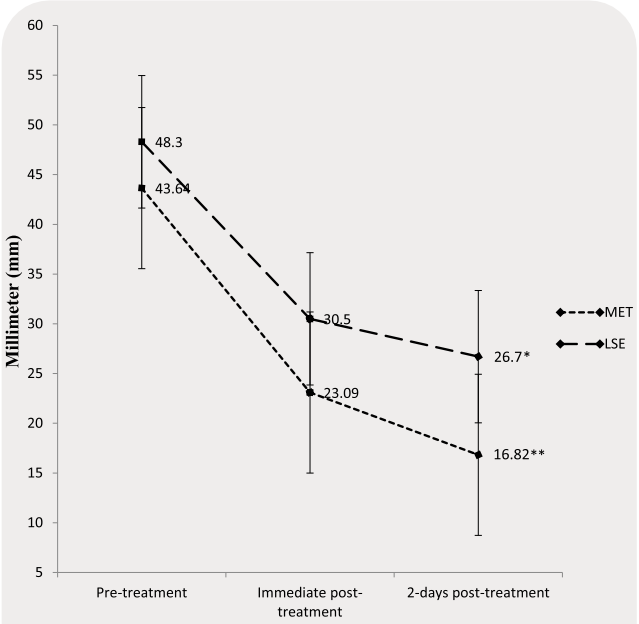


Fig. 2. Active ROM all motions for the MET and the LSE groups.

chronic LBP. This result was in accordance with a previous study in which similar effects comparing MET with ultrasound were observed.[35] However, those results should be implemented with care because they also applied the combination of treatments including moist heat, transcranial electrical nerve stimulation, and conventional exercises in both groups. These might result in the cumulative effects of several interventions.

In addition, the altered pain intensity in this study was considerably an actual change, when considering the reported minimal important change of more than 15 points or 30% improvements from the baseline interventions.[36] The mean



Notes: *significant difference between pre-treatment with 2-day post-treatment $p = 0.006$. **significant difference between pre-treatment with 2-day post-treatment $p < 0.001$.

Fig. 3. Visual analogue scale scores for the MET and the LSE groups.

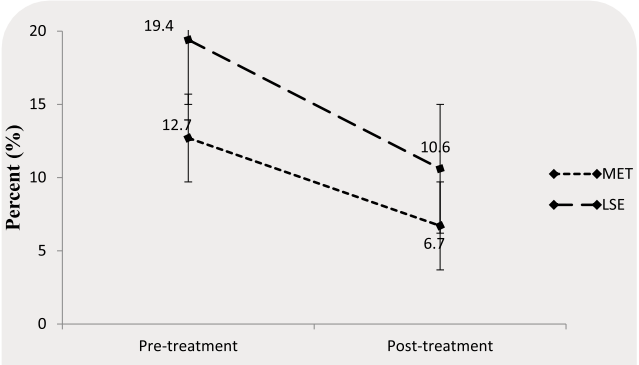


Fig. 4. Disability scores for the MET and the LSE groups.

changes of the VAS score for both groups in this study were 19.24 points at immediately after treatments, and 24.34 points at 2-day follow-up. The decreased pain levels reflected the effectiveness of both treatments in participants with moderate pain level.

The possible explanation is the light contraction forces of both techniques which could enhance hypoalgesia in chronic pain condition both central and peripheral mechanisms.[18,20,22,37] The rhythmic muscle contractions and stimulation of joint mechanoreceptors could affect the central mediated pathways through the stimulation of low-threshold mechanoreceptors. This would excite the neurons in the dorsal horn resulting in gating effects i.e., modulating the pain.[18] The descending inhibition from the higher centers of central nervous system is also hypothesized.[18] For peripheral mechanism, the light muscle contraction might stimulate fluid flow rates including blood and lymph, as well as stretch the connective tissues. The reduced pain might be associated with the change in stretch tolerance with decreasing of the muscle spindles sensitivity, and ultimately reduce pain sensitivity of both the efferent and afferent nerves.[20,22] MET was proposed to not only break the pain or spasm cycle by inhibiting alpha motor neuron activity via a stretch reflex, but also to inhibit Ia afferent nerves via post-activation depression.[22]

For disability, while considering the main effect of time, there were statistically different disability scores between times. However, from pre-treatment to 2-day follow-up, the mean change scores were 6.0 and 8.8 for the MET group and LSE group, respectively. These scores did not meet the clinically important change of 15 points in ODI score,[38] so a single session of both MET and LSE could not improve ODQ in patients with chronic LBP. A previous study suggested that the MET when combined with other treatments might be more effective on disability after multiple treatment sessions.[14] Moreover, a systematic review which included 12 trials showed a low quality of evidence of the MET as the addition or comparison to other treatments on pain and disability.[39] These findings of pain and disability levels are needed to be clarified in further studies by examining the effects of long-term and repeated MET and LSE treatment programs.

Another concern of this study is about the diagnostic tests to identify the patients with suspected pain from facet joint origin. Clinicians should be noted that the clinical criteria used in this study were based on the results of a Delphi study to gather the consensus of expert opinions.[5] Out of the 12 criteria listed, two important indicators of "positive response to intra-articular facet joint injection" and "pain relieved by fluoroscopically guided double-anesthetic blocks of the medial branch of the dorsal ramus supplying the lumbar facet joint" were also omitted due to the nature of physical examination in physical therapy practice. Therefore, the validity of facet joint diagnosis was not confirmed.

Conclusion

In conclusion, the different effects between MET and LSE were not found in this pilot study though attempting to include only patients with suspected pain of facet joint origin. Although this study showed statistically a significant increase of the active side-bending ROM to the painful side, as well as the decreases of the pain and disability levels, the results should be interpreted with care. The major limitation of considerably small sample size might lead to the insignificant different results. The study also monitored only immediate effect which does not reflect the usual treatment program. Further studies should be focused on long-term treatments and the evaluation with a larger sample size.

Conflict of Interest

The authors declare that they have no competing interests.

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Author Contributions

WW designed the study, evaluated the patients, analyze data and wrote the paper. MV proved the study design, treated the patients and edited the paper. SB, KM and RA proved the study design, assisted the patient recruitment, data collection, read and approved the paper.

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Effects of incentive spirometry on cardiopulmonary parameters, functional capacity and glycemic control in patients with Type 2 diabetes

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Background: Patients with Type 2 diabetes mellitus (T2DM) suffer cardiopulmonary impairment and may present with weakness of the inspiratory muscles.
Objective: This study was designed to determine the effects of incentive spirometry (IS) on selected cardiopulmonary parameters, functional capacity and glycemic control in patients with T2DM.
Methods: Fifty-nine participants (25 males and 34 females) recruited from the out-patient clinic of the Department of Medicine of two hospitals in Lagos State, Nigeria, who were randomly assigned into two groups, completed the study. In addition to the medical management of T2DM, IS group received incentive spirometry while control group continued with the medical management of T2DM alone. Selected cardiovascular parameters, pulmonary parameters, functional capacity (using 6-min walk test) and fasting blood glucose level were assessed at baseline and at the end of eight weeks intervention period. Data were analyzed using the Statistical Package for Social Sciences (SPSS Version 21). Level of significance was set at $p < 0.05$.
Results: There were statistically significant improvements in all the cardiovascular parameters ($p = 0.001$) of IS group except systolic blood pressure. There were significant changes in all the pulmonary parameters, functional capacity and glycemic control ($p < 0.05$) of IS group while there was none in control group. There were significant differences between the mean changes of various selected outcome measures of the two groups ($p < 0.05$) except for diastolic blood pressure and blood glucose level.

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Conclusion: IS had positive effects in improving cardiopulmonary function, functional capacity and glycemic control in patients with T2DM.

Keywords: Type 2 diabetes mellitus; incentive spirometry; cardiopulmonary function; functional capacity; glycemic control.

Introduction

Diabetes is a group of metabolic diseases in which a person cannot regulate the amount of sugar, specifically glucose, in the blood.[1] This high blood sugar produces the classical symptoms of polyuria, polydipsia and polyphagia.[2] Type 2 diabetes mellitus (T2DM) is the most common type of diabetes, it accounts for about 90–95% of all cases of diabetes mellitus, and therefore of primary interest.[3] It is characterized by insulin resistance which may be combined with relatively reduced insulin secretion.[4] It can lead to glycation of tissues, which proceeds with acute metabolic disturbances and ends with organ damage with severe health deteriorations.[5] The International Diabetes Federation (IDF) estimated that in 2011, 366 million people (8.3% of the world population) had diabetes worldwide, a figure expected to reach 552 million (9.9% of the world population) by the year 2030, with 80% of people with diabetes living in low and middle-income countries. Worldwide, approximately 200 million people have T2DM.[6]

Diabetes is known to have a profound impact on life expectancy; it is also known to affect a patient's general health and well-being. It is a significant health problem with microangiopathy and macroangiopathy resulting in many complications like, diabetic neuropathy, diabetic retinopathy, diabetic nephropathy, peripheral vascular disease, cardiovascular disease, susceptibility to infections and periodontal disease.[7–10] The presence of an extensive microvascular circulation and abundant connective tissue in the lungs raises the possibility that lung tissue may be affected by microangiopathy process and non-enzymatic glycosylation of tissue proteins, induced by chronic hyperglycemia renders the lung a "target organ" in patients with T2DM. Since normal lung mechanics and gas exchange are influenced by the integrity of pulmonary connective tissue and microvasculature, abnormalities in either of these two structural components of the lung may lead to the development of measurable abnormalities of pulmonary function.[11]

Hyperglycemia-induced microangiopathy via increased oxidative stress has also been shown to impair pulmonary and cardiovascular function.[12] Vaibhav and Chahar[9] posit that the pulmonary function abnormalities reported in T2DM patients is usually associated with chronic hyperglycemia. Deterioration of pulmonary function is seen in 80% of all patients with T2DM from the entire world population.[11] The relationship between T2DM and pulmonary function remains important because of potential epidemiological and clinical implications.[13] In 2004, Davis *et al.*[14] observed that measures of airflow limitation predict all-cause mortality in diabetes and intensive glycemic management may reduce the risk of death through improved ventilatory function independent of other beneficial effects. The function of inspiratory muscles is also frequently found to be impaired (decreased strength and/or endurance) in patients with T2DM.[15] This leads to poor exercise tolerance and decreased functional capacity.[4] So, the assessment of pulmonary function is an important investigation because early detection of pulmonary function impairment and its appropriate treatment will help to reduce morbidity and mortality. For these reasons, specific inspiratory muscle training (IMT) could be justified as a strategy with potential clinical benefits in patients with T2DM.[8] IMT can be achieved by using an inspiratory muscle trainer or incentive spirometry (IS).[16,17]

Incentive spirometry is frequently used and recommended for reducing the chance of pulmonary complications and improving pulmonary function in patients with COPD, but its efficacy in the improvement of pulmonary function in patients with T2DM is still uncertain.[17,18] Incentive spirometers are affordable and easy to use, have no side effect, and provide a direct feedback that act as an incentive for exercise.[19] Despite such advantages, the use of incentive spirometers to improve the endurance of respiratory muscles and pulmonary function indices of patients with T2DM is not a typical practice, and there is little evidence

supporting their efficacy for this application.[17] Since there is a relationship between the cardiopulmonary function and functional capacity as well as glycemic levels in patients with T2DM, any intervention that affects the respiratory function may in turn affect the other parameters.[20,21] This study was therefore designed to determine the effects of IS on selected cardiopulmonary parameters, functional capacity and glycemic control in patients with T2DM and the correlation between pulmonary function and functional capacity, duration of the disease (DOD) and glycemic control.

