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Editor-in-Chief

Professor Marco Y.C. Pang, PhD

Department of Rehabilitation Sciences,
The Hong Kong Polytechnic University, Hong Kong

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Hong Kong Physiotherapy Journal

Aims & Scope

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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.

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Gait patterns in ischemic and hemorrhagic post-stroke patients with delayed access to physiotherapy

Bianca Callegari[1,2,3,*], Daniela Rosa Garcez[4], Alex Tadeu Viana da Cruz Júnior[1,2], Aline do Socorro Soares Cardoso Almeida[1], Skarleth Raissa Andrade Candeira[1], Nathalya Ingrid Cardoso do Nascimento[1], Ketlin Jaquelline Santana de Castro[5], Ramon Costa de Lima[5], Tatiana Generoso Campos Pinho Barroso[1], Givago da Silva Souza[2,5] and Anselmo de Athayde Costa e Silva[3]

[1]*Laboratory of Human Motricity Sciences, Federal University of Pará*
Av. Generalíssimo Deodoro 01, 66050-160, Belém, Pará, Brazil

[2]*Tropical Medicine Center, Federal University of Pará*
Av. Generalíssimo Deodoro 92, 66050-240, Belém, Pará, Brazil

[3]*Master's Program in Human Movement Sciences, Federal University of Pará*
Av. Generalíssimo Deodoro 01, 66050-160, Belém, Pará, Brazil

[4]*University Hospital Bettina Ferro de Souza, Federal University of Pará*
R. Augusto Corrêa, n1, 66075-110, Belém, Pará, Brazil

[5]*Neuroscience and Cell Biology Graduate Program, Federal University of Pará*
R. Augusto Corrêa, n 1, 66075-110, Belém, Pará, Brazil

[*]*callegari@ufpa.br*

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Objectives: (1) To assess the effects of a conventional, delayed physiotherapy protocol used by Ischemic Stroke (IS) and Hemorrhagic Stroke (HS) post-stroke patients, in their electromyographic activation patterns during hemiparetic gait; and (2) to study whether this protocol may improve the functional abilities in this population.

[*]Corresponding author.

Methods: This is an observational, descriptive, and analytical quasi-experimental trial. Forty patients with unilateral IS ($n = 25$) and HS ($n = 15$) stroke were recruited; the stroke involved the motor cortex or subcortical areas, and the patients were able to walk independently. Interventions with standard protocols of physiotherapy were carried out. Evaluations (clinical and gait assessment) were performed at the time of admission and at the end of the protocol. Outcome measures include Stroke Impact Scale, Timed Up and Go Test, and gait electromyographic evaluation.
Results: Only IS patients (with an average of 124.4 ± 45.4 months delayed access to physiotherapy rehabilitation) had improvements in Timed Up and Go Test (change in speed = -8.0 seg $p < 0.05$) and presented an anticipation of the onset in Upper leg muscles after the intervention. BF ($p = 0.05$), ST ($p = 0.001$), and RF ($p = 0.024$), started their recruitment (onset) earlier at the swing phase of the gait cycle, which is more similar to the normal pattern (grey shadow). IS and HS (120.4 ± 28.4 months since last stroke) patients presented higher electromyographic activation, after physiotherapy, of the posterior leg muscles (gastrocnemius, semitendinosus and biceps femoris) during stance phase ($p < 0.05$).
Conclusion: IS patients had improvements after delayed conventional physiotherapy. For HS limited response to intervention was observed.

Keywords: Stroke; age; surface electromyography; gait; physiotherapy.

Introduction

Stroke is the second highest cause of death and contributes significantly to motor disability and compromised quality of life. Its consequences depend on its severity, brain location, and type.[1] Since stroke is a long-term condition with long-term needs, it is important to quantify the impact of differing stroke sub-types; Ischemic Stroke (IS) or Hemorrhagic Stroke (HS); and also, to identify important prognostic variables.

Post-stroke gait, known as hemiparetic gait, is altered compared to normal gait, as measured by spatiotemporal parameters, kinematic and kinetic profiles, and energy costs.[2,3] Abnormal electrical activity is associated to these clinical impairments during the gait cycle.[4–6,38,39] Some features include the absence or reduced electromyographic (EMG) amplitude with premature or delayed activation in lower leg muscles during the terminal swing and early stance phase. We have reported the electromyographic findings of a quasi-experimental trial that demonstrated changes in the hemiparetic gait cycle after physical rehabilitation in patients with delayed access to treatment.[7] Without considering the type of stroke, we found that although chronic stroke patients continued to exhibit abnormalities in the temporal characteristics of muscle activity, they anticipated Tibialis Anterior (TA) and Rectus Femoris (RF) activation in the swing phase, after rehabilitation. But no association with clinical features or with stroke type was described in that occasion. Thus, in this paper, that included some additional participants, we are reporting the correlation of this changes with some clinical outcomes and the type of stroke.

Balance improvements (i.e., better control of the body center of pressure) in stroke patients after a late physiotherapy conventional intervention were also recently reported and were observed only in IS patients, when compared to HS, besides all patients had delayed access for the treatment.[8] In addition to this reference, as far as the authors know, the effects of time after stroke (chronicity) associated with delayed access to recovery in the follow-up of patients have not been fully investigated.

Physical rehabilitation is strongly recommended as an early intervention due to its ability to improve the brain organization and plasticity. Around six months after the stroke episode, it is recommended to start the rehabilitation program.[9–12] However, the public health system in developing countries are under high demand and with limited infrastructure. Long periods waiting for treatment often makes patients become chronic and worse, compared to patients who get the recommended ideal scenario of an early intervention.[9] Moreover, as a long-term condition, it is important to quantify the impact of differing stroke subtypes to identify the prognostic. Thus, some questions remain unclear, and we intend to explore in this new study: How effective are these

late intervention for IS and HS patients? Have these patients better function scores after intervention? Do they learn effective patterns when recruiting muscles during walking?

In this study, we aimed to determine whether it is still possible to improve electromyographic gait patterns in chronic patients after later intervention. For that, we quantified the amplitude of the electromyographic activation in the lower limb muscles and timing of muscle activation during the gait cycle. We hypothesized that limited response to intervention will be observed, due to the long-time post-stroke and delayed access to treatment, turning the financial efforts not effective. We further hypothesized that among these chronic patients, and due to its severity according to the type, those that had HS could show worse results compared with subjects affected by IS stroke when receiving the same physical therapy protocol.

Methods

This is an observational, descriptive study and analytical quasi-experimental trial, that evaluated stroke patient cases referred for rehabilitation from the public health system. The treatment took place at the Demetrius Medrado Reference Center and Unit of Education and Care in Physical Therapy at the State University of Pará, Belém, Pará, Brazil. This study followed the STROBE statement and has been approved by the internal ethics committee of the Federal University of Pará (report #141.605). Participants gave their written informed consent.

Participants

We enrolled for this study 40 stroke patients. They had experienced a unilateral stroke (HS or IS), involving the motor cortex or sub-cortical areas and were able to walk independently (10 meters without any supervision or assistive devices). No physical therapy and or exercise program 24 months prior to the enrolment in the study was permitted.

Participants with no cognitive ability to understand the tasks, with other neurological or orthopedic comorbidities or under antispastic medication at the time of the study were excluded. An experienced physiotherapist performed a clinical examination to assess the baseline characteristics before any experimental procedure. The baseline characteristics were age, sex, height, weight, time since last stroke onset episode, time since last physical therapy intervention, Stroke Impact Score,[13] Timed up and Go test,[14] Berg Balance Score[15] and Brunnstom Score[16] and stroke type (Table 1).

Procedures

Clinical assessment

Researchers were blinded to the type of stroke when performing all procedures and assessed the

Table 1. Sample baseline characteristics.

	IS group ($n = 25$)	HS group ($n = 15$)	p-Value
Sex	16 M/9 F	10 M/5 F	
Age (years)	58.56 ± 10.22 (54;74)	55.0 ± 10.27 (39;71)	0.29
Height (cm)	159.1 ± 8.5 (156;175)	161.1 ± 8.0 (148;175)	0.47
Weight (kg)	69.0 ± 11.1 (60;94)	69.6 ± 10.2 (52;88)	0.66
Time of stroke (months)	124.4 ± 45.4 (84;36)	120.4 ± 28.4 (84;152)	0.94
Time since last physical therapy intervention (months)	31.68 ± 7.93 (25;48)	29.53 ± 5.24 (21;39)	0.71
Brunnstrom stage	3.44 ± 0.5 (3;4)	3.6 ± 0.5 (3;4)	0.96
SIS Movement domains	43.64 ± 17.64 (31;51)	43.53 ± 21.15 (28;53)	0.82
Timed Up and Go Test (s)	30.36 ± 10.79 (22;41)	29 ± 7.00 (25;34)	0.47
Berg Balance Scale	43.00 ± 5.01 (39;46)	42 ± 3.8 (35;47)	0.95

Notes: Values are mean $\pm$ SD. Statistical comparisons were made with unpaired t test (Stroke Impact Scale, Age, Height and Weight) and Mann–Whitney test (Timed Up and Go Test, Last Episode, Last Physio, Brunnstom stage and Berg Balance Scale). The level of significance was $p \leq 0.05$. Abbreviations: Ischemic Stroke (IS); Hemorrhagic Stroke (HS); Stroke Impact Scale (SIS).

Table 2. Standardized rehabilitation protocol implemented by physiotherapists at public treatment centers.

Intervention	Procedures	Major goal
Stretching Passive range of motion (ROM)	3 series of stretches, sustaining the position 20 s, for the main lower and upper limbs muscle groups. 10 series of passive movements, for the main lower and upper limbs muscle groups.	Increase ROM of involved extremities Reduce spasticity Maintain flexible joints and prevent contracture
Active assistive ROM Active ROM Resistance training: isometric exercise Free weights, weight machines Functional electrical stimulation of the upper and lower limb which practicing functional tasks	10 series active assistive movements (active progression), for the main lower and upper limbs muscle groups 15 minutes of Functional electrical stimulation for weak muscle during functional tasks (squat, climb step)	Increase strength and improve muscular endurance
Coordination and balance activities while sitting and standing	10 minutes of exercises: Lateral Leg Swings, Knee Raises, Bridging, Clams Exercise	Increase core or trunk musculature strength Help prevent falls Improve proprioception
Large-muscle activities such as walking, treadmill, stationary cycle, combined arm-leg ergometry, arm ergometry, seated stepper Circuit training	10 minutes walking, treadmill or stationary cycle	Reduce risk of cardiovascular disease Improve gross motor skills coordination Improve tolerance for prolonged physical activity Increase walking speed/efficiency Improve independence in ADLs
Fine- motor exercises	10 minutes picking up objects, feeding oneself, buttoning clothes and/or writing	Improve gross motor skills coordination Improve independence in ADLs
Wrist, hand or ankle splints	Continuous use, if necessary	Maintain joint range and alignment Facilitate function and increase comfort

Note: As the standard for the program, all patient received the interventions with the volume, intensity and frequency described.

patients on the Stroke Impact Scale and with Timed Up and Go Test, by the time of admission to physiotherapy (pre-physiotherapy) and after the treatment (post-physiotherapy). Only one therapist performed all baseline, clinical and gait evaluations. All subjects completed the physiotherapy intervention that totalized 20 sessions of 60 minutes carried out in 8 weeks, following the standard protocols of the public health system without any intervention from the researchers. Two therapists of the public health system provided treatments (summarized in Table 2).

Stroke impact scale

Health-related quality of life was measured using a stroke-specific, self-reported patient-perspective assessment tool called Stroke Impact Scale. This scale measures eight factors: strength, hand function, mobility, physical and instrumental activities of daily living (ADLs/IADLs), memory and thinking, communication, emotion, and social participation.[13] The Stroke Impact Scale score for each factor ranges from 0 to 100, with higher scores indicating better results. The patient's strength, hand function, mobility, ADLs/IADLs scores were combined into a composite movement Stroke Impact Scale score to demonstrate the impact of functional change as it relates to the international classification of functioning, disability, and health.

Functional assessments

Participants were evaluated using the Time Up and Go test to assess dynamic ability in this study.[14] Participants were asked to rise from a chair, walk forward for three meters, turn around, walk back, and sit in the same chair as fast as possible. The average time to complete the Timed Up and Go Test over two trials was calculated.

Gait evaluation

Volunteers walked with natural self-paced speed along a 7-meter, ethylene vinyl acetate made walkway. The following muscles were assessed: gastrocnemius lateralis (GAS), TA, semitendinosus

(ST), biceps femoris (BF), and RF muscles on the paretic side. 18 steps were used for the calculations.

An eight channel electromyographer with a 16 bits of resolution analog–digital converter (EMG System do Brasil™, São José dos Campos, Brazil) was used for acquisition of muscle activation. The signal was amplified 20 times, band-pass filtered (20–500 Hz), and sampled with a rate of 2 kHz. Active bipolar Ag/AgCl, 10 mm, electrodes were used in all channels (Meditrace, Mansfield, USA), placed in pairs, separated by 2 cm. The reference electrode was positioned on the spinous process of C7. All procedures were taken according to the standard recommendations.[17] A custom developed routine in MATLAB (Matlab 2008a, MathWorks Inc., MA, USA) was employed to quantify the electromyographic root mean square (RMS) over a 300 ms window. Tests of maximum voluntary isometric contraction (MVC) for each muscle were performed and used to normalize gait signals. Three tests of MVC were performed, where the contractions were maintained for five seconds, with a one-minute rest between contractions. The average values obtained during the MVC tests was used for normalization of each muscle's activation signal.[18] Finally, we used a second-order Butterworth low-pass filter (6 Hz cut-off), to get the linear envelope of each muscle. Timing normalization was also made using MATLAB. All steps were calculated to a percentage of the total gait cycle, using a foot switch (Heel/Toe strike transducer, Emgsystem, São Jose dos Campos, Brazil). This device was synchronized to the EMG channels and triggered the time of initial and loss of foot contact with the ground, thereby determining cycle phases, ranging from 0% and 100% of the gait cycle. Muscular onset was established based on the moment when the EMG signal exceeded 30% of the minimum amplitude of the signal average per individual.[18] Data were analyzed using the periods of muscle activation during the gait phases (as a percentage of the cycle, and the electromyographic activation (as a percentage of MVC) during the stance and swing phases. Variables were compared for the initial and final evaluation stages. When a muscle became onset earlier compared to the baseline evaluation, we considered it as an anticipation (if it was statistically significant).

Statistical analysis

Statistical procedures were carried out in RStudio (R version 3.3.2, R Core Team (2016). Shapiro–Wilk test was performed to test the data normality. Parametric variables were compared between groups using the Student's *t*-test (i.e., Stroke Impact Scale, Sex, Age, Height, Weight and Berg Balance Scale). Non-normally distributed Outcomes were compared using Wilcoxon–Mann–Whitney (i.e., Timed Up and Go test, Last Episode, Last Physio and Brunnstom stage). In addition, a two-way analysis of variance (ANOVA) was conducted on the influence of the group and stage on the Stroke Impact Scale, Timed Up and Go Test and all electromyographic gait variables. Group included in two levels (HS or IS) and stage consisted in two levels (pre or post-physiotherapy). *Post-hoc* analyses were done with Tukey HSD tests when necessary. For all these statistical treatments, the significance level was set at $p < 0.05$.

Results

Clinical outcomes

Clinical outcomes are depicted in Table 3. No significant difference was observed on movement

Table 3. Clinical outcomes measured before and after physiotherapy intervention.

Clinical outcomes	IS group ($n = 25$)	HS group ($n = 15$)
Stroke International Scale Movement (domains combined)		
Pre-physio	43.64 ± 17.64 (31;51)	43.53 ± 21.15 (28;53)
Post-physio	49.88 ± 15.15 (41; 61)	$53,33 \pm 17.49$ (45;56)
Timed Up and Go Test (s)		
Pre-physio	30.36 ± 10.79 (22;41)*#	29 ± 7.00 (25;34)
Post-physio	23.64 ± 4.63 (21;25)	33.93 ± 11.45 (26;42)

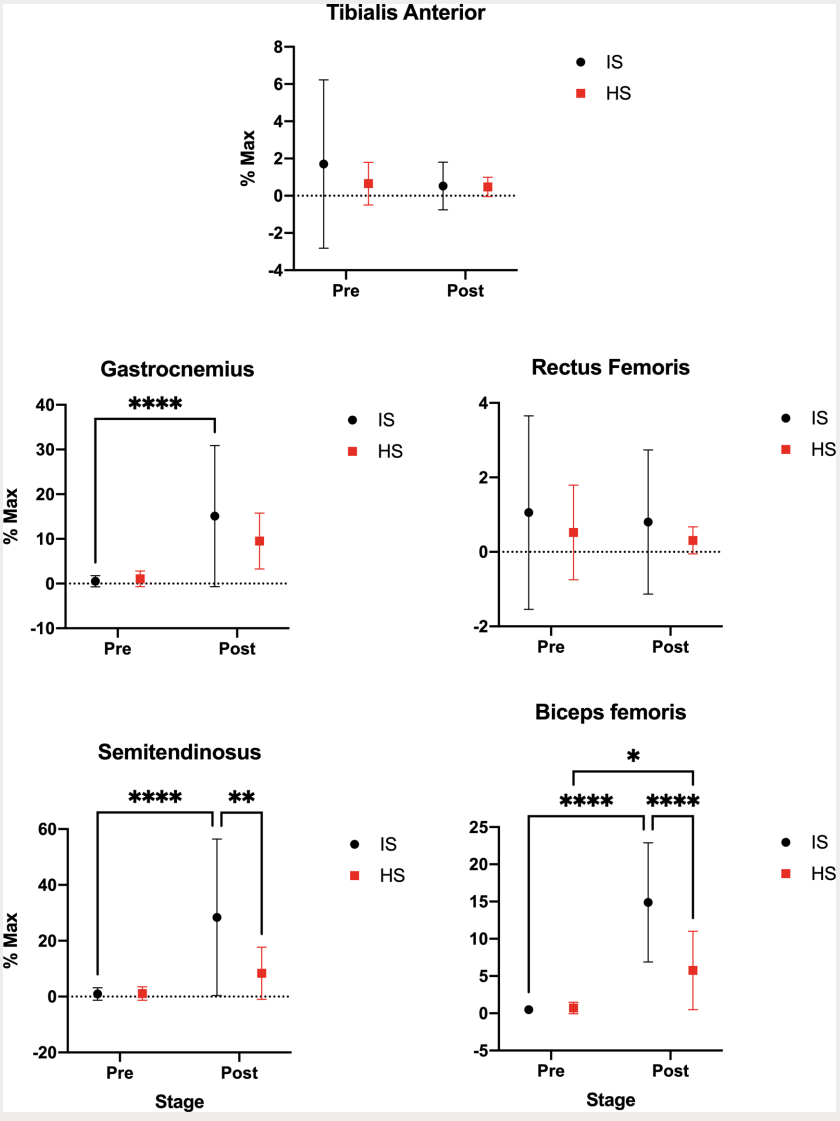
Notes: Values are mean ± SD. Statistical comparisons were made with unpaired *t* test and Mann–Whitney test. The level of significance was 0.05. Abbreviations: Ischemic Stroke (IS); Hemorrhagic Stroke (HS). #$p < 0.05$ difference between Pre-physio and Post-physio. *$p < 0.05$ interaction group *x* stage.

domain in the Stroke Impact Scale neither between groups, nor between pre and post-physiotherapy stages. For Timed Up and Go Test, there was a significant group effect that yielded an F ratio of F (1,76) = 4.75, $p = 0.032$ and significant interaction F (1, 76) = 4.5, $p = 0.036$. Thus, IS group showed reduction in Timed Up and Go Test score after physiotherapy, not observed in HS.

Gait assessment

No differences were found in the duration of the gait cycle in any phase neither between the pre- and post-physiotherapy, nor between groups. Stance phase in the pre physiotherapy stage (IS 41.9 ± 11.9%; HS 43.7 ± 11.7%) and post-physiotherapy moment (IS 40.9 ± 10.5%; HS 46.7 ± 11.4) were similar as well as the swing phase duration pre-physio moment (IS 57.1 ± 12.2%; HS 54.3 ± 12.7%) and post-physio moment (IS 60.5 ± 9.0%; HS 54.9 ± 11.7%).

Posterior leg muscles (BF, ST, and GAS) presented significant group, stage effect, and interaction. *Post-hoc* analysis revealed that the electromyographic amplitude from these muscles was higher during the stance phase after the physiotherapy, only in IS group (Fig. 1). HS group only increased BF electromyographic amplitude after the intervention. Moreover, the BF and ST muscle activation after the physiotherapy were



Notes: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ and ****$p < 0.0001$.

Fig. 1. Muscles electromyographic amplitude during the gait stance phase at the pre-physiotherapy and post-physiotherapy stage, respectively.

Table 4. ANOVA effects for muscles activation during stance and swing phases of gait.

Muscles	ANOVA		
	Stage (Pre/Post)	Group (IS/HS)	Interaction
BF			
Stance	$\boldsymbol{F(1,76) = 14.55;\ p = 0.0003}$*	$\boldsymbol{F(1,76) = 69.50;\ p < 0.0001}$****	$\boldsymbol{F(1,76) = 16.10;\ p = 0.0001}$***
Swing	$F(1,76) = 0.871;\ p = 0.35$	$F(1,76) = 0.003;\ p = 0.953$	$F(1,76) = 0.026;\ p = 0.871$
Onset	$\boldsymbol{F(1,76) = 7.03;\ p = 0.009}$***	$\boldsymbol{F(1,76) = 3.73;\ p = 0.05}$*	$\boldsymbol{F(1,76) = 4.19;\ p = 0.04}$*
ST			
Stance	$\boldsymbol{F(1,76) = 6.90;\ p = 0.010}$***	$\boldsymbol{F(1,76) = 21.181;\ p = 0.0001}$****	$\boldsymbol{F(1,76) = 7.15;\ p = 0.009}$*
Swing	$F(1,76) = 0.000;\ p = 0.989$	$F(1,76) = 0.351;\ p = 0.555$	$F(1,76) = 0.000;\ p = 0.986$
Onset	$\boldsymbol{F(1,76) = 15.62;\ p = 0.0001}$****	$F(1,76) = 0.494;\ p = 0.48482$	$F(1,76) = 9.37,\ p = 0.003$***
GAS			
Stance	$\boldsymbol{F(1,76) = 28.66;\ p = 0.0001}$****	$\boldsymbol{F(1,76) = 0.331;\ p = 0.0001}$****	$\boldsymbol{F(1,76) = 0.285;\ p = 0.0001}$***
Swing	$F(1,76) = 0.730;\ p = 0.396$	$F(1,76) = 0.765;\ p = 0.384$	$F(1,76) = 0.479;\ p = 0.491$
Onset	$F(1,76) = 1.502;\ p = 0.2245$	$F(1,76) = 3.714;\ p = 0.0581$	$F(1,76) = 0.803;\ p = 0.3733$
RF			
Stance	$F(1,76) = 0.311;\ p = 0.578$	$F(1,76) = 1.364;\ p = 0.246$	$F(1,76) = 0.002;\ p = 0.963$
Swing	$F(1,76) = 0.912;\ p = 0.343$	$F(1,76) = 2.244;\ p = 0.138$	$F(1,76) = 0.228;\ p = 0.634$
Onset	$\boldsymbol{F(1,76) = 15.25;\ p = 0.0001}$****	$\boldsymbol{F(1,76) = 10.10;\ p = 0.002}$***	$\boldsymbol{F(1,76) = 4.67;\ p = 0.034}$*
TA			
Stance	$F(1,76) = 1.787;\ p = 0.185$	$F(1,76) = 0.787;\ p = 0.378$	$F(1,76) = 0.652;\ p = 0.422$
Swing	$F(1,76) = 1.304;\ p = 0.257$	$F(1,76) = 0.022;\ p = 0.881$	$F(1,76) = 0.136;\ p = 0.713$
Onset	$F(1,76) = 1.297;\ p = 0.258$	$F(1,76) = 1.589;\ p = 0.211$	$F(1,76) = 0.730;\ p = 0.396$

Abbreviations: Ischemic Stroke (IS); Hemorrhagic Stroke (HS); Muscle abbreviations: RF — rectus femoris, BG — Biceps femoris, ST — semitendinosus, GAS — gastrocnemious and TA — tibialis anterior. *Notes*: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ and ****$p < 0.0001$.

significantly higher in IS group. No changes in leg muscle were observed during the swing phase (Table 4).

Figure 2 depicts the muscle activation during the gait cycle, before and after the intervention, in both groups (A: IS; B: HS), as well as the literature normal pattern (grey shadow).[19] Upper leg muscles presented an anticipation of the onset after physiotherapy, only in IS group. The RF onset during the initial swing phase showed a main group and stage effects, and interaction indicating an anticipation of the activation in IS compared to HS, BF, and ST onset during the swing phase presented the same behavior. Therefore, these results showed that RF, ST, and BF started their recruitment (onset) earlier at the swing phase of the gait cycle, which is more similar to the normal pattern (grey shadow). No differences were observed in lower leg muscles.

Discussion

In this study, we have measured some clinical outcomes and electromyographic features during the gait cycle and made a follow up in a group of post-stroke patients with delayed access to a rehabilitation program. Our main findings suggest some answers to our initial questions. Firstly, late intervention was more effective for IS than for HS patients, since they present higher changes in Timed Up and Go Test speed and changes in Muscle patterns and activation after the intervention. Indeed, IS patients, when recruiting muscles, were more similar to the normal standard in human walking, while no changes showed up in HS group after the intervention.

Physiotherapy intervention led to greater activation of the posterior muscles (BF, ST, and GAS) in IS patients while HS group only increased BF. IS group also presented changes in muscles onset during the gait cycle. Indeed, the thigh muscles (RF, BF, and ST) had better anticipation of muscle onset activity in post-physiotherapy stage. Patients have been reported to exhibit abnormalities in the temporal characteristics of muscle activity compared to normal gait[19] and these changes in IS group maybe an strategy in an attempt to deal with the non-functional gait.[10,20–22] As BF muscle helps the hip extension, and ST — RF co-contraction keeps the knee extension during the

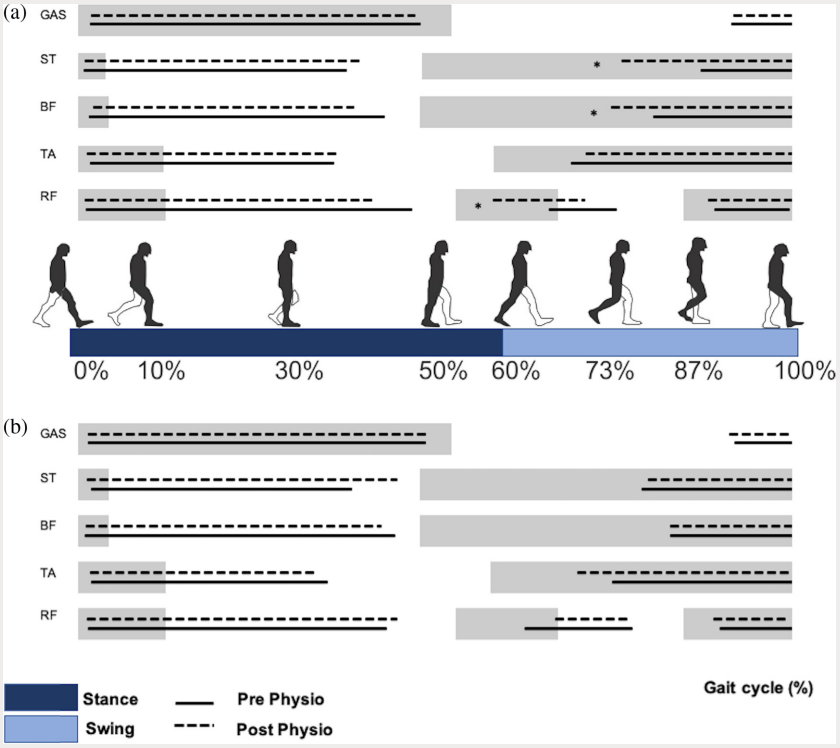


Fig. 2. Muscles onset during the gait cycle where continuous and dashed lines represent muscle activation at the pre-physiotherapy and post-physiotherapy stage, respectively. A represents IS group; B represents Hs groups. Grey shadow represents the literature normal pattern.

gait cycle,[4] the anticipation of these three muscles increases the stiffness theses joints in order to help supporting full body weight. Moreover, the weakness of the calf muscles contributes to this.[4] Compared to normal gait, IS and HS showed TA-GAS co-activation at the early stance phase.[23] This prolonged and simultaneous activation of the lower leg muscles contributes helps to maintain dorsiflexion for the initial contact, and to control foot drop[4] but lead to inversion positioning of the ankle, as previously reported.[5,24] It was observed that the physiotherapy intervention did not change the TA-GAS co-activation patterns in any group during stance, aside from the earlier onset of thigh muscles (BF-ST-RF co-activation) presented by IS in swing phase. Longer BF, RF, and GAS activity during stance phase, associated to longer duration of BF-RF co-activation were previously described in the paretic patients compared to controls[25] in an investigation during early rehabilitation (35–90 days after stroke). But, curiously, these abnormal electromyographic activation patterns remained unchanged after 60 days of physiotherapy besides these patients showed better spatiotemporal and clinical measures of mobility and function. This was attributed to a paradigm where normal patterns of muscle activity are not directly linked to functional gait recovery.[25] In our results, the changes in Timed Up and Go Test speed were found only in IS group and, on the contrary of this unlinked paradigm, IS group also showed changes in muscle patterns after delayed access to rehabilitation. However, other factors, apart from the muscle temporal organization, such as force and spasticity, are also strictly related to gait performance and even improving the muscles timing, stroke patients remained much different to the normal pattern.[25]

Authors stated that the rehabilitation program should start early to be more efficient.[11,12] although no optimal time window have been defined.[11] Some authors suggest a period within three to 30 days post-stroke.[22,26,27] while others[28] reported that even chronic patients had improvements.[29] These last studies describing “late plasticity” may be the reason why we observed changed electromyographic activation patterns in our patients. However, as we hypothesized, this was only evident in IS patients.