Methods

This study was a single blinded randomized controlled trial.

Subjects

A total of 70 patients diagnosed with T2DM were recruited for this study from the out-patient clinic of the Department of Medicine, Lagos University Teaching Hospital (LUTH), Idi Araba, Lagos State, Nigeria and General Hospital Lagos (GH), Marina, Lagos State, Nigeria. The participants were recruited based on the following inclusion criteria: Confirmed medical diagnosis of T2DM, patients above 18 years of age who had the ability to follow instructions and engage in study procedures, no structured aerobic exercise program in the preceding six months. They were non-smokers and non-alcoholics with no physical restriction in terms of mobility and had no pre-existing pulmonary infections or deformities in the trunk. Patients who have had recent abdominal surgery and those with severe complications of DM, such as neuropathy, nephropathy, and retinopathy, were excluded from the study. The sample size was determined using this formula: $n = N\ (Z_1 + Z_2)^2 / \mathrm{ES}^2$. Where $n =$ minimum sample size, $N =$ number of groups, $Z_1 = \alpha$ confidence of interval at $0.05 = 1.96$, $Z_2 = \beta$ confidence of interval at $0.20 = 0.84$, $\mathrm{ES} = \text{Effect size} = 0.80$ (using Cohen's standard effect size).[22] The number of participants for both groups was calculated as 30, this means that the calculated minimum sample size for each study group was $30/2 = 15$. Of the 70 patients recruited, six were excluded from this study. The remaining 64 were randomly assigned into two different groups (IS and Control) with 32 patients in each group using fish bowl technique. In this sampling technique, each unit of the population is represented by a slip of paper containing a number, the slips of paper are put in a box and shuffled, and the slips are then pulled out one by one without looking at them, until the number of slips selected equals the sample size.[23] The IS group received medical management of T2DM and IS while the control group continued with the medical management of T2DM alone.

However, 59 participants (25 males and 34 females) completed the study with five withdrawals from the study; two from the IS group could not keep up with the weekly appointments and three from the control group did not show up for the post test assessment. In the IS group, 14 males and 16 females completed the study while in control group 11 males and 18 females completed the study.

Ethical approval was obtained from the Research and Ethics Committee of LUTH (ADM/DCST/HREC/APP/1538) and GH Lagos through the Lagos State Health Service Commission (HSC) (LSHSC/2222/XXIII/533). All participants gave written informed consents to participate in this study. This clinical trial was registered by the Pan African Clinical Trial Registry on the 16th of November, 2017 with an identification number PACTR201711002754229.

Instruments

The following instruments were used for this study:

A flow-sensing triflo II incentive spirometer (India model SG523130993), Spirometer (Contec SP 10, China, Version 1.2), Mercury sphygmomanometer (Accoson UK, BS EN 1060-1), Stethoscope (Littmann Classic II SE, UK), Glucometer (Accu-Chek Active, Germany), Stadiometer (Seca 213, UK), Portable bathroom weighing scale (Camry BR9312, China), 30-meter wind-up tape measure (Starrett, USA), Stopwatch (Nivia JS 307, India), Mechanical lap counter (HDE, USA), Two small cones and a plastic chair with back rest.

Pre-intervention assessment

On arrival at the study site, each participant was formally welcomed and seated on a chair with back rest located near the starting position of the 30 m walking course for 10 min before the commencement of tests. During this time, the participants were examined for possible contra-indications after

which the purpose and protocol for the study were adequately explained to each of them before seeking and obtaining their written informed consent using a consent form. All participants who gave their consent to participate in the study had their baseline measurements of heart rate, blood pressure (using a stethoscope and sphygmomanometer), lung function (using a spirometer), blood sugar level (using a glucometer) and functional capacity (using 6 min walk test (MWT)) assessed and recorded. Socio-demographic data and physical characteristics such as; age, gender, height, weight and body mass index were also obtained from the participants.

Blood sugar level was measured according to the American Diabetes Association Criteria.[24] Cardiovascular parameters of heart rate, systolic and diastolic blood pressure (SBP and DBP) were measured using a sphygmomanometer and a stethoscope. Rate pressure product was calculated as the product of heart rate and systolic blood pressure.[7,25]

Pulmonary function was assessed with each of the participant seated comfortably in a chair with back rest, feet firmly on the ground and all constricting clothing such as braziers and waist belts loosened to prevent alteration of test results from restricted thoracic expansion and abdominal mobility. Guidelines suggested by American Thoracic Society/European Respiratory Society (ATS/ERS) were adopted during this technique.[26] The spirometer was cleaned with an alcohol wipe and disposable mouthpiece was used for each participant. The participants were instructed to breathe in as deeply as possible (full inspiration) and hold their breath just long enough to seal their lips around the mouthpiece and to clip the nose with a nose clip. They are then instructed to blow out through the mouth (exhale) into the mouthpiece forcibly, as hard, as fast and as long as possible (full expiration), until there is no air left to expel (at least for 6 s).[27] The procedure was repeated thrice at 15 min interval and the forced vital capacity (FVC), forced expiratory volume in 1 s (FEV_1) and peak expiratory flow rate (PEFR) readings were obtained.[25] It was ensured that repeatability was considered to be adequate, for the FVC and FEV_1, when the two highest values were within 0.150 L of each other and the higher value between the two repeatable values was the accepted value. The highest value of PEFR was the accepted value.[27,28]

Functional capacity was assessed using the 6MWT which is a performance-based tool. Prior to commencement of the test, participants were informed that the objective of the test was to walk as far as possible for 6 min by walking back and forth around the cones as quickly as possible but not to run or jog. This was demonstrated to the participants by walking one lap. Standardized instructions and words of encouragement were given to the participants during the test as provided by the ATS[29] guidelines for the 6MWT. The total distance covered by each participant in 6 min was calculated by multiplying the number of laps walked by 60 m (one lap is to and fro the 30 m walk course) plus the final partial lap in meters.[29]

Intervention

In addition to the medical management of their condition, participants in the IS group were taught how to use the flow-sensing incentive spirometer following a standard testing protocol as suggested by the American Association for Respiratory Care (AARC).[18,30] The participants were seated comfortably in an upright position and instructed to hold the incentive spirometer in an upright position, exhale normally, and then place the lips tightly around the mouthpiece. The next step was a slow inhalation to raise the ball (flow-oriented) in the chamber. At maximum inhalation the mouthpiece was removed, followed by a breath-hold (sustained for a minimum of 3 s), and normal exhalation. Participants were advised to always assume an upright position during the IMT as inspiratory muscle function is optimized in the upright position while recumbent or semi-recumbent postures impair respiratory muscle function.

Inspiratory spirometry was performed two days in a week at the clinic and the participants were encouraged to carry out training at home every day at the frequency of 10 breaths per session, five times a day for eight weeks.[31] On the other hand, participants in the control group continued receiving standard medical management without any further intervention. Participants kept daily logs of there IS sessions indicating the date and time of their training sessions. Also, all participants' phone numbers were obtained for individual home sessions and follow up. Participants withheld any structured aerobic exercise program during the experimental period.

Post-intervention assessment

The outcome variables were assessed on the next day at the end of the eighth week of study for the participants who completed their individual group assignment using the same procedure as pre-intervention assessment.

Data Analysis

Data was analysed using the SPSS Version 21. Data was summarized using descriptive statistics of frequency, mean and standard deviation. Independent *t*-test was used to analyze the data between the groups (IS and control) and paired *t*-test was used to analyze the outcomes within the two groups. Pearson correlation was used to determine the relationship between pulmonary function and functional capacity, glycemic control as well as DOD. The level of significance was set at $p < 0.05$.

Results

The mean age, BMI and DOD of the participants in the IS and control groups were 54.47 ± 9.77 years and 55.76 ± 14.56 years, $25.50 \pm 4.63\,kg/m^2$ and $26.11 \pm 4.07\,kg/m^2$ as well as 10.53 ± 6.77 years and 6.66 ± 4.89 years, respectively. There was no significant difference in the physical and other baseline characteristics of the two groups except DOD ($p = 0.014$) (Table 1). At baseline, there was no significant difference in the cardiopulmonary function parameters of the participants in the two groups with the exception of DBP which showed a significant difference ($p = 0.024$). The 6-min walk distance (6MWD) of the participants in

Table 1. Comparison of baseline physical and other characteristics of both groups.

Variables	Mean ± SD			*t*-value	*p*-value
	IS group ($n = 30$)	Control group ($n = 29$)	All participants ($n = 59$)		
Age (years)	54.47 ± 9.77	55.76 ± 14.56	55.10 ± 12.64	−0.399	0.692
Weight (Kg)	71.97 ± 11.23	71.76 ± 10.26	71.86 ± 10.67	0.074	0.941
Height (m)	1.69 ± 0.09	1.66 ± 0.07	1.67 ± 0.08	1.171	0.247
BMI (Kg/m^2)	25.50 ± 4.63	26.11 ± 4.07	25.80 ± 4.34	−0.532	0.597
DOD (years)	10.53 ± 6.77	6.66 ± 4.89	8.63 ± 6.19	2.529	0.014*

Notes: * Significant at $p < 0.05$.
BMI: Body mass index; DOD: Duration of disease; SD: Standard deviation; *n*: Number of participants in a group; Kg: Kilogram; m: meters.

Table 2. Comparison of baseline variables of both groups.

Variables	Mean ± SD		*t*-value	*p*-value
	IS group	Control group		
FVC (L)	2.02 ± 0.61	1.98 ± 0.51	0.307	0.760
FEV_1(L)	1.80 ± 0.56	1.67 ± 0.53	0.947	0.347
PEFR (L/s)	3.43 ± 1.39	4.02 ± 1.84	−1.367	0.177
SBP (mmHg)	134.13 ± 15.66	135.72 ± 15.73	−0.389	0.699
DBP (mmHg)	89.20 ± 6.94	83.83 ± 7.96	2.335	0.024*
HR (bpm)	74.90 ± 9.10	75.83 ± 11.56	−0.342	0.734
RPP	10017.73 ± 1487.02	10318.97 ± 2105.57	−0.633	0.530
FBS (mg/dl)	121.13 ± 32.81	121.86 ± 43.42	−0.073	0.942
6MWD (m)	200.77 ± 43.39	166.31 ± 62.09	2.463	0.017*

Notes: *Significant at $p < 0.05$.
FVC: Forced vital capacity; FEV_1: Forced expiratory volume in 1 s; PEFR: Peak expiratory flow rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HR: Heart rate; RPP: Rate pressure product; FBS: Fasting blood sugar; 6MWD: 6 min walk distance.

Table 3. Comparison of the pre- and post-mean values of the pulmonary parameters, cardiovascular parameters, FBS and 6MWD in IS group.