The type of stroke is highly related to the severity of the impairments. IS is seven times more common but it tends to be less severe since it leads to a loss of neurologic function that depends to the extension of the brain area that the obstructed vessel supplies.[30] HS is highly associated with deaths and those that survive often have major neurological impairments. The diameter of lesions in HS patients was by 20% larger compared to IS. This may reflect differences in recovery and may explain partially our results.[31]

Possibly, other factors, as the intervention techniques may be also involved. Common gait retraining techniques, currently in clinical use,[32] includes strength training, functional electrical stimulation (FES),[33] treadmill training (with or without partial body-weight support),[34] EMG biofeedback[35] and splinting of the lower extremity.[36] Conventional physiotherapy, as offered to our patients, seems to be more effective with early intervention while more other registered clinical trials support that more expensive and elaborate techniques such as the partial bodyweight support and treadmill training, or biofeedback training resulted in improved gait performance.[37] Unfortunately, these treatments are not available in the public health system.

In our study, assessment of stroke recovery has been limited by the measures used to evaluate recovery (Stroke Impact Scale and Timed Up and Go Test). These are functional measures and individuals may continue to recover both neurologically and achieve higher levels of functional status, but these scales are not sensitive to these changes. In order to advocate for the most appropriate rehabilitation programs for stroke patients, health professionals must understand patterns of recovery and know the limitations of existing studies. This is the main reason why we performed the EMG measurements before and after delayed physiotherapy treatment of stroke patients. However, due to the number of channels of our EMG equipment, only five muscles were accessed and only on the paretic limb, which consists in a study limitation. Another limitation is the small number of subjects with HS stroke what might have effects in the differences observed.

Conclusion

IS patients, submitted to delayed physiotherapy treatment, had greater activation of the measured posterior muscles during stance phase. Timing analysis of the swing phase found that these patients had earlier ST, BF, and TA muscle onset anticipation. These physiological modifications improved Timed Up and Go Test speed but had limited effect in Stroke Impact Scale.

Conflict of Interest

The authors declare that they have no competing interests.

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Author Contributions

ASSCA, GSS and BC conceived and designed the experiments. ASSCA, ATVCJ, SRAC, NICN, KJSC, RCL and TGCPB performed the experiments. AACS, DRG, GSS and BC analyzed the data. ASSCA, ATVCJ, SRAC, NICN, KJSC, RCL and TGCPB contributed reagents/materials/analysis tools. AACS, DRG, GSS and BC wrote the paper. All authors revised the final paper.

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Cross-cultural adaptation of the Pain Catastrophizing Scale in Greek clinical population

Anna Christakou

Department of Physiotherapy, University of West Attica
Athens, Greece; General Hospital of Evaggelismos, Athens, Greece

achristakou@phed.uoa.gr

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Background: Catastrophizing is an important psychological construct in mediating the behavioral response toward pain.
Objective: The purpose of this study is to examine the psychometric properties of the Pain Catastrophizing Scale (PCS) in Greek clinical population.
Methods: The scale was administered in 376 patients with chronic cervical and lumbar pain. Test–retest reliability, internal consistency (Cronbach α) and concurrent validity were assessed. Exploratory (EFA) and Confirmatory Factor Analysis (CFA) were used to test the factorial validity of the hypothesized three factor structure.
Results: The PCS factors suggested high levels of test–retest reliability, whereas Cronbachs' α values were acceptable. The EFA yielded a three-factor solution and indicated a marginal fit to the data. CFA procedures indicated a rather acceptable fit to the data. The concurrent validity of the instrument was confirmed.
Conclusion: PCS seems to be a reliable and valid instrument in Greek patients with chronic cervical and lumbar pain.

Keywords: Reliability; validity; chronic musculoskeletal pain; Greek patients.

Introduction

Chronic pain is a subjective and multidimensional phenomenon. Evidence supports the crucial role of psychosocial factors on chronic pain, including beliefs (e.g., catastrophizing), everyday life strategies (e.g., coping), mood (e.g., anxiety), social factors (e.g., social support) and work (e.g., job satisfaction) which may lead to illness as they are the direct expression of an individual response to pain.[1]

Pain catastrophizing is the tendency to magnify the level of threat associated with perceived pain, to feel helpless in the face of pain, and to focus excessively on pain sensations.[2] Catastrophizing could also be an important predictor of cognitive distress, pain-related disability, analgesic use, and dysfunctional adjustment to pain in clinical situations.[3] Also it affects the patients' beliefs system and coping strategies.[4]

As one of the most widely used measures of catastrophic thinking related to pain, the Pain Catastrophizing Scale (PCS) has been shown to be a brief, valid, and reliable tool for assessing pain catastrophizing across different countries and languages. The multidimensional nature of the PCS is also useful for tailoring clinical interventions to the patient's specific profile. PCS has three factors: (a) "Rumination" consists of the inability to inhibit thoughts related to pain, (b) the "Magnification" which is the augmentation of the displeasure of painful situations and (c) a sense of "Helplessness", hopelessness or inability to cope with painful situations.[2] A high score in pain catastrophizing usually leads to increased pain sensitivity, in turn, representing cognitive and emotional processes of the subjective pain experience. Therefore, pain catastrophizing is thought to be reduced in conjunction with many successful treatment interventions.

The purpose of this study is to examine the psychometric properties of the PCS in Greek clinical population. In particular, we investigated: (a) the face and content validity, (b) the factor structure, (c) the concurrent validity, (d) the reliability (internal consistency and test–re-test) of the PCS in Greek population with chronic cervical and lumbar pain.

Methods

The study is in accordance with the principles outlined in the ISPOR task force report "Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures".[5]

Patients

The study population consisted of 376 patients (114 men, 262 women) with a mean age of 45.52 years (SD = 14.18) and with chronic cervical and lumbar pain following spinal stenosis (lumbar or cervical radiculopathy) with a mean duration of 34.35 months (SD = 39.37). Each patient was referred by a physiotherapist to a private physiotherapy clinic and was asked to register with the study. All the patients were over 18 years old with adequate verbal ability and communication. Exclusion criteria from the study were as follows: (a) any significant anatomical abnormalities (e.g., kyphoscoliosis), (b) the presence of any inflammatory or neoplastic lesion (e.g., tumor or metastasis, vertebral fractures, disc herniation requiring surgical treatment) and (c) serious psychiatric disorders (e.g., severe depression, schizophrenia). This study was in accordance with the Ethics principles outlined in the Declaration of Helsinki (Date 3/2019-3/2020). All participants gave their written informed consent before taking part in the study.

Instruments and procedures

Demographics

All patients' demographic and clinical characteristics (e.g., age, gender, etc.) may be referred to Table 1.

Table 1. Demographic and clinical characteristics of patients ($n = 376$).

Demographic characteristics	Frequency f	Relevant frequency (%)
Men	170	45.21
Women	206	54.79
Education		
Elementary	75	19.95
High School-Lyceo	210	55.85
University	91	24.20
Profession		
Private servants	115	30.59
Public servants	94	25
Retired	57	15.16
Housewives	79	21.01
Manual professions	31	8.24
Marital status		
Married	290	77.13
Non married	86	22.87
Visit to physician		
Yes	350	93.10
No	26	6.90
Medication		
Yes	310	82.45
No	66	17.55

Pain Catastrophizing Scale (PCS)

Pain Catastrophizing Scale (PCS) instructions ask participants to reflect on past painful experiences and to indicate the degree to which they experienced each of 13 thoughts or feelings when experiencing pain, on 5-point scales with the end points (0) not at all and (4) all the time. A total score is computed by summing the responses to each item which can range from 0 to 52, with higher scores representing greater use of catastrophic thinking in response to pain. The PCS subscales are computed by summing the responses to the following items: "Rumination" (e.g., "I can't stop thinking about how much it hurts") (8, 9, 10, 11 items), "Magnification" (e.g., "I'm afraid that something serious might happen") (6, 7, 13 items) "Helplessness" (e.g., "There is nothing I can do to reduce the intensity of my pain") (1, 2, 3, 4, 5, 12 items). The PCS can be completed and scored in less than 5 min. The simplicity and usefulness of PCS led to various translations across languages and cultures, for example, Arabic,[6] Afrikaans,[7] Brazilian,[8] Catalan,[9] China,[10,11] Dutch,[12] French,[13] German,[14] Italian,[15] Japan,[16] Korean,[17] Malay,[18] Norwegian,[19] Sinhala,[20] Spanish,[21] Swedish[22] and Turkish.[23]

Short-Form McGill Pain Questionnaire (SF-MPQ)

The Short-Form McGill Pain Questionnaire (SF-MPQ) has been developed for adults.[24] The component of the SF-MPQ consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale as 0 = none, 1 = mild, 2 = moderate or 3 = severe. The SF-MPQ, also, includes the Present Pain Intensity (PPI) index with 1 item and 1 item for a 10 cm visual analogue scale (VAS) for average pain. SF-MPQ has acceptable psychometric properties and it has been used in several studies of chronic pain, like athletes' knee,[25] neck pain,[26] etc. The SF-MPQ has been translated into many languages, including Arabic,[27] Brazil,[28] Greek,[29] etc. The SF-MPQ takes approximately five minutes to complete and score.

Procedure

First, the PCS was translated from English to Greek by two individuals' specialists in English language with excellent knowledge of it. The translators were given a clear explanation of the concepts in the PCS in order to capture the conceptual meaning of the items. Both of them had PhDs in physiotherapy, taught at a university level, and one of them had experience in questionnaire validation. One of the English translators and the first author compared the translations, reached a consensus and modifications were made as needed, resulting in the penultimate version of the PCS.

A back translation then was done by an independent, bilingual (English and Greek translator), who was unaware of the original English version of the PCS and his mother tongue was English. Afterwards, the first author reviewed these translations and, with the help of the back-translator, ensured that the Greek version reflected the same item content as the original version and was conceptually equivalent.

An expert bilingual committee of two different physiotherapists, one methodologist, and the three translators chaired by the first author explored the semantic, idiomatic, and conceptual equivalence of the items and answers to identify any discrepancies or mistakes. The final Greek version of the instrument derived after the reconciliation report was compiled by the expert committee.

The initial form of the translated PCS was first given to a group of 30 patients with chronic pain to ensure that it can be fully comprehended by a psychologist. It was administered face-to-face and the participants were asked whether they fully understood all items and whether they had problems with the formulation of the questions and/or answers. This group of participants had the same inclusion criteria and clinical characteristics with the sample of the study, i.e., over 18 years old with chronic low back pain, neck pain and or limp pain for at least six months. The first author and the expert committee reviewed the results of the cognitive debriefing with the aim of identifying any modification necessary to improve the Greek form. From this procedure, some minor revisions (i.e., grammatical, syntax changes on difficulty in completing the scale and understanding the text) were made according to patients' suggestions by the first author and the expert committee.

Then, the PCS was completed by 376 patients with chronic pain. The patients were contacted directly by the second author who collected the data and were informed about (a) the purpose of the study, (b) the voluntary participation and (c) the confidentiality of the responses. Patients, who

met the inclusion criteria and were interested in participating in the study, were asked to sign an informed consent document. Also, they complete the demographic questionnaire, the SF-MPQ, VAS and PPI. The completion of these instruments took approximately from 8 to 12 min.

Data analysis

Statistical analyses were performed using the Statistical Package for Social Science (SPSS; Version 14.0). A level of $P < 0.05$ was considered statistically significant. Descriptive statistics are reported using means (M), standard deviations (SD) and frequencies (f) for patients' demographic characteristics. Structural Equation Modeling Software 5.7 b (EQS) for Windows[30] was used to perform Confirmatory Factor Analysis (CFA) to assess the factor structure of the PCS.

Construct validity

An Exploratory Factor Analysis (EFA) was chosen to examine the factor structure of the scale. Maximum likelihood (ML) method with direct oblimin rotation was used to determine if the PCS represented the three factors. The ML method was used as the factor extraction method to examine the factor solution, which best fit the measurement variables.[31] This method provides the means to conduct significance tests and to derive confidence intervals. It examines the possibility that the correlation matrix is derived from a population, in which the structure of the most dominant factor supports certain scoring of answers.[32] It also examines the statistical significance of factor loading and factor correlation.[33]

Five criteria were considered in determining the number of factors rotate: (a) the scree plot test, (b) the eigenvalue-greater-than-one rule, (c) the percentage for variance accounted for by each component, (d) the percentage of total variance accounted for by the retained components and (e) the number of interpretable components.[32,33] Also, specific criteria were employed in order to accept the factor structure of the scale: (a) a factor-loading criterion of 0.40,[34] (b) a statistical significance of each item's factor loading[35] and (c) a criterion of 0.30 for an item's communality.[36]

A Confirmatory Factor Analysis (CFA) was conducted to further examine the factorial validity of two models of the scale (a) the original three-factor model reported by Sullivan *et al.*[2] and (b) the two-factor model reported by Osman *et al.*[37] CFA assumes the multivariate normality of the CPS items; therefore, univariate skewness and univariate kurtosis, and multivariate normality were investigated.[38] Maximum likelihood estimation was used which is the standard method of estimating free parameters in a structural equation method.[31] A number of fit indices were investigated to evaluate the hypothesized model and the two alternative models: (1) Chi-square (χ^2),[39] (2) *Satorra–Bentler* χ^2/df *ratio* or *Q test*,[30,40] (3) *Non-Normed Fit Index* (NNFI),[30,40] (4) *Comparative Fit Index* (CFI),[30,40] (5) *Standardized Root Mean Squared Residual* (SRMR)[41] and (6) *Root Mean Squared Error of Approximation* (RMSEA) and the *90% CI of the RMSEA*.[41]

A non-significant χ^2 index indicates a good fit and a χ^2/df ratio or Q test, which is smaller than 2.00, suggests a very good fit. Bentler[42] reported that values of NNFI and CFI above 0.900 support the model fit. Moreover, close fit is typically defined for SRMR and RMSEA less than 0.050.[43] However, Hu and Bentler[41] recommended the criteria of 0.950 for NNFI and CFI and close to 0.080 and 0.060 for SRMR and RMSEA, respectively. Furthermore, the values of factor loadings of the items above 0.400 were considered indicative of an acceptable model fit. In addition, an average off-diagonal standardized residual smaller than 0.050 reflects a model that fits a data set reasonably well.[30,40]

Concurrent validity

Concurrent validity was used to assess the relationships between PCS scores, SF-MPQ, VAS and PPI intended to examine same constructs (i.e., chronic pain). The measurement of an instrument with the same constructs will indicate high correlations. The concurrent validity was assessed using correlations by Spearman's Rho correlation coefficient among the PCS and the other instruments.

Reliability

Coefficient alpha, item means and variances, inter-item correlations and item-total correlations were examined for the PCS. The Cronbach's a coefficient was accepted when its value was larger than 0.70 according to Tabachnick and Fidell.[34] Intra-class correlation coefficients with a one-week interval were assessed for the PCS.

Results

Table 1 presents the main demographic characteristics of the study's sample. Of the 385 patients approached, 376 patients with a mean age of 45.52 years (SD = 14.18) were eligible to take part in the study and completed the questionnaires. No missing data from the 376 patients were recorded. The participants had chronic cervical pain (45%) and low back pain (55%) with a mean duration of pain of 34.35 months (SD = 39.37, range 6–150 months).

Face and content validity

Regarding the face validity, the translation of the instrument seemed to be valid. It was well accepted by the small group of 30 patients as the psychologist and the two physiotherapists had reported. Regarding the content validity, the expert committee resulted that the instrument was found to include necessary questions for creation of an accurate impression of the degree of pain beliefs.

Construct validity

The results of EFA showed that Bartlett's test of sphericity was significant (1599.281, df 110, $p < 0.000$) and the value of the Kaiser–Meyer–Olkin measure of sampling adequacy (0.83) was high. Therefore, the data were appropriate to be used in a factor analysis.[34] Also, values of univariate skewness (from 1.65 to 0.03) and kurtosis (from 2.18 to 0.05) were lower than the cut-off criteria of two for skewness and seven for kurtosis, which demonstrate the normality of the variables.[38] The EF showed a three-factor solution with eigenvalues from 4.13 to 1.98 which accounted for 76.03% of the total variance (Table 2). The first factor (Helplessness), the second factor (Rumination) and the third factor (Magnification) consisted of six, four and three items, respectively.

Maximal Likelihood (ML) was the factor extraction method which has been used to analyze the factor structure of the PCS. Mardia's coefficient (normalized estimate = 101.620) revealed acceptable multivariate kurtosis among the items. This value is smaller than the cut-off point of 208 [13 items of PCS X (13 items + 3) = 208].[43] The results of CFA showed that the three first-order-factor solution (FM_3) displayed a very good fit [$\chi^2(df54) = 106.970$; $p < 0.001$; NNFI = 0.957; CFI = 0.988) (Table 3). The Satorra–Bentler χ^2/df ratio and the values of SRMR and RMSEA indices suggesting that they are acceptable indexes.

Another alternative model was examined to further test the structure of the PCS. The alternative two-factor model (FM_2) showed a poor fit based on the fit indices. The χ^2/df ratio (χ^2/df ratio = 5.360) was higher than the 3-factor model. The NNFI and CFI did not reach the cut-off

Table 2. Exploratory factor analysis: Factor loadings, communalities, eigenvalues, and percentage of explained variance of the pain catastrophizing scale ($n = 376$).

	Factor loadings			
Pain catastrophizing scale	Factor 1 Helplesssness	Factor 2 Rumination	Factor 3 Magnification	Communalities
Item 1	0.73			0.59
Item 2	0.76			0.57
Item 3	0.79			0.54
Item 4	0.85			0.68
Item 5	0.67			0.46
Item 12	0.66			0.44
Item 8		0.73		0.58
Item 9		0.81		0.62
Item 10		0.82		0.65
Item 11		0.64		0.41
Item 6			0.64	0.46
Item 7			0.58	0.37
Item 13			0.81	0.58
Eigenvalues	4.13	3.13	1.98	
% explained variance	36.21	23.45	16.37	

Table 3. Fit indices of the two measurement models of the PCS ($n = 376$).

Models	χ^2_k	df_κ	$\Delta\chi^2$	Δ_{df}	χ^2/df	NNFI	CFI	SRMR	RMSEA (90% CI)
FM_3	106.970	54	3.106	—	3.011	0.957	0.988	0.056	0.081 (0.073–0.092)
FM_2	253.111	54	113.156	0	5.360	0.757	0.813	0.167	0.130 (0.092–0.126)

Notes: χ^2_k = chi-square statistic for the hypothesized model, df_κ = degrees of freedom for the hypothesized model, $\Delta\chi^2 = \chi^2$ difference, $\Delta_{df} = df$ difference, NNFI = Non-Normed Fit Index, CFI = Comparative Fit Index, SRMR = Standardized Root Mean Squared Residual, RMSEA (90% CI) = Root Mean Squared Error of Approximation (90% Confidence Interval), FM_3 = original three first-order factor model, FM_2 = two first-order factor model.

criterion of 0.900 and the SRMS and RMSEA were higher than the cut-off criteria. Thus, CFA revealed the same structure as in the original version of the scale and indicated a marginal fit to the data. The fit indices of the two measurement models are presented in Table 3.

Concurrent validity

In order to examine the concurrent validity of the PCS, patients completed the SF-MPQ, VAS, and PPI which have acceptable content and concurrent validity and acceptable reliability indexes. The results of the study showed a positive acceptable correlation between the PCS and the other instruments (Table 4). Particularly, the results of the study showed a positive acceptable correlation between total PCS and "Sensory" subscale of SF-MPQ (Spearman's rho = 0.219, $P < 0.05$) and "Affective" subscale of SF-MPQ (Spearman's rho = 0.245, $P < 0.05$). Also, the total PCS was correlated with the VAS (Spearman's rho = 0.211, $P < 0.05$) and the PPI (Spearman's rho = 0.226, $P < 0.05$) (Table 4).

Reliability

Both Cronbach's α internal consistency coefficients and intraclass correlation coefficients (ICCs) for PCS were acceptable. The item means, the item variances, the inter-item correlations, the item-total correlations, and the internal consistency coefficients of the PCS factors are summarized in Table 5. The reliability coefficients for the three factors were high. In particular, the ICC for the total PCS was 0.850 (95% C.I.: $0.816 \leq \text{ICC} \leq 0.870$), for the first factor (Helplessness) was 0.810 (95% C.I.: $0.76 \leq \text{ICC} \leq 0.85$), for the second factor (Rumination) was 0.850 (95% C.I.: $0.831 \leq \text{ICC} \leq 0.876$) and for the third factor (Magnification) was 0.843 (95% C.I.: $0.826 \leq \text{ICC} \leq 0.851$).

Discussion

One of the most widely used specific scales of assessing pain catastrophizing is the PCS which is short, easily comprehended and simple to complete. Our aim was to investigate the reliability and

Table 4. Correlations among the factors of the PCS and SF-MGPQ, VAS and PPI.

	Pain catastrophizing scale			
	Helplessness	Rumination	Magnification	Total PCS
Short Form-McGill Pain Questionnaire				
Sensory Subscale	0.213*	0.127*	0.323	0.219*
Affective Subscale	0.218*	0.321	0.111*	0.245*
Total SF-McGill Pain Questionnaire	0.234*	0.125	0.267*	0.119*
Visual Analogue Scale	0.441*	0.336*	0.278*	0.211*
Present Pain Index	0.367**	0.286*	0.319*	0.226*

Notes: $^{**}p < 0.01$, $^{*}p < 0.05$. Pain Catastrophizing Scale (PCS), Short-Form McGill Pain Questionnaire (SF-MGPQ), Visual Analogue Scale (VAS), Present Pain Index (PPI).

Table 5. Internal consistency indices (mean, minimum value, maximum value) for the pain catastrophizing scale ($n = 376$).

Pain Catastrophizing Scale	Item means (Min–Max)	Item variances (Min–Max)	Inter-item correlations (Min–Max)	Item-total correlations (Min–Max)	Cronbach α
Helplessness	1.768 (1.58–1.976)	0.495 (0.353–0.553)	0.427 (0.362–0.585)	0.832 (0.760–0.997)	0.830
Magnification	1.811 (1.753–1.968)	1.343 (1.265–1.401)	0.804 (0.787–0.906)	0.781 (0.654–0.863)	0.809
Rumination	1.162 (1.061–1.272)	0.478 (0.322–0.506)	0.556 (0.439–0.675)	0.807 (0.796–0.922)	0.854

validity of the PCS in Greek patients with chronic musculoskeletal pain. The findings of this study suggest that the PCS can be a valid, reliable, and useful research or assessment tool for evaluating overall pain catastrophizing to guide case formulation, treatment planning, or process analysis of treatment in pain centers in Greece.

Forward and back translators prepared the Greek scale and a committee produced the final Greek version of the PCS. In this study, both CFA and PCA suggested the same 3-factor structure which obtained an excellent goodness-of-fit with a low RMSEA and a high fitting indexes. Thus, the construct validity of the PCS reports the 3-factor structure of the scale. Similarly, the 3-factor structure remains consistent in the Chinese,[11] English,[45] French,[13] German,[14] Hong Kong,[10] Italian,[15] Korean,[17] Norwegian,[19] Sweden[22] and Turkish versions.[23] However, the EFA of the Arabian version suggested a two-factor structure and the CFA comparing the 2-factor model, Sullivan's original 3-factor model, and a 1-factor model based on the total score all provided adequate fit to the data.[6]

To examine the reliability of the Greek version of the PCS, first, the internal consistency was calculated from 374 patients using Cronbach's α coefficients. The scores measured in the PCS factors were statistically significant ($p < 0.001$) and showed that the translated version is reliable with low standard error of measurement. Particularly, it found high internal consistency for the three factors on the contrast with other studies which found lower Cronbach α value, particularly for "Magnification" factor, probably because of its few items.[12,19,22,46] The reason may reflect differences in how individuals appraise the questions dependent on the diversity of pain situations that individuals historically have encountered and taken into consideration in completing the questionnaire.[22] We reported a high value of Cronbach α in "Magnification" factor like Brazilian Portuguese version (α value of 0.80)[7] probably because both of us used large samples which may indicate that α value may also be a consequence of sample size. The test–retest reliability of the PCS was highly significant (ICC = 0.85), higher than English (ICC = 0.73), German (ICC = 0.80), and Korean (ICC = 0.79) versions, similar to German (ICC = 0.83), Italian (ICC = 0.84), Norwegian versions (ICC = 0.85), and Spanish (ICC = 0.84), but lower than the versions in African (ICC = 0.91), Chinese version (ICC = 0.96), Dutch (ICC = 0.92), and Hong Kong (ICC = 0.97). In conclusion, this study confirms the acceptable reliability of the PCS.

The Greek version of PCS showed moderate correlations with pain. This finding is consistent with previous studies showing a strong correlation between PCS and pain intensity and pain interference[14,17,37,47] and the other adapted versions.[9,10,21] The results confirmed that compared with "Rumination" and "Magnification", "Helplessness" was more highly correlated with pain intensity.

A limitation of this study is the absence of examining any correlation between PCS and the psychological status of our patients. Also, relationships between self-reported beliefs and physical tests were not investigated as only self-administered measures were used. A self-administered scale had possible limitations in clinical application. It is uncertain whether the present findings can be extended to other chronic complaints; thus further analyses of the PCS should be carried out. This study did not evaluate the discriminant validity between clinical chronic pain patients and adult community samples.

In future studies, the evaluation of the consistency of the results in this study across samples should be considered for example, in potentially more specific and/or qualitatively different pain

experience (e.g., peripheral neuropathic pain). The PCS can be used in future studies to further assess catastrophizing as a potential predictor, moderator or mediator in a number of treatments for long-standing pain, both medical and behavioral, such as surgery for low back pain, cognitive behavior therapy (CBT), and physiotherapy.[48] Future studies should also evaluate other aspects of validity (e.g., predictive validity), for example, using longitudinal designs in which baseline levels of catastrophizing are used as predictors of changes in pain symptoms and pain-related functioning over time. Also, given that the questionnaire should be used in clinical evaluations, the questionnaire's sensitivity to change also needs to be investigated systematically. The construct and factorial stability of the PCS needs to be further explored in the community. Lastly, the responsiveness of PCS scores to interventions needs to be evaluated in future studies.