Variables	Mean ± SD		t-value	p-value
	Pre	Post		
FVC (L)	2.02 ± 0.61	2.50 ± 0.76	−4.586	0.001*
FEV_1 (L)	1.80 ± 0.56	2.16 ± 0.67	−5.134	0.001*
PEFR (L/s)	3.43 ± 1.39	4.85 ± 1.62	−7.621	0.001*
SBP (mmHg)	134.13 ± 15.66	130.40 ± 17.20	1.587	0.123
DBP (mmHg)	89.20 ± 6.94	82.60 ± 9.91	4.902	0.001*
HR (b/m)	74.90 ± 9.10	68.97 ± 11.54	4.179	0.001*
RPP	10017.73 ± 1487.02	8966.40 ± 1786.79	4.282	0.001*
FBS(mg/dl)	121.13 ± 32.81	102.13 ± 36.90	2.804	0.009*
6MWD (m)	200.77 ± 43.39	229.50 ± 53.32	−6.845	0.001*

Notes: * Significant at $p < 0.05$.
FVC: Forced vital capacity; FEV_1: Forced expiratory volume in 1 s; PEFR: Peak expiratory flow rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HR: Heart rate; RPP: Rate pressure product; FBS: Fasting blood sugar; 6MWD: 6 min walk distance.

the two groups also showed a significant difference at baseline ($p = 0.017$) while FBS showed no significant difference (Table 2).

Tables 3 and 4 show the comparisons of pre and post intervention mean values of the pulmonary parameters, cardiovascular parameters, fasting blood sugar level (FBS) and functional capacity (6MWD) in the IS group and control group, respectively. The paired t-test analysis showed statistically significant improvements in all the pulmonary function parameters, FBS and 6MWD in the IS group ($p < 0.05$). There were also significant improvements in all cardiovascular parameters in the IS group ($p < 0.05$) except for SBP which showed no significant difference ($p = 0.123$) (Table 3).

There were no significant differences in any of the pulmonary function parameters, cardiovascular parameters, FBS and 6MWD in control group ($p > 0.05$) (Table 4).

The comparison of the mean changes in the pulmonary parameters, cardiovascular parameters, FBS and 6MWD post intervention (at the end of the eighth week) between the two groups showed significant differences in all the pulmonary function parameters (FVC, FEV_1 and PEFR) ($p = 0.001$,

Table 4. Comparison of the pre- and post-mean values of the pulmonary parameters, cardiovascular parameters, FBS and 6MWD in the control group.

Variables	Mean ± SD		t-value	p-value
	Pre	Post		
FVC (L)	1.98 ± 0.51	1.98 ± 0.52	−0.095	0.925
FEV_1 (L)	1.67 ± 0.53	1.69 ± 0.51	−0.928	0.361
PEFR (L/s)	4.02 ± 1.84	4.07 ± 1.84	−0.506	0.616
SBP (mmHg)	135.72 ± 15.73	135.17 ± 12.95	0.510	0.614
DBP (mmHg)	83.83 ± 7.96	83.83 ± 7.96	−0.225	0.824
HR (b/m)	75.83 ± 11.56	76.72 ± 8.73	−0.958	0.346
RPP	10318.97 ± 2105.57	10373.90 ± 1543.84	−0.326	0.747
FBS (mg/dl)	121.86 ± 43.42	114.93 ± 28.53	1.547	0.133
6MWD (m)	166.31 ± 62.09	173.75 ± 58.99	−1.824	0.079

Notes: * Significant at $p < 0.05$.
FVC: Forced vital capacity; FEV_1: Forced expiratory volume in 1 s; PEFR: Peak expiratory flow rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HR: Heart rate; RPP: Rate pressure product; FBS: Fasting blood sugar; 6MWD: 6 min walk distance.

Table 5. Comparison of the mean changes in the pulmonary parameters, cardiovascular parameters, FBS and 6MWD Post-intervention between the two groups.

Variables	Mean changes ± SD		*t*-value	*p*-value
	IS Group	Control Group		
FVC	0.48	0.02	5.041	0.001*
FEV_1	0.36	0.02	4.697	0.001*
PEFR	1.42	0.05	4.933	0.001*
SBP	3.73	0.55	3.356	0.002*
DBP	6.60	0.01	1.784	0.080
HR	5.93	0.89	2.854	0.006*
RPP	1051.33	54.93	3.569	0.001*
FBS	19.00	6.93	1.572	0.123
6MWD	28.73	7.44	3.255	0.002*

Notes: *Significant at $p < 0.05$.
FVC: Forced vital capacity; FEV_1: Forced expiratory volume in 1 s; PEFR: Peak expiratory flow rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HR: Heart rate; RPP: Rate pressure product; FBS: Fasting blood sugar; 6MWD: 6 min walk distance.

respectively) and 6MWD ($p = 0.002$). There were also significant differences in all the cardiovascular parameters (SBP, HR and RPP) ($p < 0.05$) except for DBP. No significant difference was seen between the mean changes in FBS of the two groups (Table 5).

The analysis of the relationship between changes in pulmonary function (FVC, FEV_1 and PEFR) and 6MWD, FBS as well as the DOD of the participants using the Pearson's correlation coefficient showed that there was no correlation between 6MWD, FBS, DOD and FVC, FEV_1. There was a significant correlation between PEFR and 6MWD ($r = 0.281; p = 0.033$) as well as DOD ($r = 0.333; p = 0.010$) (Table 6).

Discussion

The purpose of this study was to determine the effects of IS on selected cardiovascular parameters,

Table 6. Relationship between changes in pulmonary function and functional capacity; glycemic control; duration of the disease of the participants.

Variables	FVC	FEV_1	PEFR
6MWD	$r = 0.176$ $p = 0.186$	$r = 0.250$ $p = 0.058$	$r = 0.281$ $p = 0.033$*
FBS	$r = 0.029$ $p = 0.830$	$r = 0.181$ $p = 0.171$	$r = 0.141$ $p = 0.286$
DOD	$r = 0.220$ $p = 0.085$	$r = 0.204$ $p = 0.122$	$r = 0.333$ $p = 0.010$*

Notes: *Significant at $p < 0.05$.
FVC: Forced vital capacity; FEV_1: Forced expiratory volume in 1 s; PEFR: Peak expiratory flow rate; FBS: Fasting blood sugar; 6MWD: 6 min walk distance; DOD: Duration of disease; *r*: Correlation coefficient; *p*: Significance value.
Correlation Guide: 0.00–0.19 "Very weak"; 0.20–0.39 "Weak"; 0.40–0.59 "Moderate"; 0.60–0.79 "strong"; 0.80–1.0 "Very strong"; (Evans *et al.* 1996).

pulmonary parameters, functional capacity and glycemic control in patients with T2DM and the correlation between pulmonary function and functional capacity, DOD and glycemic control. IS had significant effect on all cardiovascular parameters (DBP, HR and RPP) except SBP. It had significant effect on all pulmonary parameters (FVC, FEV_1 and PEFR), functional capacity and glycemic control. There was no significant correlation between the changes in pulmonary function (FVC and FEV_1) and functional capacity, glycemic control as well as DOD except weak correlation between PEFR and functional capacity as well as DOD.

The significant different baseline data in DOD, DBP and 6MWD between the two groups (Tables 1 and 2) did not matter after all as the mean changes of these outcome variables were eventually used for comparison between the two groups (Tables 5 and 6) instead of the actual values post intervention. Among these three parameters, only DBP showed no statistically significant difference when the mean changes of the selected outcome measures were compared between the two groups (Table 5) even though the mean changes in DBP was more in the IS group (6.60 mmHg) than the control group (0.01 mmHg).

The finding that there were significant changes in pulmonary function parameters (FVC, FEV_1 and PEFR) of participants in the IS group following eight weeks of IS using incentive spirometer while there was no significant change in the control group implies that IS training brought about the change. This is also buttressed by the significant differences observed in the comparison between the mean changes in pulmonary function parameters of the two groups. This improvement could be associated with the fact that the visual feedback provided by the incentive spirometer encourages the inspiratory performance of the participants and sustained maximal inspiration and hyperpnoea aim to gain pulmonary volume.[32] It is also known that maximum inspiration causes the increase of the trans-pulmonary pressure and the increase of the pulmonary volume. Furthermore, resting at the end of inspiration keeps up the increase of the trans-pulmonary pressure and ensures the alveolar stability. All of these enhance gas exchange, improve lung compliance, perfusion and reduce the work of breathing.[33]

This corroborates the findings of Paiva *et al.*[16] who investigated the effect of IMT in healthy sedentary females and reported an increase in pulmonary function post IMT using incentive spirometer for 30 days. However, these findings differ from that of Correa *et al.*[4] which showed no significant change in the pulmonary function of patients with T2DM with inspiratory muscle weakness who were grouped into an experimental and a placebo group. The experimental group had eight weeks of IMT and the authors explained that this result could be because diabetes mellitus results in attenuation of inspiratory muscle metaboreflex.[4] Increase in inspiratory muscle strength with no consequent increase in pulmonary function has also been documented for patients with diabetic autonomic neuropathy post IMT.[15] This difference could be because of the small sample size used in these studies. Likewise, Bavarsad *et al.*[34] reported no significant change in pulmonary function of patients with chronic obstructive pulmonary disease (COPD) who had eight weeks of IMT using a flow-volumetric incentive exerciser and those who had no IMT. It was posited that it could be because of the structural changes that occur in COPD. These structural changes are found in the central airways, peripheral airways, lung parenchyma, and pulmonary vasculature and such changes are not fully reversible. The results seen on pulmonary function tests in patients with COPD are evidence of over-inflation of the lung (Bullae formation), decreased airflow and abnormalities in gas exchange.[35]

The observation that almost all the cardiovascular parameters (DBP, HR and RPP) showed significant changes in the IS group while the control group showed no significant change also implies that IS brought about the changes. This positive change could be explained by the fact that respiratory modulation is known to be related to cardiovascular modulation and it plays a vital role in blood pressure control. This important interactivity is noted by the generalized alteration that occurs in cardiovascular control in conjunction with respiratory pattern modifications. This relationship is likely related to baroreceptor and chemoreceptor sensitivity interaction and its influence on the mechanisms of blood pressure control.[36] Comparing the mean changes in the cardiovascular parameters of both groups showed significant differences in all parameters except DBP although the mean changes in DBP was more in the IS group than the control group. May be with longer use of incentive spirometer by patients with T2DM, the

comparative mean changes in DBP between the two groups would become significantly different. There is paucity of data on the effect of IS on cardiovascular parameters in patients with T2DM but Ferreira *et al.*[36] reported that eight weeks of IMT was able to reduce systolic and diastolic blood pressure in patients with hypertension while Mello *et al.*[37] observed that heart rate and arterial blood pressure in patients with chronic heart failure were not significantly changed in both Control and IMT groups. The differences in the findings of these studies may be due to the different pathologies of the different conditions in the studies.