Conclusion

PCS in the Greek language form provided reliable and valid instrument for evaluating Greek patients with chronic musculoskeletal pain based on its satisfactory internal consistency, acceptable test–retest reliability, and verification of the construct by CFA, and the confirmation of anticipated correlations of the PCS to relevant psychometric measures.

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Conflict of Interest

The author declares that there is no conflict of interest related to this article.

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Author Contributions

The author conducted the conception and design of the study. Also the author performed the assessment procedure, analysis, and interpretation of the data, preparation of this paper, revision and approval of the final paper.

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Ambulatory chest physiotherapy in mild-to-moderate acute bronchiolitis in children under two years of age — A randomized control trial

Frederico Ramos Pinto[1,*], Ana Silva Alexandrino[2], Liane Correia-Costa[3,4,5] and Inês Azevedo[4,6,7]

[1]*Department of Physical Medicine and Rehabilitation*
Centro Hospitalar Universitário de São João
Alameda Professor Hernâni Monteiro, 4202-451 Porto, Portugal

[2]*Department of Physiotherapy, School of Health*
Polytechnic of Porto, 4200-465 Porto, Portugal

[3]*Instituto de Ciências Biomédicas Abel Salazar*
Universidade do Porto, 4050-313 Porto, Portugal

[4]*EPIUnit, Instituto de Saúde Pública*
Universidade do Porto, 4050-600 Porto, Portugal

[5]*Division of Pediatric Nephrology, Centro Materno-Infantil do Norte*
Centro Hospitalar Universitário do Porto, 4050-371 Porto, Portugal

[6]*Department of Obstetrics-Gynecology and Pediatrics*
Faculty of Medicine, Universidade do Porto
4200-319 Porto, Portugal

[7]*Department of Pediatrics, Centro Materno-Pediátrico*
Centro Hospitalar Universitário de São João
4200-319 Porto, Portugal

[*]*frederico.ramospinto@gmail.com*

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[*]Corresponding author.

Objective: The aim of this study was to compare the role of a chest physiotherapy (CP) intervention to no intervention on the respiratory status of children under two years of age, with mild-to-moderate bronchiolitis.
Methods: Out of 80 eligible children observed in the Emergency Room, 45 children completed the study with 28 randomized to the intervention group and 17 to the control group. The intervention protocol, applied in an ambulatory setting, consisted of combined techniques of passive prolonged slow expiration, rhinopharyngeal clearance and provoked cough. The control group was assessed with no chest physiotherapy intervention. The efficacy of chest physiotherapy was assessed using the Kristjansson Respiratory Score at the admission and discharge of the visit to the Emergency Room and during clinical visits at day 7 and day 15.
Results: There was a significant improvement in the Kristjansson Respiratory Score in the intervention group compared to the control group at day 15 [1.2 (1.5) versus 0.3 (0.5); p-value= 0.005, in the control and intervention groups, respectively], with a mean difference (95% CI) of −0.9 (−1.6 to −0.3).
Conclusion: Chest physiotherapy had a positive impact on the respiratory status of children with mild-to-moderate bronchiolitis.
Clinical Trial Registration: https://clinicaltrials.gov/ct2/show/NCT04260919.

Keywords: Bronchiolitis; chest physiotherapy; outpatients.

Introduction

Acute bronchiolitis is the most common lower respiratory tract infection in infants and children younger than two years of age. It occurs in a seasonal pattern with significant burden on infants, their families and the healthcare system.[1] Acute bronchiolitis is usually a self-limited condition, characterized by acute inflammation, oedema and necrosis of the epithelial cells lining small airways, and increased mucus production. Clinically, it is typically characterized by a 2–3 day prodrome of coryza and cough, followed by signs of respiratory distress as nasal flaring, tachypnoea and chest retractions, with rales, fine crackles or wheezing on auscultation.[2,3] The severity of the acute episode of bronchiolitis is usually established by a physician, based on clinical findings.[2,4] In most cases, the disease is mild to moderate and can be treated at home; however, 1–3% of the cases develop severe disease and require hospitalization.[5,6] In up to 85% of the hospitalized cases, the disease is caused by respiratory syncytial virus (RSV).[2,4]

The best treatment approach for children hospitalized with bronchiolitis remains controversial and there is still substantial variation regarding the practices followed by physicians. Current scientific guidelines recommend that the standard treatment of choice should be supportive, which includes supplemental oxygen when needed, appropriate fluid therapy and overall a "minimal handling approach".[1,7] According to guidelines and systematic reviews published to date, chest physiotherapy (CP) is not recommended as a standard treatment for bronchiolitis.[2,4,8,9]

However, it is of note that most of these recommendations and reviews are based on studies which applied classical CP methods, such as clapping, percussion or vibration technics, to hospitalized patients with bronchiolitis. To date, very few studies have been conducted with the application of more modern CP techniques in hospitalized patients.[10–12] Furthermore, although the majority of bronchiolitis cases are mild to moderate, most of the studies conducted so far focused on more severe cases.

The few studies that tested modern CP techniques in acute bronchiolitis patients, such as prolonged slow expiration (PSE) and rhinopharyngeal retrograde clearance (RRC), presented favorable results, suggesting that the use of CP techniques in the management of bronchiolitis could be considered, if not recommended, in some cases, depending on the severity of the disease.[10,12,13] To the best of our knowledge, no randomized study has yet tested the efficacy of any kind of CP, neither classical nor more recent technics, in mild-to-moderate acute bronchiolitis cases managed as outpatients.

The main objective of the study was to analyze the role of a modern CP intervention to no intervention on the respiratory status of children under two years of age, with mild-to-moderate bronchiolitis.

Methods

Patients

The inclusion criteria considered children up to two years of age admitted at the Paediatric Emergency

Department (PED) with a diagnosis of acute bronchiolitis and clinical conditions that allowed the child to be discharged home after acute management in the PED.

The diagnosis of acute bronchiolitis was established by the attending physicians, based on the classical clinical signs and symptoms, including the presence of coryza, cough, fever, chest hyperinflation, increased respiratory rate (RR) or other signs of respiratory distress, wheezing or wheezing with crackles on auscultation, and changes of feeding routine.[2,4]

Exclusion criteria were: (1) Severe bronchiolitis: RR$\geq$ 70 bpm or 50 bpm (in children younger than six months or older, respectively), global retractions, apnea, nasal flaring, oxygen saturation (SpO_2) $\leq$ 88%, lethargy, dehydration and abnormal peripheral perfusion; (2) need for admission to the inpatient department; and (3) presence of comorbidities, namely prematurity, chronic pulmonary or neuromuscular diseases, congenital heart diseases, trisomy 21 or other congenital malformations.

Settings

The study was conducted during two epidemic seasons, from December to March of 2011 and 2012, at the PED of a Northern Portugal tertiary hospital [Centro Hospitalar Universitário de São João, Porto (CHUSJ)].

All children fulfilling the inclusion criteria and none of the exclusion criteria were invited to participate and their parents/legal guardians were given detailed information on the study protocol provided by the responsible physiotherapist of the study.

The trial was registered at ClinicalTrials.gov (NCT04260919) and was reported according to CONSORT guidelines.[14]

Randomization was conducted by permuted blocks.[15] Allocation envelopes were stored in sequentially numbered (from 1 to 6), opaque, sealed envelopes, prepared by a person not involved in the study, and opened after the inclusion of a new case.

Observations and study intervention

All children were observed in a quiet environment, while awake and not crying, and were submitted to a standard protocol consisting of clinical demographic data collection and assessment of oxygen saturation using pulse oximetry and of the Kristjansson Respiratory Score (KRS) to quantify the severity of the respiratory status of the child.[16–18] Although Wang Respiratory Score (WRS) is a more widely used score, studies comparing it with KRS show that this has better interobserver reliability, a very important aspect to this study.[17,18] This assessment was attributed to each child, at PED admission, at PED discharge and at day 7 and day 15.

Children allocated to the intervention group (IG) underwent a standard intervention CP protocol between PED admission and discharge, and after PED discharge. The protocol was performed by a single physiotherapist and consisted of a 20-min session taking place during working days in the first week (five sessions), and every other day during the second week (three sessions), with a total of eight sessions. All sessions were carried out, as outpatients, in the Physical Medicine and Rehabilitation Department of CHUSJ. A series of exams were carried out in every session, namely the CP protocol, repeated lung auscultation and continuous monitoring of peripheral oxygen saturation levels and heart rate (Nonin Medical, Inc., Model 3100, Plymouth, MN, USA). If desaturation $SpO_2 < 92\%$ or signs of severe respiratory distress, such as global retractions, cyanosis or nasal flaring, fever, irritability or lethargy were identified by the CP protocol initiation or occurred during the session, the intervention was immediately canceled and medical evaluation was requested.[19]

The CP protocol included the application of three different techniques: PSE, RRC and provoked cough (PC). PSE was achieved by applying bimanual pressure over the thoracic cage and the abdomen at the beginning of the expiratory phase down to the residual volume and maintained for 2–3 respiratory cycles.[10,20] RRC was accomplished by instillation of isotonic saline solution (0.9% NaCl) through the nostrils, followed by mouth closure, forcing inspiration through the nasals cavities and removing secretions from this area to the oropharyngeal cavity.[21–23] These maneuvers were carried out during consecutive breathing cycles in order to promote the mobilization of secretions towards the proximal airways. This stimulated the mechanical receptors and made the children cough spontaneously.[10,20] If no spontaneous coughing occurred, coughing was triggered by PC, accomplished by smoothly pressuring the trachea at the level of the suprasternal notch at the end of the inspiration.[10,20,21]

Children from the control group (CG) were not submitted to any CP protocol and were assessed at

the same moments of evaluation (admission/discharge of PED, day 7 and day 15). Both groups received similar recommendations on general support measures and were medicated, as needed, by the physician responsible for the child discharge from the PED. The assessment with KRS and SpO_2 in the PED was performed by the physician responsible for the initial assessment of the children. During the subsequent two weeks, CG was assessed by the physiotherapist responsible for the study and IG was assessed by a physician of the Physical Medicine and Rehabilitation Department of CHUSJ.

Considering the nature of this study, a double-blind assessment was not possible, as both physiotherapist and parents were aware of the intervention.

Outcome measures

The primary outcome was respiratory status, assessed by KRS on day 15. The secondary outcome was respiratory status, assessed by KRS on day 7. This is a five-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, with the severity being established as the total score increases (Table 1).[16–18]

Statistical analysis

Data was analyzed using IBM SPSS Statistics version 23.0. Continuous variables are presented as mean and standard deviation. To check the homogeneity of groups, the *t*-test was used for independent samples on the continuous variables and Qui-square test for categorical variables. Differences between groups were evaluated using ANOVA. Statistically significant differences ($p < 0.05$) were noted with an asterisk ($*$).

The assumptions of ANOVA for repeated measures include normality, homogeneity of variances, homogeneity of the matrix of variances and sphericity.[24] In this study, normality, skewness and kurtosis values were verified, in order to validate the results obtained from the F statistics.[25] The absolute values of skewness and kurtosis can be slightly higher than $(-1.96; 1.96)$, namely $(-3; 3)$ and $(-7; 7)$, respectively, without any problem in the analysis of linear models, as in the case of ANOVA.[24,26]

After verifying each assumption, it was possible to apply ANOVA for repeated measures, proceeding with Bonferroni's post-hoc tests.[25] The main factors were tested by SPSS, while multiple comparisons were obtained by Syntax.

Ethics

The study was approved by the Ethics Committee of CHUSJ, and complied with both the Helsinki Declaration and the current national legislation. Verbal and written consent were obtained from caretakers on behalf of all children enrolled in the study.

Results

During the study period, a total of 105 children were assessed for eligibility to participate in this study, but 15 fulfilled the exclusion criteria (prematurity: 5, chronic pulmonary diseases: 2, chronic neuromuscular disease: 2 and congenital heart disease: 6) and 10 were admitted into hospital because of the severity of the respiratory distress. The remaining 80 cases were randomly assigned to the IG ($n = 42$) and to the CG ($n = 38$). In the end, a

Table 1. The KRS scores.

Score	0	1	2
Respiratory rate (breaths/min)	< 40	40–60	> 60
Chest recessions	None	Moderate (costal diaphragmatic)	Severe (as in 1 plus rib and jugular retraction)
Breath sound	Vesicular	Wheeze +/− rhonchi/rales	Severe wheeze +/− rhonchi/rales
Skin color	Normal	Pallor	Cyanosis
General condition*	Not affected	Moderately affected	Severely affected

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

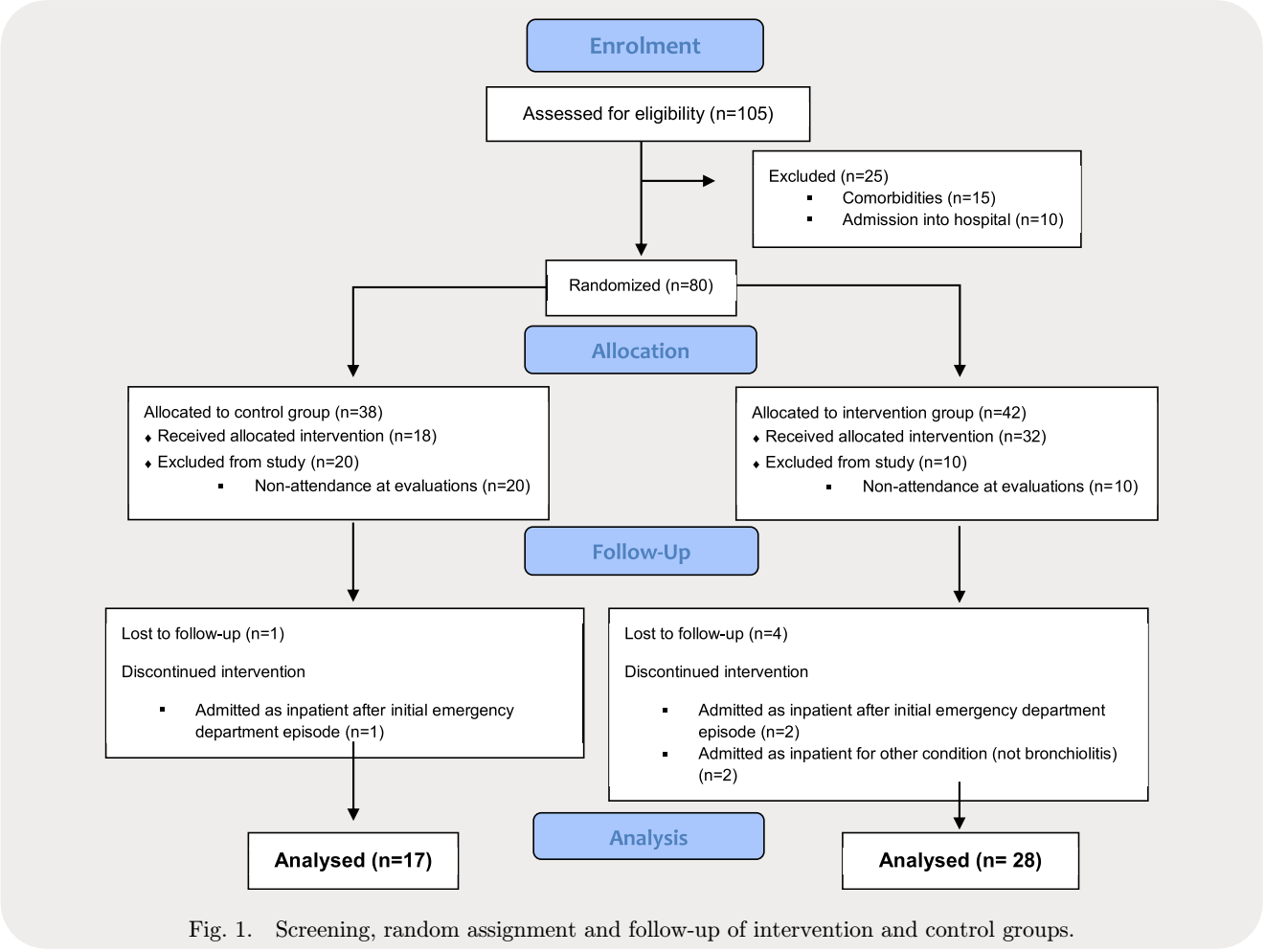

Fig. 1. Screening, random assignment and follow-up of intervention and control groups.

total of 45 children completed the study ($n = 28$, IG; $n = 17$, CG) (Fig. 1). Loss to follow-up was mainly due to non-attendance at the scheduled re-evaluation sessions, 10/42 (23.8%) in IG and 20/38 (52.6%) in CG or by indication to be withdrawn from the study due to hospital admission following clinical worsening (IG, $n = 2$; CG, $n = 1$) or other clinical problems [gastroenteritis or vascular disease (IG, $n = 2$)]. The baseline demographics of children, parents' educational level and clinical characteristics are described in Table 2. No differences were found between the groups in the baseline demographic or clinical variables.

Concerning the four assessments, there was a trend towards a significant improvement in KRS at day 7, where the IG shows better results compared to the CG [mean difference (95% CI) = −0.6 (−1.3–0.01); p-value = 0.054] which became a significant improvement by day 15 [mean difference (95% CI) = −0.9 (−1.6 to −0.3); p-value= 0.005] (Table 3).

When each assessment was compared with the following assessments, the IG had a significant improvement in the KRS score over time indicating a resolution of respiratory severity (Table 4). The CG did not show a significant improvement in KRS score when comparing discharge to the following assessments (Table 4).

Table 5 indicates the individual score items for the KRS at admission and day 15. While there was no significant difference in any individual parameter between the groups at admission, there were significant improvements at day 15 in the IG compared to the CG in respiratory frequency and chest retractions.

An important point to mention is that there were zero cases in the intervention group that experienced clinically relevant side-effects.

Discussion

To the best of our knowledge, this is the first study evaluating the effects of modern CP techniques in mild-to-moderate bronchiolitis in an outpatient setting. In this study, aiming to analyze the impact

Table 2. Baseline demographic and clinical characteristics of the patients.

	Control group ($n = 17$)	Intervention group ($n = 28$)	p-Value
Demographics characteristics			
Male gender	14 (82.4)	20 (7.4)	0.408
Age (months)	11.5 (6.737)	9.3 (5.463)	0.228
Educational level			
Father	9 (3.204)	9.15 (4.504)	0.909
Mother	10.35 (3.101)	10.54 (4.238)	0.878
Clinical characteristics			
First episode of bronchiolitis (yes)	11 (64.7)	14 (50)	0.372
Respiratory rate (> 40 cpm)	13 (76.5)	19 (67.9)	0.737
Peripheral oxygen saturation (%)			
At admission	95.5 (1.505)	96 (2.085)	0.254
At discharge	96.7 (2.144)	97.7 (1.517)	0.082
*Medication in emergency department**			
Salbutamol	16 (94.1)	26 (92.8)	
Hypertonic solution	1 (5.9)	2 (7.2)	
Ipratropium bromide	7 (41.1)	19 (67.9)	
Betamethasone	5 (29.4)	4 (14.3)	
Ibuprofen	1 (5.9)	0 (0)	
Antibiotic	0 (0)	1 (3.6)	
No medication	0 (0)	1 (3.6)	

Notes: The values presented are mean (SD) or n (%). *Some children received more than one medication.

Table 3. Comparison of groups at each assessment with the KRS ($n = 45$).

KRS	Assessment	Intervention group mean (SD)	Control group mean (SD)	Mean difference (95% CI)	p-Value
	Admission	3.4 (1.3)	3.3 (1.3)	0.1 (−0.7–0.9)	0.805
	Discharge	1.9 (0.9)	1.4 (1.1)	0.6 (0–1.2)	0.058
	Day 7	1 (0.8)	1.6 (1.3)	−0.6 (−1.3–0.01)	0.054*
	Day 15	0.3 (0.5)	1.2 (1.5)	−0.9 (−1.6 to −0.3)	0.005*

Note: *Statistically significant ($p < 0.05$).

Table 4. Comparison between assessments in both the groups ($n = 45$).

Group	Assessment (A)	Assessment (B)	Mean difference ($A - B$) (95% CI)	p-Value
Control Group ($n = 17$)	Admission	Discharge	1.9 (1.1–2.8)	< 0.001*
		Day 7	1.7 (0.7–2.7)	< 0.001*
		Day 15	2.1 (1.1–3.1)	< 0.001*
	Discharge	Day 7	−0.2 (−1.2–0.8)	1
		Day 15	0.2 (−0.6–1)	1
	Day 7	Day 15	0.4 (−0.5–1.3)	1
Intervention Group ($n = 28$)	Admission	Discharge	1.5 (0.8–2.1)	< 0.001*
		Day 7	2.4 (1.6–3.2)	< 0.001*
		Day 15	3.1 (2.4–3.9)	< 0.001*
	Discharge	Day 7	1 (0.2–1.7)	0.008*
		Day 15	1.7 (1.1–2.3)	< 0.001*
	Day 7	Day 15	0.7 (0–1.4)	0.053

Notes: *Statistically significant ($p < 0.05$). In this table, a positive improvement in the mean difference indicates an improvement in the KRS.

Table 5. Respiratory severity assessment of each clinical parameter of KRS, at hospital admission and after 15 days of follow-up.

		Admission *n* (%)			Day 15 *n* (%)		
		Control group ($n = 17$)	Intervention group ($n = 28$)	*p*-Value	Control group ($n = 17$)	Intervention group ($n = 28$)	*p*-Value
Respiratory frequency	< 40	4 (23.5)	9 (32.1)	0.515	9 (52.9)	24 (85.7)	0.016*
	40–60	10 (58.8)	17 (60.7)		8 (47.1)	4 (14.3)	
	> 60	3 (17.6)	2 (7.1)		0 (0)	0 (0)	
Chest retractions	None	3 (17.6)	1 (3.6)	0.091	13 (76.5)	28 (100)	0.027*
	Moderate	14 (82.4)	23 (82.1)		3 (17.6)	0 (0)	
	Severe	0 (0)	4 (14.3)		1 (5.9)	0 (0)	
Breath sounds	Vesicular	0 (0)	1 (3.6)	0.428	13 (76.5)	26 (92.9)	0.220
	Wheeze and rales	15 (88.2)	26 (92.9)		3 (17.6)	2 (7.1)	
	Severe wheeze ± pronounced rales	2 (11.8)	1 (3.6)		1 (5.9)	0 (0)	
General condition	Not affected	11 (64.7)	17 (60.7)	0.728	15 (88.2)	27 (96.4)	0.285
	Moderately affected	6 (35.3)	10 (35.7)		2 (11.8)	1 (3.6)	
	Severely affected	0 (0)	1 (3.6)		0 (0)	0 (0)	
Dermal coloration	Normal	16 (94.1)	25 (89.3)	0.581	17 (100)	28 (100)	—
	Pallor	1 (5.9)	3 (10.7)		0 (0)	0 (0)	
	Cyanosis	0 (0)	0 (0)		0 (0)	0 (0)	

Notes: *Statistically significant ($p < 0.05$). "—" denotes that no statistics are computed because Dermal coloration at the 15th day is a constant.

of an ambulatory modern CP intervention based on PSE associated with RRC and PC in the recovery of mild-to-moderate acute bronchiolitis, in children under the age of two years, we found that the respiratory status, assessed by a respiratory score, KRS, on day 15, significantly improved in children submitted to the tested intervention, when compared to the CG.

At the second assessment, at emergency room discharge, after only one intervention in the PED, the IG showed already a trend towards a better clinical status, when compared to the CG. At the end of the intervention, the IG showed a total normalization of the respiratory status, while in the CG, a small percentage of cases presented abnormal breath sounds and signs of respiratory effort, as chest retractions. Wheezing and chest retractions indicate an increase of ventilation effort, that in acute bronchiolitis may be related to inflammation, oedema and hyperproduction of mucus.[20,27,28] Our results suggest that CP with PSE, RRC and PC was effective in removing secretions from the airway, decreasing bronchial obstruction and improving the respiratory status of children with mild-to-moderate bronchiolitis.

The reason for selecting these techniques was based on the pathophysiology of bronchiolitis in newborns and infants who have a very different anatomy and physiology in relation to older children or adults.[10,20] In the four studies included in a recently published Cochrane review on CP in bronchiolitis, the use of PSE was reported to be associated with a reduction of the wheezing, respiratory work and discomfort of inpatients with bronchiolitis.[8] Also, regarding RRC, there is some evidence of its effect in clearing the upper respiratory tract, and very encouraging results given that it is a non-pharmacological form of intervention without clinically relevant side-effects.[23,28]

The choice of an adequate CP technique is very important in regard to the safety and efficacy of intervention in bronchiolitis. Most guidelines worldwide discourage the use of classical CP (clapping, percussion or vibration technics) or acceleration of expiration flow in hospitalized children with bronchiolitis, as there is no evidence regarding its beneficial effect on reducing the length of hospital stay or on improving health status. Moreover, some of the techniques were associated with several adverse side-effects, such as atelectasis, vomiting and discomfort.[29–31]

Until today, only a few studies have focused on the use of more recent CP techniques in patients with bronchiolitis admitted to the hospital, leaving us with insufficient data to assess the efficacy of such techniques in improving clinical signs of upper

and lower respiratory airways obstruction.[11,12,20] Two studies, from 2011 and 2012, show a sustained reduction in the score used, over several days, suggesting that there is an accumulative effect of CP with the techniques of PSE and RRC.[10,11] More recently, in 2020 a study compared the PSE and PC with high-frequency chest wall compression in outpatients with bronchiolitis.[32] This mechanical device had the same positive results as the manual techniques. Both methods were able to reduce significantly the score and increase the airways clearance.[32] Another study, carried out in Spain using the same techniques, obtained a reduction in hours of oxygen therapy during the period of hospitalization.[10–12] In our study, the score was totally reduced after two weeks of treatment.

One of the major strengths of our study was the use of some of the most recent techniques of CP in children with mild-to-moderate bronchiolitis in an ambulatory setting, a situation in which CP might result in a faster recovery of the respiratory status. As stated, few studies have focused on the use of PSE and RRC in acute bronchiolitis and this study was the first to be conducted in a PED and continued in the ambulatory setting.[8] The finding that CP is a relevant option in the management of mild and moderate cases of bronchiolitis in an outpatient setting is of utmost importance, given that it has shown to help avoid long recovery periods affecting both children and their families.[28,33] Despite limited in scope, these findings confirm recent interest in these techniques, and surely warrant further studies and the collection of more data in support of a more robust understanding of the potential advantages and safety of these techniques.

As with any study, this study had expected limitations which we would like to address at this stage. The assessment of infants with bronchiolitis is difficult due to the clinical variability of the disease and there is a lack of evidence on the best tools to assess severity.[2,28,34] Both physiotherapy techniques used in this study are highly specialized and need a well-trained physiotherapist to perform them. In our study, all the techniques were applied by the same physiotherapist, so results cannot be generalized to all practitioners. Also, there was a high rate of dropout in both arms of the study. Dropout in longitudinal randomized controlled trials is common and a potential source of bias.[35] In both groups, treatment and assessment sessions non-attendance was the main reason for dropout, especially in the CG. In this group, this might be due to the fact that the parents/caregivers did not see any advantage in coming to the hospital only for regular clinical assessment. A sham intervention could have decreased the dropout rate in the CG, but ethical and psychological questions can be raised, and administering fake procedures is uncomfortable to professionals trained to perform interventions that they believe are useful for patients.[36] The IG also showed a high rate of dropout, although the value was lower than in the CG. This leads us to question the number of sessions included in this study which may be too high and cumbersome. Future studies should take this into consideration and consider a lower number of sessions to address this issue.

Conclusion

In conclusion, our study showed that in an ambulatory setting, a CP intervention, based on passive prolonged slow expiration associated with rhinopharyngeal clearance and provoked cough, had a positive and significant impact on respiratory status of children under two years of age with mild-to-moderate bronchiolitis.

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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.

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Author Contributions

Frederico Ramos Pinto conceptualized and designed the study, analyzed the data and drafted

the initial manuscript and approved the final manuscript as submitted.