There was a statistically significant increase of 28.73 m in functional capacity (6MWD) of the IS group post eight weeks of IS compared to a non-statistically significant increase of 7.44 m in the control group who had no IS. This increase of 28.73 m may not be clinically significant as Shoemaker *et al.*[38] in a systematic review recommended that an increase of 54 m in the 6MWT was considered to be clinically significant. To improve the functional capacity of patients with T2DM so that it is clinically significant, we propose higher intensity IS and longer training period like 12 weeks. Little is known in literature about the effect of IS on the functional capacity of patients with diabetes using 6MWT although the studies by Correa *et al.*[4] and Kaminski *et al.*[15] did not show improvement in the functional capacity of patients with diabetes following IMT. This disparity may be because these researchers employed low intensity inspiratory loading (30% of maximal static inspiratory) because various studies where higher intensity IMT were employed showed increases in functional capacity following IMT in patients with COPD, atrial fibrillation and asthma.[34,39,40]

The significant reduction in the fasting blood glucose level (FBS) observed in the IS group and non-significant reduction in the control group imply that IS brought about the difference although the comparison between the mean differences of the two groups showed no significant difference. This is similar to the findings of Correa *et al.*[20] who reported that high resistance of inspiratory muscle exercise reduces blood glucose levels. It was also posited that IMT improves insulin sensitivity in elderly patients with insulin resistance, hence leading to reduction in blood glucose level.[41] In another study by Silva *et al.*,[21] IMT induced a reduction in fasting glucose levels and improved the secretory capacity of pancreatic β cells. These findings are at variance with the study by Ahmad *et al.*,[42] which observed that IMT with low inspiratory loading failed to demonstrate any significant improvements in blood glucose levels in female patients with type T2DM. This discrepancy could be attributed to the intensity of inspiratory load and the duration of inspiratory exercises. This explanation could be supported by reports from The American College of Sports Medicine and the American Diabetes Association, both of which stated that the reductions in blood glucose levels are related with exercise intensity and duration.[43] The researchers also explained that the non-significant improvement in blood glucose could be as a result of daily hassles and family stress experienced and reported by some patients in the study group which could have led to elevated plasma glucose levels most of the time. The mechanism is through the direct physiological effects of stress on counter-regulatory hormones, which in turn increases blood glucose.[42]

The finding that there was no significant correlation between most of the pulmonary function parameters (FVC and FEV_1) and functional capacity, glycemic control as well as DOD except weak correlation between PEFR and functional capacity as well as DOD may imply that the state of the pulmonary function parameters has no relationship with glycemic control but has minimal relationship with functional capacity and DOD in patients with T2DM. This minimal relationship between the pulmonary function parameters and functional capacity may be due to the fact that the improvements in the pulmonary function parameters within eight weeks of use of incentive spirometer is not sufficient enough to bring about massive improvement in the functional capacity in these patients. If the study had lasted longer, the relationship might have been stronger as greater changes in the pulmonary function parameters may bring about more improvement in the functional capacity in these patients. There is dearth of literature on the relationship between pulmonary function and functional capacity in patients with T2DM. The no significant correlation between the pulmonary function parameters and glycemic control may also be explained by the duration of training with incentive spirometer in these patients. Longer training with incentive spirometer (more than eight weeks) by patients with T2DM may result in significant negative correlation between the pulmonary function parameters and

glycemic levels as both parameters were improving significantly with IS training. Shah *et al.*[13] and Yadav *et al.*[44] also reported that there is no correlation between pulmonary function and glycemic levels. They argued that glycated Haemoglobin (HbA1c) level is an indicator of glycemic control for a short period of one to two months and that short duration of hyperglycemia was not adequate to influence PFTs. However, Davis *et al.*,[14] Jamatia *et al.*[45] and Singh *et al.*[46] observed a negative correlation between pulmonary function and glycemic levels, indicating that a poor lung function was associated with a poor glycemic control. These authors did not explain the exact pathophysiological mechanism for this association. Concerning DOD, Shah *et al.*,[13] Yadav *et al.*[44] and Singh *et al.*[46] established that there was no relationship between pulmonary function and DOD, hence explaining that DOD did not affect pulmonary function. On the other hand, Davis *et al.*[14] in their community-based cohort documented that pulmonary function decreased at an average of between 1.1% and 3.1% per year.

Conclusion

IS brought about significant improvements in the cardiopulmonary function, functional capacity and glycemic control in patients with T2DM. There was no relationship between pulmonary function parameters (FVC and FEV_1) and functional capacity although a weak relationship exists between PEFR and functional capacity as well as DOD. There was also no relationship between pulmonary function parameters and glycemic control.

Relevance of the Study

Based on the findings of this study, it is hereby advocated that IS should be included as a vital aspect of cardiorespiratory physiotherapy in the management of patients with T2DM. More so, it is a cost effective, simple and non-invasive tool that can easily be used by patients.

Implication for Further Studies

The long-term efficacy of IS training on cardiopulmonary parameters, functional capacity as well as blood glucose levels in patients with T2DM should be researched.

Conflict of Interest

The authors declare no competing interest, financial or otherwise.

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Author Contributions

Happiness A. Aweto and Bosede A. Tella were responsible for conception and design of the study, analysis and interpretation of data, revising the manuscript critically and approval of the final version of the manuscript. Esther O. Obikeh was responsible for acquisition of data as well as drafting and revision of the manuscript.

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The effect of the type of foam pad used in the modified Clinical Test of Sensory Interaction and Balance (mCTSIB) on the accuracy in identifying older adults with fall history

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Background: The type of foam pad used in the modified Clinical Test of Sensory Interaction and Balance (mCTSIB) influences the accuracy with which elderly fallers are identified. Two types of foam are commonly used in practice: Airex and Neurocom foam.
Objective: The aim of this study was to assess the accuracy with which elderly fallers can be identified when the Airex foam and Neurocom foam are used in the mCTSIB.
Methods: One hundred eighty-four elderly participants with a mean age of 69 years were classified into faller and nonfaller groups based on their 12-month fall history. Balance stability was measured under four conditions of the mCTSIB for 120 s each: standing on a floor or a foam pad with their eyes open or eyes closed. The time needed to maintain stability was measured by a stopwatch, and postural sway characteristics were measured using an acceleration-based system. Comparisons between groups were performed by two-way mixed ANOVA. The accuracy of differentiating elderly fallers from nonfallers with different foam types was evaluated using receiver operating characteristic curve (ROC) analysis. The time to maintain stability under four conditions of the mCTSIB (composite score) and under two conditions on the foam (foam score) were used for the ROC analysis.

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Results: The results showed that the nonfallers required more time to maintain stability and had a smaller sway area than the fallers ($p < 0.001$). The foam led to a larger difference between groups, suggesting the use of foam in examining the risk of falls. The Airex and the Neurocom foam pads led to a large area under the curve (0.93 to 0.95) in identifying elderly fallers and nonfallers when the composite and foam scores were used. A cutoff score of 447/480 s for the composite score and 223/240 s for the foam score yielded a posttest accuracy of 88% to 89%, with a sensitivity of 0.80–0.92 and specificity of 0.88–0.95.
Conclusion: In conclusion, Airex and Neurocom foam can be used interchangeably with guidance in the mCTSIB, as they led to the accurate identification of elderly fallers among older persons who could walk and live independently in the community.

Keywords: Falls; older adult; postural stability; sensory integration.

Introduction

Elderly persons frequently fall, and falls can result in minor or major life-threatening injuries that subsequently lead to a decline in their health-related quality of life.[1] The ability to screen for elderly people at high risk of falls can guide the development of a suitable fall prevention program. Many factors lead to an increased risk of falls in elderly persons, including balance problems, environmental hazards (e.g., poor lighting and an unsafe walking surface),[2,3] cognitive impairment,[4] and the long-term usage of medications affecting balance.[5] Among these factors, the impairment of the sensory systems used for balance is one of the important factors related to falls in elderly persons.[6,7] Previous studies have shown that age-related declines in the function of the vestibular system,[8] visual impairments,[6,9] impaired somatic sensation,[7,10] and impairment of the sensory systems used for balance were associated with a high risk of falls.[11,12]

A clinical test of sensory interaction and balance (CTSIB) was developed to assess the role of different sensory systems in balance control. The CTSIB consists of six balance conditions: standing on an unstable surface or a stable surface with eyes open, eyes closed, or a visual-conflict dome.[13] Each condition lasts for 30 s and is repeated 3 times. An unstable surface is used to determine the ability of the central nervous system (CNS) to maintain stability when somatosensory input is an unreliable source of information. Standing with the eyes closed tests one's ability to use proprioceptive or vestibular input for balance control. Wearing a visual-conflict dome tests one's ability to select a reliable type of sensory input when the sensory information about the body's position received from different sources is conflicting.[13] The total duration required to maintain stability in all six conditions of the CTSIB has been used to identify elderly fallers (mean age of 80.5 years, SD = 9.0), with a cutoff value of less than 260 s, a maximum duration of 540 s, a specificity of 0.90, and sensitivity of 0.44.[14] This criterion of CTSIB for identifying elderly fallers is not practical in clinical practice, as it takes 9 min of quiet standing to obtain the results.[15] Moreover, some test conditions in the CTSIB seem to be redundant; for example, the visual-conflict dome condition results were not different from those from the standing on unstable surface conditions.[16]

The modified CTSIB (mCTSIB) takes less time to administer than the original CTSIB due to the exclusion of 2 dome conditions, so it only lasts 4 min. The mCTSIB has been used to assess sensory interactions used for balance in adults (age range 22–83 years) with vestibular disorders[16] and in patients with multiple sclerosis.[17] The mCTSIB is preferable for use in the clinic due to its ease of use.[15] All 4 conditions of the mCTSIB (standing on a floor or a foam pad with eyes open or with eyes closed) demonstrated excellent test–retest reliability (ICC = 0.91 to 0.97)[18] and moderate to high intrarater reliability (kappa = 0.31 to 0.81).[19] In order to identify fallers, a previous study showed that the measurement of the center of mass (CoM) acceleration during the mCTSIB test could identify fallers among patients with idiopathic Parkinson's disease, suggesting that the mCTSIB was a valid clinical test to identify elderly people with neurological pathologies with a history of falls.[20] In addition, scores on the sensory orientation test (e.g., standing on firm surface with eyes open, on foam and incline surfaces with eyes closed) demonstrated high accuracy in identifying elderly fallers.[12] However, another study reported that the measurement of center of pressure sway speed during the mCTSIB

test could not predict fall in community-dwelling elderly peoples who are active and independent.[21] Therefore, it is a challenge to identify fallers among older people who are active and independent in the community using a simple clinical tool such as the mCTSIB.

The selection of a proper foam pad to be used in the mCTSIB test is also important for obtaining and interpreting accurate test results. A variety of foam types have been used among different studies of sensory interactions used for balance.[15,22,23] Foam pads with different densities and Young's modulus yielded different balance test results.[22,24] Foam with proper density allowed the foam to comply with the body weight and trigger body sway in the appropriate amount, while foam with the highest Young's modulus can be used to differentiate body sway between young and older adults better than foams with lower Young's modulus.[22] The Neurocom foam (Natus Incorporated, Inc.) and Airex foam (Airex AG, Inc.) have been widely used in clinical and laboratory settings.[20,22] Both of them have yielded fair to good reliability (ICC $(3,1) = 0.41$ to 0.81) in assessing balance with the mCTSIB test,[25] but the costs of these foam pads are vastly different (the Airex foam is 160$USD, the Neurocom foam is 970$USD). A comparison of the foam pads' clinical properties may provide information useful for selecting a cost-effective foam pad to screen for elderly fallers in the community. However, there is no study available at present that examines the accuracy of different foam types in identifying elderly fallers. Therefore, this study aimed to assess and compare the accuracy of using Airex and Neurocom foam pads to differentiate elderly fallers from nonfallers. Regarding to similar physical properties of Airex and Neurocom foam pads, we hypothesized that both types of foam would demonstrate similar accuracy in identifying older persons who had a history of falls.