Ana Silva Alexandrino participated in the initial analyses, reviewed and revised the manuscript and approved the final manuscript 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 manuscript and approved the final manuscript as submitted.

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Does additional weekend and holiday physiotherapy benefit geriatric patients with hip fracture? — A case-historical control study

Dennis Kim Chung Mo[1,*], Ken Kin Ming Lau[1], Donna Mei Yee Fung[1], Bosco Hon Ming Ma[2], Titanic Fuk On Lau[1] and Sheung Wai Law[3]

[1]*Physiotherapy Department*
Tai Po Hospital, Hospital Authority, Hong Kong

[2]*The Chinese University of Hong Kong, Hong Kong*

[3]*Department of Orthopaedic Rehabilitation*
Tai Po Hospital, Hospital Authority, Hong Kong

[*]*Dennis.Mo@link.cuhk.edu.hk*

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Objective: To evaluate the new service model of additional weekend and holiday physiotherapy (PT) by comparing functional outcomes and hospital length of stay between a group of geriatric patients with hip fracture receiving daily PT training and a group of geriatric patients with hip fracture receiving weekdays PT training.
Methods: A retrospective case-historical control chart review was conducted and a total of 355 patients were identified. Between-group comparisons were done on functional outcomes including Modified Functional Ambulation Classification (MFAC), Elderly Mobility Scale (EMS), Modified Barthel Index (MBI) and process outcome in terms of length of stay (LOS) in hospitals.
Results: With similar characteristics, patients who received weekend and holiday PT training had a significant higher percentage of MFAC Category III and a significant lower percentage of MFAC Category II ($p = 0.015$) and significant higher MBI scores (mean $\pm$ standard deviation, median; Study group: 47.4 ± 19.6 points, 51 points; Control group: 43.0 ± 20.0 points, 43 points; $p = 0.042$) upon admission to rehabilitation hospital. A similar trend in EMS scores (Study group: 8.2 ± 5.5 points, 7 points; Control group: 8.4 ± 6.1 points, 6 points;

[*]Corresponding author.

$p = 0.998$) and MBI scores (Study group: 63.0 ± 23.4 points, 68 points; Control group: 61.2 ± 26.1 points, 64 points; $p = 0.743$) were observed upon discharge from the rehabilitation hospital. The average LOS in acute hospitals remained static (Study group: 7.7 ± 3.9 days, 7 days; Control group: 7.4 ± 5.0 days, 6 days; $p = 0.192$). The average LOS in rehabilitation hospital (Study group: 20.0 ± 5.5 days, 20 days; Control group: 24.3 ± 9.9 days, 23 days; $p < 0.001$) and total in-patient LOS (Study group: 26.7 ± 6.4 days, 26 days; Control group: 30.7 ± 11.2 days, 28 days; $p < 0.001$) were significantly reduced. A higher percentage of days having PT training during hospitalization in rehabilitation hospital was shown with the implementation of new service (Study group: 89.1%; Control group: 65.9%, $p < 0.001$).

Conclusion: Additional weekend and holiday PT training in post-operative acute and rehabilitation hospitalization benefits geriatric patients with hip fracture in terms of improved training efficiency, where hospital LOS was shortened with more PT sessions, without any significant impacts on functional outcome.

Keywords: Geriatric; hip fracture; physiotherapy.

Introduction

Hip fracture not only causes personal impairment and disability, but also leads to major economic burden on public healthcare system.[1,2] As projected by the Census and Statistics Department of Hong Kong Government, number of elderly persons aged 65 and over will experience an increase from 1.16 to 2.37 million and the number will remain for 30 years.[3] Although reports by International Osteoporosis Foundation pointed out that Hong Kong has a lower rate in hip fracture than Caucasians, the problems associated with hip fractures may be magnified by the aging population and shrinking overall population.[3,4] The actual number of hip fractures is on the rise.[5] Therefore, it is of paramount importance to develop strategies to improve rehabilitation outcomes and lower cost related to the care of patients with hip fractures in view of the growing number of incident cases of hip fracture every year.

In Hong Kong, Hospital Authority (HA), which is the major provider of public hospital services, has reviewed the rehabilitation services for hip fracture as one of the illustrative disease groups. As mentioned in the Strategic Service Framework for Rehabilitation Services published by HA in 2016, in-patient rehabilitation in weekends and public holidays was limited.[6] In the first to second quarters of 2013, with weekday rehabilitation only, 16 sessions of physiotherapy (PT) and 14 sessions of occupational therapy were received by patients who need in-patient rehabilitation during their average 24-day stay in extended-care hospitals. They could only receive physical training in about 60% of their stay in hospitals.[6] Thus, there is much room for improving the in-patient rehabilitation service efficiency.

In line with the recommendation of the Strategic Service Framework for Rehabilitation Services, regular 7-day per week PT service for fragility fractures has been started in several hospitals, including both acute and rehabilitation hospitals, since 1 October 2017. This is a brand-new service model for PT in the HA. This study was launched in a regional rehabilitation hospital as evaluation of a new clinical service.[7]

Several studies have shown that additional weekend PT service is effective in terms of length of stay (LOS), cost-effectiveness and functional recovery.[8–12] English *et al.*,[8] Brusco *et al.*[9] and Maidment *et al.*[10] reported additional weekend PT service may reduce LOS in hospital for patients with acute stroke, geriatric orthopedic or neurological problems and knee arthroplasty, respectively. Pengas *et al.*[11] concluded weekend PT as a cost-effective program as the cost saved from the reduced LOS outweighed the extra cost paid to physiotherapists. Peiris *et al.*[12] reported Saturday PT service may improve individuals' functional ability and reduce LOS.

Several studies concerning the effects of additional PT training on geriatric patients with hip fracture were published. A systematic review, by Auais and colleagues, showed that extended exercise program has a positive impact on physical functional recovery of hip fracture patients.[13] However, the extended program is focusing on community setting and not assessing for more intense in-patient training. Recently, Hasebe *et al.*[14] reported that the additional weekend rehabilitation training led to a faster functional recovery and reduce LOS for Japanese patients with hip fracture.

We hypothesized that functional outcomes could be improved and length of hospital staying

might be shorter in geriatric patients with hip fracture who received additional weekend and holiday PT training than those who received only weekdays PT training.

The purposes of this study were to: (1) compare the ambulatory status, functional mobility and basic activities of daily living (ADL) levels between groups of geriatric patients with hip fracture received daily PT training and received only weekdays PT training and (2) compare the change in LOS in acute, rehabilitation hospitals and overall LOS respectively between groups of geriatric patients with hip fracture received daily PT training and received only weekdays PT training.

Methods

Study design

This was a retrospective case-historical control study in which medical records of geriatric patients with hip fracture were reviewed. It was conducted in compliance with the Declaration of Helsinki and ethical approval was granted from The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee.

Study subjects

We analyzed the case notes of geriatric patients, aged $\geq$ 60 years, who were transferred from acute hospital to Department of Orthopaedic Rehabilitation of Tai Po Hospital with a new diagnosis of fracture hip (ICD-9-CM 820.X). The line for assigning case and control was 1 October 2017 when the weekend service of PT rehabilitation commenced. Patients admitted between 1 October 2017 and 31 March 2018 were included in the study group while those admitted between 1 October 2016 and 31 March 2017 were included in the control group. The main difference was that the study group received daily PT mobilization training if not contraindicated, from post-operation until discharge from hospital, while control group did not receive any weekend or holiday PT mobilization training.

Patients with hip fracture for conservative treatment, or drop-out individuals (like transferred to medical ward for active medical problems; discharged against medical advice), or patients with incomplete outcome data in Clinical Management System (CMS) of HA were excluded.

Geriatric hip fracture care (acute hospital)

Concerning PT training, assessment and treatment were part of routine acute care of geriatric hip fracture. Week-day PT training with chest PT, mobilization and strengthening exercise, mobility and gait training were provided while chest PT was offered to selected cases for life-saving maintenance in weekend and holiday before 1 October 2017. After the commencement of new program, daily PT training, including mobilization and gait training, was offered if it was not contraindicated.

Geriatric hip fracture care (rehabilitation hospital)

Before 1 October 2017, one PT session were offered every weekday. The service included comprehensive physical and social assessment and treatments, with mobilization and strengthening exercise, balance training, functional mobility and gait training, stairs, slope and outdoor walking endurance training, patient and caregiver education on home exercise, fall prevention and walking aids prescriptions according to individuals' needs. Daily PT training was provided after 1 October 2017. Despite the service extension, the content, duration, intensity and mode of delivery remained unchanged.

Outcome measures

Primary outcome measure included functional outcomes. Clinical assessment scales including Modified Functional Ambulation Classification (MFAC), Elderly Mobility Scale (EMS) and Modified Barthel Index (MBI) were used to measure individuals' ambulatory status, functional mobility and basic ADL level, respectively. Secondary outcome measure included LOS in hospitals, i.e. acute, rehabilitation and total.

Modified Functional Ambulation Classification (MFAC)

MFAC is an ordinal scale with seven categories commonly used in Hong Kong public hospitals to grade individuals' walking ability.[15] The scale ranges from Category I to VII, indicating recliner to independent outdoor walker and walking aids

were not taken into account. It has been validated in patients with hip fracture.[16]

Elderly Mobility Scale (EMS)

EMS is a 7-item, 20-point scale to assess frail elderly mobility.[17] Higher marks indicate a better mobility performance. The scale ranges from 0 to 20 and the range of 0–9, 10–13 and 14–20 indicates dependent, assisted and independent mobility, respectively.[17] The seven items included are lying to sitting, sitting to lying, sitting to standing, standing, gait, timed walk for 6 m and functional reach. Study has shown that EMS is reliable and valid to be used in frail elderly people.[17]

Modified Barthel Index (MBI)

MBI is a 10-item, 100-point scale to assess participant's basic ADL performance.[18] The scale ranges from 0 to 100, with 0–20, 21–60, 61–90, 91–99 and 100 representing total, severe, moderate, slight and no dependence in ADL, respectively.[18] Ten items of the index include feeding, grooming, dressing, toileting, bathing, transfer, ambulation, stairs, bowel and bladder control.[18] Study has shown that MBI is reliable to be used.[19]

Length of hospital stay (LOS)

Post-operative acute hospital stay was counted as the exact number of days between date of orthopedic surgery received by patient and date of discharge from acute hospital. The recorded operation date was defined as Day 0. Rehabilitation hospital stay was counted as the exact number of days between the date of admission to rehabilitation hospital and date of discharge from it. Post-operative total in-patient stay was counted as the exact number of days between the date of surgery and the date of discharge from rehabilitation hospital.

Number of PT training sessions was counted as number of days with PT records during hospitalization.

Assessments were done by case therapist-in-charge once individuals were admitted to and before discharged from the in-patient rehabilitation unit. All data were collected and recorded in the medical records by case therapist-in-charge. Data were then retrieved from the medical records by authors for analysis in this study.

Statistical analysis

Shapiro–Wilk tests were used to check the normality of data. Age, EMS and MBI scores and LOS data were not normally distributed, thus non-parametric statistics were applied. Mann–Whitney U tests for continuous variables with skewed distributions or Chi-square tests for categorical data were used to compare demographic data between groups. Comparisons between groups were done on the median scores of patients on admission to rehabilitation hospital and before discharge from rehabilitation hospital. Between-group difference on median scores/numbers of day was compared by Mann–Whitney U tests, except MFAC was compared by Chi-square tests. All statistical analyses were conducted using the IBM SPSS Statistics for Windows, Version 24.0 (Armonk, NY: IBM Corp). The statistical significance level was set at 0.05.

Results

There were 204 patients and 191 patients identified for study and control groups, respectively.

For study group, 15 patients were transferred back to acute hospitals, three patients managed conservatively, one patient aged < 60 years old were excluded from the study. There were totally 185 patients included in study group.

For control group, 10 patients were transferred back to acute hospitals, one patient discharged against medical advice, three patients managed conservatively, six patients aged < 60 years old, one patient with missing data. There were totally 170 patients included in control group.

Both groups share similar demographic data with no significant difference in terms of age, gender, pre-morbid MFAC and diagnosis (Table 1).

For functional outcome when patients admitted to rehabilitation hospital, the Chi-square test of the MFAC scores with adjusted standardized residual analysis ($p = 0.015$) (Table 2) shows that there were statistically significantly higher percentage of patients of Category II in control group (35.9%) and statistically significantly higher percentage of patients of Category III in study group (31.4%). Significantly better basic ADL level, represented by MBI, was found in study group (mean $\pm$ standard deviation, median: 47.4 ± 19.6 points, 51 points) than in control group (43.0 ± 20.0 points, 43 points) ($p = 0.042$) (Table 2). Similar functional mobility, represented by EMS, was found

Table 1. Demographics and clinical characteristics of patients.

		Study group ($n = 185$)	Control group ($n = 170$)	p-value[a]
	Age (years)	83.0 ± 8.1, 84	83.5 ± 8.6, 85	0.452
	Males, n	55 (29.7%)	44 (25.9%)	0.419
	Pre-morbid MFAC	Median: VI	Median: VII	0.637
		I: 0 (0.0%)	I: 1 (0.6%)	
		II: 1 (0.5%)	II: 2 (1.2%)	
		III: 5 (2.7%)	III: 5 (2.9%)	
		IV: 21 (11.4%)	IV: 12 (7.1%)	
		V: 13 (7.0%)	V: 12 (7.1%)	
		VI: 53 (28.6%)	VI: 43 (25.3%)	
		VII: 92 (49.7%)	VII: 95 (55.9%)	
Diagnosis	Fracture neck of Femur	97 (52.4%)	84 (49.4%)	0.638
	Trochanteric fracture of Femur	85 (45.9%)	81 (47.6%)	
	Sub-trochanteric fracture of Femur	3 (1.6%)	5 (2.9%)	

Notes: Data shown as mean ± standard deviation, median or n (%). MFAC = Modified Functional Ambulation Classification.
[a]p-values of Mann–Whitney U-test for age; Chi-square tests for others.

Table 2. Comparisons of functional scores of individuals on arrival of rehabilitation hospital.