Methods

Study design

This observational study was approved by the Human Research Protection Committee in Faculty of Physical Therapy, Srinakharinwirot University in Thailand (code: PTPT2017-010, approved date: 22 July 2017). Data collection was performed in the suburban communities in Pathum Thani Province in Thailand from July 2017 to July 2018.

Participants

Male and female elderly individuals aged over 60 years, who could stand independently without assistive devices for at least 2 min, were able to walk independently with or without walking aids for at least 6 m and did not have a history of neurological diseases were recruited from suburban communities in Pathum Thani Province in Thailand. Individuals were excluded from this study if they met the following criteria: had signs or symptoms of vertigo, nystagmus, blindness, uncontrolled cardiovascular conditions, or neuropathy; had a severe musculoskeletal problem affecting balance performance; or were taking medications affecting balance (i.e., sedatives and hypnotics, antidepressants, and benzodiazepines).[5] In addition, elderly individuals who had comprehension problems indicated by a score of less than 24 out of 30 on the Mini-Mental State Examination-Thai version 2002 (MMSE-Thai 2002)[26] and had a body mass index (BMI) of equal to or higher than $30\,\mathrm{kg}\cdot\mathrm{m}^{-2}$ were excluded from this study. Informed consent was obtained from each participant before they participated in the study.

One hundred eighty-four was the target sample size of elderly persons for this study. The mean and standard deviation of the time to maintain balance with the mCTSIB test that were reported in a previous study[14] were used to calculate the sample size. The participants were classified into non-fallers and fallers (i.e., persons who had fall at least once) based on their 12-month fall history. In this study, a fall was defined as coming to rest inadvertently on the ground or other lower level, excluding intentional change in position to rest in furniture, wall or other objects.[27] To meet the target sample size, 325 elderly persons were recruited. Sixty-four persons were excluded from the study because they had neurological diseases (19 persons), had severe musculoskeletal problems (28 persons), were taking medications affecting balance (17 persons), or had personal issues that were not related to health problems (77 persons).

Procedures

The participants were interviewed about their medical history, current medication use, 12-month fall history, ability to walk, and use of a walking aid. Manual muscle tests for the hip, knee, and ankle muscles were performed to characterize lower

limb muscle strength. The fear of falling of each participant was determined using the falls efficacy scale (FES). The total score of the FES ranges from 0 to 100. A higher FES score indicates lower confidence in performing daily activities and a higher fear of falling.[28]

Two types of foam pads, the Neurocom and Airex foam pads, were used in the foam conditions in the mCTSIB. The dimensions of the Neurocom and Airex foam pads were 0.46×0.46 m and 0.50×0.41 m, respectively. Two pieces of the Airex foam pads were stacked to ensure that the two types of foam had similar thicknesses (0.12 m for the Airex and 0.13 m for the Neurocom foam). Volume and mass of the foam pad were used to calculate density. Densities of a stacked of two-pieces Airex foams and one piece of the Neurocom foam had density of $55\,\mathrm{kg \cdot m^{-3}}$ and $60\ \mathrm{kg \cdot m^{-3}}$, respectively.

A fabric cover was used to cover each type of foam pad to blind the participants to the foam type. Prior to the data collection, an examiner (BK) demonstrated the test, and the participants were allowed to practice the test until they became familiar with each test condition. All the participants underwent the four conditions of the mCTSIB, including standing on the floor or on foam with their eyes open or eyes closed. Our pilot study showed that elderly participants who met our inclusion and exclusion criteria could stand for more than 30 s but not longer than 120 s. Therefore, the allowed duration for each condition was extended from 30 s, as indicated in the original protocol, to 120 s.[16] The participants were asked to maintain stability in a standing posture: standing barefoot with their feet shoulder width apart and arms crossed, touching their shoulders for as long as possible, for up to 120 s. Each condition of the mCTSIB test was performed once, resulting in a total of 6 conditions: (1) eyes open and standing on the floor, (2) eyes closed and standing on the floor, (3) eyes open and standing on the Neurocom foam pad, (4) eyes closed and standing on the Neurocom foam pad, (5) eyes open and standing on the Airex foam pad, and (6) eyes closed and standing on the Airex foam pad. Each participant performed a total of six trials in a random order using computer-generated randomization. A few minutes of rest between trials was allowed, in which the participated sat, stretched their lower limb muscles and walked a few meters to prevent fatigue. To ensure participant safety, vital signs and blood pressure were monitored prior to and after the test, and closed guarding during the tests was administered. The test was discontinued if any of the following criteria were met: the participant left the study before completion or had signs and symptoms such as dizziness, confusion, vomiting, angina or chest pain at rest, a blood pressure higher than 160/100 mmHg at rest, or a heart rate of more than 100 bpm at rest. The test was stopped immediately if needed. The total testing duration for each participant was approximately 40 min. According to those criteria, none of participants was discontinued from the test.

The time required to maintain stability in the standing posture and postural sway characteristics of the participants were measured during the mCTSIB. A stopwatch was used to record the time from when a researcher (BK) said "start" to when the participant could not maintain the starting position. A trial was terminated if the participant's feet or arms changed positions, his or her eyes opened during the eyes closed condition, he or she required manual assistance to prevent a fall,[15] or the maximum time limit was reached. The measurement of postural sway characteristics was used with an acceleration-based equipment and ISway software plug-in (APDM, Mobility Lab$^{\mathrm{TM}}$).[29] Prior to each testing condition, an OPAL inertial sensor strapped at the fifth lumbar vertebra (L5). The acceleration signals were collected at a sampling rate of 50 Hz for further processing by the software plug-in. The evaluation was performed in the same setting, and all participants received the same verbal instructions. Our pilot study was performed in 10 elderly persons and the reliability of the measurement was analyzed using an intraclass correlation coefficient, ICC (2,1). The pilot results showed an excellent intrarater reliability of a stopwatch measurement (ICC = 0.998, 95% CI = 0.996–0.999, $p < 0.001$) and the inertial sensor-based assessment (ICC = 0.999, 95% CI = 0.996–0.999, $p < 0.001$) of time required to maintain stability.

Data Analysis

The demographic and clinical characteristics of the participants were assessed using descriptive statistics. The baseline characteristics between the fallers and nonfallers were examined using a two-sample t-test. The mean and standard deviation of the time required to maintain stability and

postural sway for each group were estimated for each test condition. The software plug-in (APDM, Mobility Lab^{TM}) contained algorithms for estimation of the CoM position and automatically computed postural sway measures. The area enclosed by the acceleration path in the medial-lateral plane (sway area) ($m^2 \cdot s^{-4}$) and root mean square of acceleration ($m \cdot s^{-2}$) in the anteroposterior (RMS-AP) and mediolateral directions (RMS-ML) were used to characterize the postural sway of the participants. The raw trace of the CoM acceleration in the horizontal plane during the test were plotted using a software, MALTAB^{TM} and representatives of a faller and a nonfaller participant in the mCTSIB using the Neurocom foam and the Airex foam were selected (Fig. 1). The effect of testing

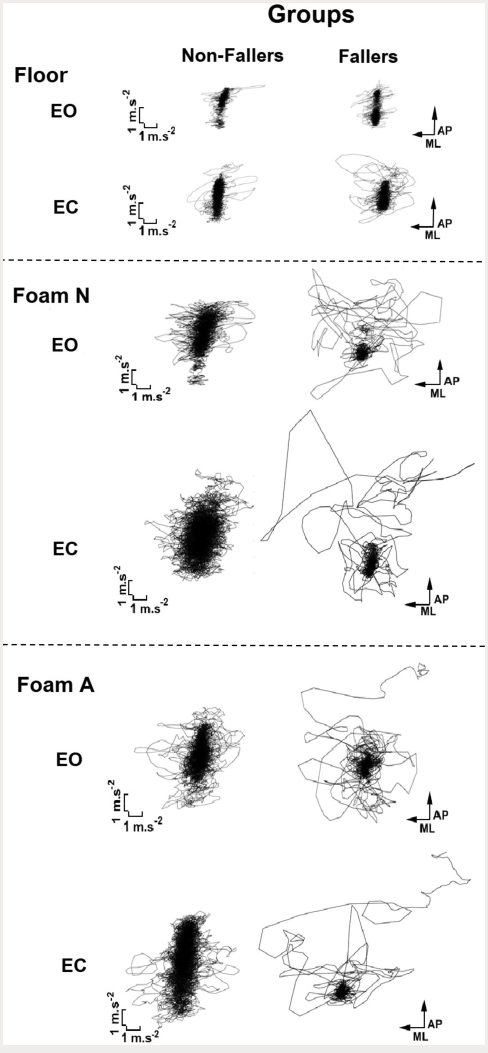

Fig. 1. The raw trace of center of mass acceleration in the horizontal plane for two representative participants in the mCTSIB using the Neurocom foam (Foam N) and the Airex foam (Foam A). AP: anteroposterior, ML: mediolateral.

conditions (4 conditions) and groups (faller and non-faller) of each foam on balance performance was examined using a 2-way mixed ANOVA. Interaction effect of conditions and groups was analyzed to determine whether the testing condition influenced balance performance differently between faller and nonfallers. Bonferroni correction was used as *post hoc* tests. Statistical significance was set at a p-value of less than 0.05. The analysis was performed with IBM SPSS® Statistics, version 25 (ICN: 7937000).

The amount of time a participant could stand in each test condition was used to calculate the total time required to stay in the standing posture. Two methods for calculating the total time were used. The first method involved the calculation of a composite score, which was defined as the sum of the time required to maintain stability under the four conditions of the mCTSIB test; the maximum total score was 480 s (4 conditions × 120 s per condition). The second method involved the calculation of the foam score, which as defined as the sum of the time required to maintain stability when standing on foam in the foam conditions. The total possible score for the foam score was 240 s (2 conditions × 120 s per condition). The composite and foam scores were compared between 2 foam types and 2 groups of elderly persons using two-way mixed ANOVA. The level of statistical significance was set at a p-value of less than 0.05.

The accuracy of the foam used in the balance test in differentiating fallers and nonfallers was analyzed using receiver operating characteristic (ROC) analysis.[30] The cutoff points of the foam score that maximized the sensitivity and specificity were chosen. Likelihood ratios were calculated to determine the strength of the foam test.

Results

One hundred eighty-four elderly persons, participated in this study, and 92 persons were in each of the two groups (fallers and nonfallers). None of them were taking medications affecting balance. The participants' demographics, clinical characteristics, and fall histories are summarized in Table 1. The faller and the nonfaller groups had similar demographic and clinical characteristics ($p > 0.050$), except for the FES scores ($p = 0.010$), where the faller group showed significantly higher scores (Table 1).

Table 1. Participants' demographic and clinical characteristics.

Demographic and characteristics		Nonfallers ($n = 92$)	Fallers ($n = 92$)	P-value
Age (years)		68.2 ± 5.6	69.5 ± 5.8	0.109
Weight (kg)		66.1 ± 6.1	67.87 ± 6.3	0.055
Height (cm)		166.28 ± 5.9	165.35 ± 5.5	0.271
BMI (kg/m^2)		23.81 ± 2.2	24.75 ± 2.6	0.074
Sex (%)	Female	55.4	58.7	
	Male	44.6	41.3	
Number of falls (%)	0	100.0	0.0	
	1	0.0	38.0	
	More than 1	0.0	61.9	
Fall locations (%)	Indoor	0.0	42.4	
	Outdoor	0.0	57.6	
Types of falls (%)	Slip	0.0	30.4	
	Trip	0.0	47.8	
	Postural transition	0.0	21.7	
Taking medications (%)	Antihypertensive drugs	13.0	7.6	
	DM medications	7.6	8.6	
Walking aids (%)	Cane	4.3	17.3	
	Walker	2.1	5.4	
LE muscle strength (/5)		4	4	—
FES score		67.5 ± 6.8	94.7 ± 5.5	0.001*
MMSE-Thai 2002 (/30):		27.1 ± 1.9	26.6 ± 1.9	0.096

Notes: Values are shown as the mean ± SD, except the lower extremity (LE) muscle strength is presented as the median. LE strength refers to the hip, knee, and ankle muscle strength. kg = kilogram; cm = centimeter; BMI = Body mass index; bpm = beats per minute; MMSE-Thai 2002 = The Mini Mental State Examination-Thai version 2002.
* = significant difference between fallers and nonfallers at $p < 0.05$.

Time to maintain stability was significantly affected by groups (fallers and nonfallers) ($F_{(1,182)} = 160.05$, $p < 0.001$) and conditions, six combinations of two visual conditions and three surface conditions ($F_{(2.57,467.53)} = 55.89$, $p < 0.001$). In addition, this parameter was significantly affected by an interaction effect of conditions and groups ($F_{(2.57,467.53)} = 8.62$, $p < 0.001$). The differences in the time required to maintain stability between the faller and nonfaller groups were evident during all testing conditions ($p < 0.001$), except the eyes open while standing on the floor condition ($p = 0.620$) (Fig. 2). The major differences in the time required to maintain stability between the faller and nonfaller groups were found between the conditions in which the participants stood on the foam (Fig. 2). These findings were similar for the Neurocom and Airex foam conditions (Fig. 2). The CoM acceleration trajectories during standing in the mCTSIB conditions for a representative faller and nonfaller are shown in Fig. 1. The magnitudes of acceleration were larger and more dispersed in the fallers compared to the nonfallers for all mCTSIB conditions and all types of foam, except when the participants stood on the floor (Fig. 1). The sway area was significantly

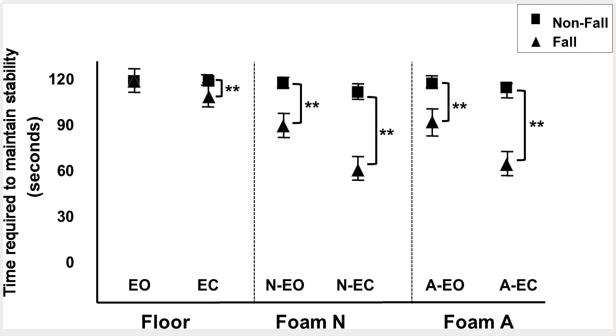

Fig. 2. Comparison of the time required to maintain stability in each condition between the fallers and nonfallers. Values are shown as the mean ± SD, EO; floor - eyes opened, EC; floor - eyes closed, N-EO; Neurocom foam - eyes opened, N-EC; Neurocom foam eyes closed, A-EO; Airex foam - eyes opened and A-EC; Airex foam eyes closed. **Significant difference between fallers and nonfallers at $p < 0.001$.

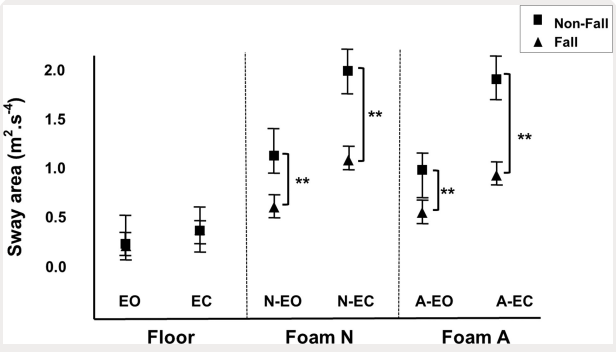

Fig. 3. Mean sway area in the mCTSIB conditions between faller and nonfaller groups when using the Neurocom and Airex foam. Values are shown as the mean ± SD, EO; floor - eyes opened, EC; floor - eyes closed, N-EO; Neurocom foam - eyes opened, N-EC; Neurocom foam eyes closed, A-EO; Airex foam - eyes opened and A-EC; Airex foam eyes closed. **Significant difference between fallers and nonfallers at $p < 0.001$.

Table 2. Means and standard deviations of composite and foam scores in the faller and nonfaller groups.

	Fallers ($n = 92$)		Nonfallers ($n = 92$)	
Types of score	Mean ± SD	Range	Mean ± SD	Range
Composite score (/480 s)				
Neurocom	382 ± 64	220–470	471 ± 25*	325–480
Airex	388 ± 63	223–471	474 ± 21*	332–480
Foam score (/240 s)				
Neurocom	152 ± 54	15–230	231 ± 25*	85–240
Airex	159 ± 53	18–231	234 ± 21*	92–240

Notes: *Significant difference in the composite scores and foam scores between the fallers and nonfallers at $p < 0.001$. *N*: number of participants, SD: standard deviation.

affected by groups ($F_{(1,182)} = 15.65$, $p < 0.001$) and conditions ($F_{(2.57,410.07)} = 184.96$, $p < 0.001$). In addition, this parameter was significantly affected by an interaction effect of conditions and groups ($F_{(2.57,410.07)} = 115.54$, $p < 0.001$). Significant differences in the sway area between groups were found when the participants stood on the foam ($p < 0.001$) but not when they stood on the floor ($p = 0.615$ to 0.862) (Fig. 3). In addition, the RMS-AP and the RMS-ML of the CoM acceleration were different between the faller and nonfallers ($p < 0.001$).

The mean and standard deviation of the composite and foam scores are shown in Table 2. There was a significant effect of group ($p < 0.001$) without an interaction effect ($p = 0.053$), indicating that the faller group had a significantly lower composite score than the nonfaller group ($p < 0.001$) when either the Neurocom foam or Airex foam was used in the mCTSIB ($p < 0.001$). Consistent results were found for the foam scores; the faller group had significantly lower foam scores than the nonfaller group when using either foam ($p < 0.001$). The composite and foam scores may be used to reveal differences in balance ability between the faller group and the nonfaller group. Therefore, both scores were used in the receiver operating curve (ROC) analysis.

The Neurocom and the Airex foam yielded high accuracy in differentiating fallers from nonfallers, with a large area under the ROC curve (0.93 to 0.95) when using the composite score and foam score. High sensitivity (0.80 to 0.92) and high specificity (0.88 to 0.95) were obtained at a cutoff score of 447 out of 480 s and 223 out of 240 s for the composite score and the foam score, respectively (Table 3).

Table 3. Area under the curve, cutoff score, sensitivity, specificity, likelihood ratio and percentage accuracy of foam score.

	Composite score		Foam score	
Measures	NeuroCom	Airex	NeuroCom	Airex
AUC (95% CI)	0.94 (0.90–0.97)	0.95 (0.92–0.98)	0.93 (0.90–0.97)	0.95 (0.92–0.98)
Cutoff score	447/480	447/480	223/240	223/240
Sensitivity (95% CI)	0.89 (0.81–0.93)	0.80 (0.80–0.81)	0.92 (0.87–0.98)	0.90 (0.86–0.98)
Specificity (95% CI)	0.89 (0.83–0.95)	0.95 (0.94–0.95)	0.88 (0.81–0.95)	0.92 (0.82–0.95)
Positive LH	8.17	14.18	7.73	11.86
Negative LH	0.12	0.21	0.09	0.11
Posttest accuracy (%)	89.13	88.00	90.00	91.00

Notes: AUC: area under the curve, CI: confidence interval, posttest accuracy was calculated using the selected cutoff score, LH: likelihood ratio.

Discussion

The aim of this study was to compare the accuracy of using Airex and Neurocom foam pads to differentiate elderly fallers from nonfallers. The results demonstrated that both Airex and Neurocom foam are accurate in identifying elderly persons with a history of falls. Our findings also supported the use of foam in examining the risk of falls because the foam conditions showed larger differences in balance control between fallers and nonfallers than the floor conditions. The between-group differences in the time required to maintain stability and sway characteristics that were evident only in the foam conditions were similar to those reported in previous studies in which different methods (e.g., center of pressure balance assessment) were used to determine the duration required to maintain balance and postural sway.[11,31,32] The similarity of the clinical properties (time required to maintain stability and sway characteristics) between the Airex foam and the Neurocom foam may be explained by the similarity in their densities (55 $kg \cdot m^{-3}$ and 60 $kg \cdot m^{-3}$, respectively), Young's modulus elasticity values (0.26 and 0.14 megapascal, respectively), and their size.[22,25] These properties cause the foam to be an unstable support surface and trigger an individual to use his or her vestibular system to control his or her balance.[24] Because the mechanical properties of the two types of foam are similar, the balance control system of a participant is challenged to the same extent when he or she stands on either type of foam.

In addition to density and Young' s modulus, thickness of foam pad (a stack of 2 Airex foams) may cause the Airex foam in this study to produce large postural sway and reveal similar test results as compared to the Neurocom foam. A previous study in healthy adults reported that one Airex foam could not differentiate postural sway between standing on floor and on foam, while a blue latex pad and an air-filled circular pad could.[33] The thickness of one Airex foam may cause the foam to become a floor-like surface, thus reducing the ability to produce unstable surface. Another study focusses on the effect of foam on postural sway in participants of different weights.[34] One-piece Airex foam produced largest sway in persons with less than 90-kilogram body weight,[34] suggesting that one piece of this foam had low ability to produce sway when it was used in a person with heavy weight. In contrast, our current study used a stack of two-piece Airex foam pads (0.12 m thickness), thus, allowing the Airex foam to appropriately produce unstable condition for assessing balance and screening falls in a comparable manner to the Neurocom foam.

The cutoff scores for the Neurocom and the Airex foam in the mCTSIB provided high sensitivity and specificity when the composite score and foam score were used in the ROC analysis. The high positive likelihood ratio, which was greater than 5, and the low negative likelihood ratio, which was not more than 0.2, confirms that the strength of the test is very good.[35] These results indicated a high probability of identifying elderly fallers and a high probability that elderly nonfallers will screen negative when these foam pads are used in the standing balance test. The cutoff scores presented in this study (447 out of 480 s for the composite score and 223 out of 240 s for the foam score) differed from the score reported in a previous study (260 out of 540 s).[14] However, a specificity of over 90% for identifying fallers was reported in both studies.[14] The discrepancy in the cutoff scores between the present and the previous study is due to differences in the number of conditions, the repetitions of the test performed, and the duration of the trial performed for each condition. In the previous study, three repetitions of the six conditions of the CTSIB (30 s each condition) were administered, whereas the present study allowed no repetitions of the foam conditions in the mCTSIB, and each condition lasted for 120 s. This study demonstrated that the mCTSIB test was accurately identify fallers, while the previous study found that the mCTSIB failed to predict fall in community-dwelling elderly people.[21] Disagreement in findings in both studies could be due to the differences in testing duration. As oppose to 2-min trial in current study, the 20-s trial used in the previous study may not be sufficient to differentiate balance ability between elderly who prone and not prone to fall in those who were active elderly.

Time constraints and the ability of the participants can be used to guide the selection of either the composite score or the foam score in practice. To use the composite score, 8 min of testing are required to complete the four test conditions (standing on the floor or on foam with two visual conditions). Not only is standing quietly for 8 min time consuming, but it can also lead to physical fatigue. However, the conditions in which the participant stands on a floor with eyes open or eyes

closed can be used to ensure individuals' safety. Fear of falling[36] and visual dependence[37] in elderly people can generally increase the risk of an individual losing his or her balance. This characteristic was also observed in the present study, where the elderly fallers had higher FES scores than the nonfallers did. Therefore, starting the test with the standing on a floor condition, which is a less challenging task, may help to reduce the participant's fear of falling when performing the mCTSIB, especially for those who may not feel comfortable with their eyes closed. In contrast, it takes less time (4 min) to calculate the foam score, as only the conditions in which the participant stands on the foam with eyes open or eyes closed are performed. However, to use the foam score, the therapist should ensure that the participants are able to stand independently with their eyes open and eyes closed prior to asking them to stand on the foam. Moreover, the foam pad used in this study was covered with the fabric cover. Different materials of fabric cover may influence the testing difficulty and hence this aspect needs to be addressed further in the future study.

This study has limitations. The fall-related information was acquired retrospectively; thus, this information may be subjected to recall bias. However, the fact that our participants were able to provide details on their falls (locations and types of falls) indicated that their fall history information was fairly reliable. The generalization of the results is limited to elderly persons who have no neurological diseases and are able to walk independently with or without walking aids over at least for a short distance (6 m). Future studies should also be carried out in frail elderly individuals. In this study, although a single testing for each condition of mCTSIB was administered, participants were allowed to practice until they are familiar with the testing condition. This could also be a limitation in the clinical practice where there was not sufficient time for assessment. However, conducting an additional trial of balance tests and using the average of several trials would be better for reliability of outcome assessment. Having a foam pad that is more accessible and less expensive than the foam pads used in this study may increase the likelihood that this screening test is used in community practices. Therefore, a foam pad needs to be developed domestically, and additional studies need to be conducted to evaluate its clinical properties.

Conclusion

In conclusion, Airex foam and Neurocom foam can be used interchangeably with strict guidance when administering the mCTSIB test to identify elderly individuals who have a history of falls. Preparation of the equipment (two pieces of the Airex foam with fabric cover), assessment procedure, and the selection of scoring methods should be considered for clinical application of this test. Cutoff scores from 2 methods of analysis, including the total time required for the four conditions of the mCTSIB (composite score) and the total time required for only two foam conditions (foam score), can be used to identify elderly fallers with high accuracy. The cutoff values are 223/240 s for the composite score and 447/480 s for the foam score.

Conflict of Interest

There were no conflicts of interest. No authors have financial interest in any of the research materials or equipment used in this study.

Author Contributions

Conception and design of study: Rumpa Boonsinsukh; acquisition of data: Bodin Khumnonchai; analysis and/or interpretation of data: Nithinun Chaikeeree, Bodin Khumnonchai. Drafting the manuscript: Bodin Khumnonchai, Nithinun Chaikeeree; revising the manuscript critically for important intellectual content: Rumpa Boonsinsukh, Nithinun Chaikeeree.

All authors approved the version of the article to be published.

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Comparison of Kristjansson Respiratory Score and Wang Respiratory Score in infants with bronchiolitis in a hospital emergency department

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Objective: Several respiratory scores have been created to evaluate bronchiolitis' severity level, but it is still not clear which is the best score. The aim of this study is to compare the Wang Respiratory Score (WRS) and the Kristjansson Respiratory Score (KRS) in the setting of an emergency room.

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Methods: We performed a prospective observational study with 60 infants with bronchiolitis admitted to a paediatric emergency department. For both scores, we assessed inter-rater reliability between two different health professionals (physician and physiotherapist), internal consistency, and correlation with SpO_2 testing the intraclass-correlation coefficient (ICC), weighted kappa, Cronbach α coefficient and Spearman tests, respectively.
Results: The inter-rater reliability was higher in KRS (ICC 0.79) and the Cronbach α and weighted kappa had similar values in KRS versus WRS. The correlation between the KRS/WRS and SpO_2 was poor/moderate upon admission and discharge for the first observer and the second observer.
Conclusions: While the internal consistency was similar in both scores, inter-rater reliability of KRS was higher than WRS, which allows us to conclude that it would have more consistent results when used to assess bronchiolitis' level of severity by health personnel in a busy hospital emergency room.

Keywords: Bronchiolitis; infants; symptom assessment; severity score.

Introduction and Objectives

Acute bronchiolitis, an inflammation of the lower respiratory tract, is one of the most common respiratory diseases affecting infants and it imposes an enormous burden on healthcare resources worldwide.[1] In most cases, however, it is a self-limited condition and one that can be treated at home.[1–3] In fact, only 1–3% of children need to be hospitalized.[4,5] Aspects such as clinical history, respiratory parameters, risk factors and oxygen saturation levels, are used by physicians in emergency departments to distinguish between a mild, moderate or severe case of bronchiolitis, in order to decide if hospitalization is necessary.[3]

An accurate assessment of the level of severity is thus crucial in the case of bronchiolitis for two main reasons: (a) to decide on the need for close monitoring and hospitalization; and (b) for research purposes, to allow comparisons between study groups. Several respiratory scores have been created to assess the level of severity and progression of the disease as well as the efficacy of therapeutic interventions. Examples of such scores are the Tal Score,[6] the Modified Tal Score (MTS),[7] the Respiratory Distress Assessment Instrument (RDAI),[8] the Wang Respiratory Score (WRS)[9] and the Kristjansson Respiratory Score (KRS).[10] Most of these scores use the main clinical signs of bronchiolitis for assessment of severity level, not being clear which is the best score and which should be used in a given setting.

Currently, the RDAI is the score most commonly used by physicians in a clinical trial setting, but although it has adequate inter-rater reliability, the construct validity ranges from poor to moderate. In addition, its use by health professionals can be challenging,[11] as it is difficult to evaluate the presence of wheezing throughout the respiratory cycle at high respiratory rates.

In the context of this study, we have decided to examine WRS[9] and KRS,[10] scores specifically developed to assess bronchiolitis' severity level. The motivations behind this choice were threefold: (a) the acknowledged need for a score easy to use in a hospital emergency by health professionals other than physicians; (b) the advantage of being easy to apply in emergency departments; and (c) the fact that these scores had been designed on the basis of specific physical parameters common in children with acute lower airway infections, such respiratory frequency, chest recessions and wheezing.[12,13]

Both scores are very similar in terms of the parameters they include (the difference being that KRS additionally includes 'skin color'), and had never been studied/used by different health professions. Chin and Seng[14] study was the first which compared these two scores, but included only physicians. The purpose of this study is to compare WRS and Kristjansson Score and establish the inter-rater reliability and internal consistency when used by physicians and a physiotherapist.

Materials and Methods

Study design and population

This was a prospective observational study in a convenience sample of Portuguese infants admitted with acute bronchiolitis. Data were collected between January and May of 2010, in the paediatric emergency department of the Centro Hospitalar Universitário São João, Porto (CHUSJ), a tertiary

care hospital. Inclusion criteria were: all children aged less than 24 months diagnosed with bronchiolitis by a physician from one of two different emergency teams working on Monday and Wednesday (from 4 p.m. to 2 a.m.) or Saturday and Sunday (from 9 a.m. to 2 a.m.) in weekend. Children with history of prematurity, underlying cardiopulmonary disease or immunodeficiency were not excluded from the study, since the aim of this study was to evaluate the performance of respiratory scores in defining the level of respiratory distress, regardless of the presence of risk factors. Exclusion criterions were as follows: all children with severe hypoxemia, needing oxygen supplementation or needing invasive or non-invasive ventilation. These are all criteria for inpatients with bronchiolitis and thus not compatible with this study focused on outpatients only.

Assessment

Two observers (one physician and one physiotherapist) independently assessed all children using both WRS (Table A.5) and KRS (Table A.6) in the paediatric emergency department. This was completed upon admission and discharge within a time frame of approximately 15 min between observations. The first assessment was always made by the physician, being the physiotherapist the second before the medical treatment starts. Before the start of the study, all observers were briefed on the purpose of the study and how to fill in each respiratory score. The first observer (from a group of 24) was a physician, a paediatrician or a resident in paediatrics, and the second observer was one physiotherapist, the main investigator. The physician's years of experience were not taken into account and their inter-rater reliability was based in the Chin and Seng[14] study, when distributing the cases in the emergency department and each observer was blinded to the other observer's assessment. The children were evaluated in a calm environment, while awake and not crying.

The WRS is a 4-item score which includes respiratory rate, wheezing, chest retraction and general condition. Each clinical sign is scored from zero to three except for the general condition, which is scored zero for normal, or three for irritability or lethargy. The total score ranges from 0 to 12.[9] The KRS is a 5-item score which includes respiratory rate, chest recessions/retractions, breath sound/wheezing, skin color and general condition. Each clinical sign is scored from zero to two and the total score ranges from 0 to 10.[10] Both scores establish severity as the total score increases.

The respiratory rate was determined by counting the number of breath cycles during 60 s. Chest recessions/retractions, skin color and general condition were assessed by observation and breath sounds/wheezing with a stethoscope.

The SpO_2 was recorded in all children, while breathing room-air, with a pulse-oximeter (Dinamap DPC301N-PR, GE Medical Systems Information Technologies, Inc. Milwaukee, USA). The maximum SpO_2 was determined both upon admission and discharge, after the pulse-oximeter had been branched for at least two minutes. If the SpO_2 was below 92%, supplemental oxygen was provided to the patient.

For each patient, additional baseline data were collected, including demographic data, personal and family past medical history. This comprised of medical diagnosed food allergies, rhinitis, asthma and atopic dermatitis, exposure to tobacco smoke, contact with other children, parents schooling level, and medication administered in the emergency department, including supplemental oxygen.

This study was approved by the Ethics Committee of the CHUSJ, Porto. It also complied with the Helsinki Declaration and the current national legislation. Verbal and written consent was obtained from caregivers on behalf of all children enrolled in this study.

Statistical analysis

Data were analyzed using IBM SPSS Statistics version 23.0. A Kolmogorov–Smirnov normality test was used and a p value of $p = 0.002$ suggested strong non-normality, leading us to the use non-parametric tests to analyze the data. Skewed variables are presented as median and 25th and 75th percentiles. Differences between groups were evaluated using Mann–Whitney tests, for continuous variables, or Chi-square tests, for categorical variables. The internal consistency of scores items was evaluated by calculating the Cronbach α coefficient; values above 0.70 were considered to represent a good internal consistency.[15,16] Inter-rater reliability of the scores between the first and the second observer were determined using weighted kappa for ordinal variables and intra-class-correlation coefficient (ICC) for continuous variables, on mean-rating ($k = 2$), one-way

random-effects model.[17,18] Power of ICC was established *post hoc*. The idea of using weighted kappa is that disagreements involving distant values are weighted more heavily than disagreements involving more similar values. Agreement was considered to be almost perfect if k was greater than 0.80, substantial if within the range 0.61–0.80, moderate if within the range 0.41–0.60, fair if within the range 0.21–0.40, and slight if below 0.20.[18,19] The correlation of total respiratory scores with SpO_2 was determined using Spearman tests, considering ≤ 0.25 as little or no correlation, fair if within the range 0.25–0.50, moderate to good if within the range 0.50–0.75, and good to excellent if ≥ 0.75.[20] A p value of less than 0.05 was considered statistically significant.

Results

Sixty children were enrolled (median age of 6 (4–10) months) of which 51.7% had six months or less and 21 were male (54.5%). Ten children had a history of prematurity or presented a previous diagnosis of a cardiopulmonary disease. Moreover, 50% of the children were diagnosed with a first episode of bronchiolitis. The baseline characteristics of the sample, according to the age group (<= or > 6 months of age), are depicted in Table A.1.

The median value of SpO_2 was 96% (93–98) upon admission and 97% (95–99) at discharge. In the emergency department, 15% of children ($n = 9$) were managed without specific therapeutic interventions while all the others were treated with bronchodilators, hypertonic saline, and/or oral steroids. Oxygen was prescribed in 3.3% of cases ($n = 2$) (Table A.1). 75% ($n = 45$) of the children were discharged from the emergency department (Table A.1).

The data collected through the WRS and KRS respiratory scores are detailed in Table A.2. The median (IQ) score of WRS was 5.5 (4–7) and 6 (5–9) upon admission, and 3 (2–5) and 5 (3–7) at discharge, for the first (physician) and second (physiotherapist) observer, respectively. The median score of KRS was 4 (3–5) and 4.5 (4–5) upon admission, and 3 (2–4) and 3 (3–5) at discharge, for the first and second observer, respectively.

There was a fair correlation between KRS/WRS and SpO_2 upon admission and discharge for the first observer and the second observer (Table A.3). The inter-rater reliability was good for KRS (ICC 0.78) and moderate for WRS (ICC 0.69), with a power of 0.756 (Table A.3). Internal consistency of KRS was graded as sufficient with a Cronbach α ranging from 0.43 to 0.78 (Table A.4). The inter-rater reliability for individual clinical signs in KRS was similar to WRS, with weighted kappa ranging from 0.21 (0.04–0.39) to 0.50 (0.33–0.68), and the respiratory rate presented the highest reliability with a kappa value of 0.50 (0.33–0.68), followed by chest recession with 0.46 (0.23–0.64), skin color with 0.46 (0.13–0.78), breath sounds with 0.36 (0.15–0.57) and general condition 0.21 (0.04–0.39) (Table A.4).

Discussion

In this study, we report a sufficient internal validity and good reliability of both scoring systems, when applied by physicians and a physiotherapist to assess the clinical severity of a child's observed bronchiolitis in the setting of a busy emergency department. Both scores performed well with each item significantly contributing to the overall score. The correlation with SpO_2 was fair in both scores and the inter-rater reliability obtained a correlation magnitude higher in the KRS than in the WRS.

The SpO_2 determined by pulse oximeter is usually used by physicians to establish bronchiolitis severity, but should be considered alongside other factors such as respiratory frequency, heart rate, age and feeding intake to get the most accurate assessment of bronchiolitis level of severity.[3,21,22] The average negative correlation between SpO_2 and both respiratory scores obtained in our study was similar to that reported by Chin and Seng.[14] The fair correlation could not be seen as a negative outcome because a large fluctuation of SpO_2 is normal during a bronchiolitis episode and it is normal to observe low levels of SpO_2 in light or moderate bronchiolitis.[22] This could be the reason for the fair correlation with both scores.

Despite the fact that the physician's level of experience varied considerably, the inter-rater agreement was found to be good. The respiratory rate was shown to be the best parameter to determine respiratory distress in both scores and for both observers, followed by breath sounds/wheezing in WRS and chest recessions in KRS. These findings were expected and other researchers have

also previously reported that objective physical signs present a higher inter-rater agreement than subjective physical signs.[9,23]

General condition showed to be the least reliable parameter in both respiratory scores. This may be explained in part by the brief explanation of scores given to first observers and by the subjectivism of this parameter. In the case of KRS, observers had a footnote explaining that under 'General Condition', observers should assess the general complexion of children in addition to asking caretakers if they had noticed a food intake decrease or change in sleeping pattern. However, in the case of WRS, observers did not have this kind of guidance and could only score as zero or three upon a simple observation of children complexion at that moment. This might have led to doubt in cases with small decreases in nutrition intake or slight alteration in sleeping pattern — in most cases, these were recorded as a zero when they should have been recorded as 3.[9,10]

Our study did not aim to determine a model for predicting admission but to examine the inter-rater agreement of the scoring system when used by different health professionals with different levels of experience, not only for clinical purposes but also for research purposes. We can consider that this objective was accomplished as we reported an inter-rater reliability higher than 0.70, with KRS obtaining 0.78 and WRS 0.69.

One of the identified strengths of our study was the fact that among the participants not only children with a first episode of bronchiolitis were included, but also children with exclusion factors (e.g., cardiopulmonary disease, prematurity) allowing us a larger generalization in terms of population. Another positive aspect was the fact that the assessments between observers were all performed within 15 min of each other — this not only followed the practice in other studies[7,24] and allowed comparison, but also reduced the probability of having the change in the children's clinical condition interfering with the clinical score assignment.

Most of the previous comparative studies between two scores, or treatments efficacy studies using one specific score, were conducted in inpatients and only few studies have been conducted in an emergency department environment and outpatients.[21,25–27] This is probably due to the fact that it is easier to obtain a sample of hospitalized patients than that of outpatients, since it is unpredictable when eligible patients access the emergency department and are in conditions to be discharged home. In our study, although recognizing the challenges of recruiting patients in the emergency department, we specifically tried to evaluate the performance of respiratory scores used by different health professionals in an emergency department. In a hospital, this is after all the first point of call for patients with bronchiolitis and a very different setting from the regular ward, given the higher number of patients and medical personnel. It was thus a particularly positive result to find a good KRS inter-rater reliability and a sufficient internal consistency in this different setting.

Some of the limitations of our study were the sample size and the study design, which limited our capacity to assess other important properties of the scores, namely their construct validity in regard to decision to admit or discharge comparing with length of stay, and responsiveness. The number of physicians and the number of physiotherapists involved should be more balanced, given that in this study, the unbalanced distribution turned out to limit our ability to calculate a more accurate inter-rater reliability. The difference in number of physicians and physiotherapists also violated some Kappa calculation, leading to an overestimation of the results which should be taken as a reference only.

Finally, another limitation was the insufficient information briefed to physicians, with no previous contact with the respiratory scores — this has led to unforeseen difficulties which might explain some of the reported inconsistencies.

In a future larger study, the construct validity of KRS should be established to prove the utility of this score in an emergency department.

Conclusions

Both respiratory scores and most of the physical signs showed high agreement between observers. In fact, both scores present similar results in regard to their internal consistency. However, given that inter-rater reliability was higher in KRS than in WRS, KRS seems more consistent for use by health personnel in the assessment of children with bronchiolitis in the setting of an emergency room.

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Conflict of Interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this paper.

Author Contributions

Frederico Ramos Pinto conceptualized and designed the study, analyzed the data and drafted the initial paper, and approved the final paper as submitted.

Inês Azevedo and Liane Correia-Costa conceptualized and designed the study, supervised data collection, participated in and supervised data analyses, reviewed and revised the paper, and approved the final paper as submitted.

Appendix A

Table A.1. Baseline characteristics of participants and selected outcomes according to age groups.

	≤6 Months ($n = 31$)	> 6 Months ($n = 29$)	p value
Demographics characteristics			
Gender, male, n (%)	21 (54.5)	19 (47.5)	0.004
Clinical history			
Prematurity, n (%)	3 (9.7)	2 (6.9)	> 0.001
Cardiopulmonary disease, n (%)	1 (3.2)	4 (13.8)	> 0.001
First episode of bronchiolitis, n (%)	20 (64.5)	13 (44.8)	0.577
Oxygen saturation			
At admission, median, IQR	97 (95–99)	96 (92–97)	0.088
At discharge, median, IQR	98 (95–100)	97 (95–98)	0.056
Hospital admission, n (%)	9 (29.0)	6 (20.7)	0.020

Notes: Values presented are n (%) or median (P25–P75); mo: months; Entr/Disch: entrance/discharge.

Table A.2. Total respiratory scores at admission and discharge, by observers.

		Admission	Discharge
WRS	1st Obs., median (IQR)	5.5 (4–7)	3.0 (2–5)
	2nd Obs., median (IQR)	6.0 (5–9)	5.0 (3–7)
KRS	1st Obs., median (IQR)	4.0 (3–5)	3.0 (2–4)
	2nd Obs., median (IQR)	4.5 (4–5)	3.0 (3–5)

Notes: WRS: Wang respiratory score; KRS: Kristjansson respiratory score; Obs.: observer.

Table A.3. Correlation of SpO_2 with totals of WRS and KRS and Inter-rater reliability between the two observers.

	SpO_2				
	1st Observer		2nd Observer		
	Admission	Discharge	Admission	Discharge	ICC
WRS	−0.299 ($p = 0.020$)	−0.313 ($p = 0.015$)	−0.295 ($p = 0.022$)	−0.409 ($p = 0.001$)	0.686 ($p = 0.001$; 95% CI = 0.475–0.812)
KRS	−0.397 ($p = 0.002$)	−0.349 ($p = 0.006$)	−0.324 ($p = 0.012$)	−0.427 ($p = 0.001$)	0.780 ($p = 0.001$; 95% CI = 0.633–0.868)

Notes: SpO_2: Oxygen saturation; WRS: Wang Respiratory Score; KRS: Kristjansson Respiratory Score; ICC: Intraclass Correlation Coefficient.

Table A.4. Internal consistency and inter-rater reliability for individual clinical signs in WRS and KRS.

		Cronbach α values	Weighted kappa (95% CI)
WRS	Respiratory rate	0.78	0.52 (0.35–0.69)
	Chest retraction	0.76	0.39 (0.19–0.59)
	Wheezing	0.68	0.50 (0.33–0.66)
	General condition	0.43	0.23 (0.03–0.43)
KRS	Respiratory rate	0.69	0.50 (0.33–0.68)
	Chest recession	0.65	0.46 (0.23–0.64)
	Breath sounds	0.70	0.36 (0.15–0.57)
	General condition	0.53	0.21 (0.04–0.39)
	Skin color	0.69	0.46 (0.13–0.78)

Notes: WRS: Wang Respiratory Score and KRS: Kristjansson Respiratory Score.

Table A.5. Wang respiratory score.

Score	0	1	2	3
Respiratory Rate (breaths/minute)	< 30	30–45	46–60	> 60
Wheezing	None	Terminal expiration or only with stethoscope	Entire expiration or audible on expiration without stethoscope	Inspiration and expiration without stethoscope
Retraction	None	Intercostal recession	Trachea-sternal recession	Severe with nasal flow
General Condition	Normal			Irritable/lethargic/poor feeding

Table A.6. Kristjansson respiratory score.

Score	0	1	2
Respiratory Rate (breaths/minute)	< 40	40–60	> 60
Chest Recession	None	Moderate (costodiaphragmatic)	Severe (as in 1 plus rib & jugular retraction)
Breath Sound	Vesicular	Wheeze +/− rhonchi/rale	Severe wheeze +/− rhonchi/rale
Skin Color	Normal	Pallor	Cyanosis
*General Condition	Not affected	Moderately affected	Severely affected

Notes: *(a) Not affected if activity and feeding is normal; (b) moderately affected if activity and feeding is less than normal and (c) severely affected if child looks ill and feeds poorly.

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