	Study group ($n = 185$)	Control group ($n = 170$)	p-value[a]
MFAC	Median: III	Median: III	0.015*
	I: 6 (−1.6)	I: 12 (1.6)	
	II: 48 (−2.0)	II: 61 (2.0)	
	III: 58 (3.1)	III: 29 (−3.1)	
	IV: 58 (0.4)	IV: 50 (−0.4)	
	V: 11 (−0.2)	V: 11 (0.2)	
	VI: 4 (−1.1)	VI: 7 (1.1)	
EMS (points)	3.8 ± 3.0, 3	4.0 ± 3.7, 3	0.518
MBI (points)	47.4 ± 19.6, 51	43.0 ± 20.0, 43	0.042*

Notes: Data shown as mean ± standard deviation, median; each MFAC category with number of count (adjusted standardized residual). EMS = Elderly Mobility Scale; MBI = Modified Barthel Index; MFAC = Modified Functional Ambulation Classification. *$p < 0.05$.
[a]p-values of Chi-square tests for MFAC; Mann–Whitney U tests for others.

Table 3. Comparisons of functional scores of individuals upon discharge from rehabilitation hospital.

	Study group ($n = 185$)	Control group ($n = 170$)	p-value[a]
MFAC	Median: IV	Median: IV	0.003*
	I: 3 (−0.8)	I: 5 (0.8)	
	II: 14 (−3.2)	II: 32 (3.2)	
	III: 25 (1.4)	III: 15 (−1.4)	
	IV: 57 (2.2)	IV: 35 (−2.2)	
	V: 47 (0.7)	V: 38 (−0.7)	
	VI: 37 (−0.3)	VI: 36 (0.3)	
	VII: 2 (−2.3)	VII: 9 (2.3)	
EMS (points)	8.2 ± 5.5, 7	8.4 ± 6.1, 6	0.998
MBI (points)	63.0 ± 23.4, 68	61.2 ± 26.1, 64	0.743

Notes: Data shown as mean ± standard deviation, median; each MFAC category with number of count (adjusted standardized residual). EMS = Elderly Mobility Scale; MBI = Modified Barthel Index; MFAC = Modified Functional Ambulation Classification.
[a]p-values of Chi-square tests for MFAC; Mann–Whitney U tests for others.

in both study (mean ± standard deviation, median: 3.8 ± 3.0 points, 3 points) and control groups (4.0 ± 3.7 points, 3 points) ($p = 0.518$) (Table 2).

For functional outcome when patients upon discharged from rehabilitation hospital, the Chi-square test of the MFAC scores with adjusted standardized residual analysis ($p = 0.003$) (Table 3) shows that there were statistically significantly higher percentage of patients of Category II in control group (18.8%), statistically significantly higher percentage of patients of Category IV in study group (30.8%) and statistically significantly higher percentage of patients of Category VII in control group (5.3%). Similar functional mobility, represented by EMS, was found in both study (mean ± standard deviation, median: 8.2 ± 5.5 points, 7 points) and control groups (8.4 ± 6.1 points, 6 points) ($p = 0.998$) (Table 3). Similar basic ADL level, represented by MBI, was found in both study (mean ± standard deviation, median:

Table 4. Comparisons of LOS and PT training sessions.

	Study group ($n = 185$)	Control group ($n = 170$)	Between groups difference (mean, percentage change)	p-value[a]
Post-operative acute LOS (days)	7.7 ± 3.9, 7	7.4 ± 5.0, 6	0.3, 3.8%	0.192
Rehabilitation hospital LOS (days)	20.0 ± 5.5, 20	24.3 ± 9.9, 23	−4.3, −17.6%	< 0.001*
Post-operative in-patient LOS (days)	26.7 ± 6.4, 26	30.7 ± 11.2, 28	−4.0, −12.9%	< 0.001*
PT sessions	17.8 ± 5.2, 18	16.0 ± 6.7, 15	−1.8, 11.5%	< 0.001*

Notes: Data shown as mean ± standard deviation, median. *$p < 0.05$. LOS = length of hospital staying day; PT = Physiotherapy.
[a]p-values of Mann–Whitney U tests.

63.0 ± 23.4 points, 68 points) and control groups (61.2 ± 26.1 points, 64 points) ($p = 0.743$) (Table 3).

For post-operative acute hospital stay, similar LOS was found in both study (mean ± standard deviation, median: 7.7 ± 3.9 days, 7 days) and control groups (7.4 ± 5.0 days, 6 days) ($p = 0.192$) (Table 4). For rehabilitation hospital stay, significant shorter LOS was found in study group (20.0 ± 5.5 days, 20 days) than in control group (24.3 ± 9.9 days, 23 days) ($p < 0.001$) (Table 4). For post-operative total in-patient stay, significant shorter LOS was found in study group (26.7 ± 6.4 days, 26 days) than in control group (30.7 ± 11.2 days, 28 days) ($p < 0.001$) (Table 4).

For number of PT training sessions, significant more training session was found in study group (mean ± standard deviation, median: 17.8 ± 5.2 sessions, 18 sessions) than in control group (16.0 ± 6.7 sessions, 15 sessions) ($p < 0.001$) (Table 4). A higher percentage of day having PT training during rehabilitation hospital stay was shown with the implementation of new service (Study group: 89.1%; Control group: 65.9%, $p < 0.001$).

Discussion

Our results suggest that additional weekend and holiday PT training has positively contributed to rehabilitation for geriatric patients with hip fracture, in terms of service efficiency of public healthcare system.

First, additional weekend and holiday PT training may contribute to a more efficient in-patient functional training. Studies have concluded that additional weekend and holiday PT service may possibly reduce hospital LOS for individuals with various disease groups receiving in-patient rehabilitation.[8–10,14,20] Results of our study are in line with the literature. Results suggested that similar functional mobility ($p = 0.998$) and ADL level ($p = 0.743$) were achieved with a shorter LOS ($p < 0.001$) when patients were discharged from rehabilitation hospital in study group.

Similar to literature, short intensive in-patient rehabilitation was an effective mode to improve mobility and functional performance for geriatric individuals with hip fracture.[21–23] As Heiberg *et al.*[24] suggested, daily walking and other functional training give positive impact on physical outcomes than limited PT interventions on weekdays in geriatric patients with hip fracture. Although PT training in our center is not as comprehensive as the one in Heiberg's study, daily functional training has been in place after launching of additional weekend and holiday PT service. As systematic review by Scrivener *et al.*[25] concluded, additional physical rehabilitation improves functional outcome without impact in LOS. These studies suggested that with similar LOS, individuals with additional weekend and holiday PT training may possibly train up to a higher mobility level. Our results shown an improved LOS with similar functional outcomes. Here, the same principle was shared, individuals with additional PT service may have a higher rate in functional regain.

Cary *et al.*[26] reported that patients with hip fracture who have longer in-patient rehabilitation LOS are related to higher functional performance on discharge. However, prolonged mobility deterioration was expected in geriatric patients with hip fracture after discharge from hospital. Local data show that deteriorated mobility was found when compared to pre-morbid, in 3-month and 1-year time post-operation in 77.5% and 69.9% of individuals, respectively.[27] These data reveal that prolonged recovery is needed, but not having a

significant change just by adding 1.8 more PT training sessions ($p < 0.001$) in average, after our service extended. The goal of geriatric hip fracture in-patient rehabilitation is to optimize their functional level, once patients reach a certain level in functional performance and with adequate social support, they would be considered to be discharged. Now, weekend PT training may speed up patients' recovery to the level.

Second, additional weekend and holiday PT training may contribute to an improved efficiency of rehabilitation hospital stay. Results suggested that geriatric patients with hip fracture now have an 89.1% of rehabilitation hospital staying day receiving PT training. A 23% increase shown when comparing to control group with only 65.9% days with PT training. Statistically, it is an encouraging result in responding to the document of Strategic Service Framework for Rehabilitation Services in terms of expanding inpatient rehabilitation service coverage.[6]

Clinically, this was 1.8 more PT sessions received in average ($p < 0.001$), with 4.3 days less LOS ($p < 0.001$) in study group for rehabilitation hospital training. Great improvement is not expected with only 1.8 more PT session provided. However, the continuous training may affect the efficiency for staying in rehabilitation hospital. Additional weekend and holiday PT training is especially valuable for those who needed to stay in hospital during long public holidays, in preventing them to be sedentary for consecutive days during hospital stay. According to National Institute for Health and Care Excellence (NICE) guideline[28] on fracture hip management, daily mobilization and regular PT review were recommended. The extended PT service greatly improved the compliance to this recommendation. Patients have chance to mobilize and walk daily and therapists can plan for regular review without interruption by long public holiday. The time used for assessing all accumulated new cases during holiday or cases needed to be reviewed is now greatly lowered as number of new cases referral and review cases may be more evenly distributed in between the holidays, thus with more appropriate evaluation and training progression can be made on time.

Third, more patients were trained up to walk with assistance in acute phase after additional weekend and holiday PT service started. As patients would receive PT assessment within one day after admitted to rehabilitation hospital, the scores taken in admission can be considered as the status when individuals were discharged from acute hospital. Results shown that higher percentage of patients of MFAC Category III in study group (31.4%) and higher percentage of patients of MFAC Category II in control group (35.9%) ($p = 0.015$), and there were no statistically significant differences in other MFAC categories of both groups.

As the retrospective analysis done by Maidment *et al.*[10] suggested that patients with weekend PT training achieved milestone of PT treatment in a shorter period without affecting hospital staying period. These results were in line with our findings and revealed that patients in post-operative acute care period were benefited in terms of functional outcome, from the additional weekend and holiday PT training. The additional one to two PT training sessions cannot be a major reason for having more dependent walkers and less sitters in study group ($p = 0.015$), but the effect of early mobilization counts.[21,29] Previously, if patients received operation near weekend or holiday, they needed to wait until the first working day to have their 'first walk'. Mobilization was then delayed and possibly lead to higher rate of complications.[30] Now, daily PT service providing individuals timely access to rehabilitation service and chances to have early mobilization if it is not contraindicated.

For the post-operative acute LOS, as suggested by Maidment *et al.*,[10] prolonged hospital LOS may be due to administrative or organizational delay, and thus, individual mobility is only one of the determinants. These factors might also be present in this study when individuals were transferred to rehabilitation hospital. However, relevant information was not retrieved for analysis in this study.

Finally, additional weekend and holiday PT training may contribute to a cost-saving service. Geriatric patients with hip fracture had a shorter post-operative in-patient LOS ($p < 0.001$) after PT service extended to 7-day per week. According to the 'Asia-Pacific regional audit' published in 2013 by International Osteoporosis Foundation (IOF), everyone with hip fracture occupied 27 hospital bed days and leaded to USD$10,782 hospital cost in Hong Kong.[4] As our results show, the 4.0 days shorter in post-operative in-patient LOS give a clinical significance reduction in cost for each geriatric patient with hip fracture. As estimated, fragility hip fracture in Hong Kong will experience an increase from 4579 cases in 2011 to more than

14,500 cases in 2040.[5] With this single strategy on additional weekend and holiday PT service, it may possibly save a great amount of hospital staying cost. Cost-effective strategies not only will lower the financial impact toward the public health care system, but also improve the bed space availability for the increasing case number.

As mentioned before, geriatric patients with hip fracture experience a long journey in their functional recovery, more than half of them still experience a deteriorated mobility when compared to pre-morbid state.[27] In-patient rehabilitation is then a small, but critical part of geriatric hip fracture rehabilitation.[28,30,31] As suggested by Lau *et al.*,[31] simple measures in standardizing clinical pathway with multi-disciplinary approach would improve outcomes and quality of care in geriatric patients with hip fracture. Detail and precise pre-discharge planning and continuous training in ambulatory or community settings may possibly affecting further functional recovery.[22,28,30] Being a healthcare profession, we always strive for service improvement in any parts in geriatric hip fracture management for better outcomes and quality of care.

To further investigate the effect of additional weekend and holiday PT training toward geriatric patients with hip fracture, analysis on sub-group (like classify with pre-morbid mobility level or with type of surgery done, etc.) is suggested. As the staffing capacity is now limited in weekend service, only certain number of cases can be served. Case selection may be needed when facing a growing case number, results from sub-group analysis will serve as a triage purpose. Also, different modes of additional service can be studied. As mentioned in literature, extra PT time may possibly deliver with a different mode, benefit can be achieved in terms of functional outcomes and LOS.[20] The study on different modes of additional service and cost-effective strategies may provide insight in the possibility of achieving higher functional level with a shorter LOS.

Limitations of this study include: (1) the study design, (2) single hospital cases were reviewed and (3) effects of other new service were not considered. First, this is a case-historical control study of retrospective review of medical records, therefore, extra cautions should be paid when we induce causal relationship from the data. Also, as other clinical variables (like cognitive state, time to surgery, post-operative complications, etc.) were not captured in our study, there were potentially confounding factors. However, it is still an appropriate method to evaluate the new service. Randomized controlled trial is not pragmatic as this is an evaluation of a new service program with resources injected. Second, the single-center design limits its generalizability to other centers. Other hospitals may have different structure of geriatric hip fracture rehabilitation program and different criterion for discharge. Third, some new service, like Medical-Social Collaboration program and Geriatrician weekly case conference, were launched in part of the inclusion period of study group, which may possibly affect the results of LOS in some patients.

To conclude, additional weekend and holiday PT training shorten the LOS in rehabilitation hospital and total in-patient hospital stay with more PT sessions during hospitalization, without any significant impacts on functional outcome.

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Conflict of Interest

The authors declare that there is no conflict of interest relevant to this paper.

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Author Contributions

All the authors contributed to the conception and design of study and approval for the submission to publication. K.C. Mo and H.M. Ma contributed to the data analysis and interpretation. K.C. Mo and K.M. Lau contributed to the manuscript drafting. M.Y. Fung, H.M. Ma, F.O. Lau and S.W. Law contributed to the manuscript revision.

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Limiting potential COVID-19 contagion in squatting public toilets

Li Pan[1], Shuang-Lan Chen[1], Yi-Sha Guo[1], Yu-Xiang Du[1], Xiao-Di Wu[1], Alice Y. M. Jones[3,*] and Jia Han[1,2,4]

[1]*Department of Physiotherapy, School of Kinesiology*
Shanghai University of Sport, Shanghai 200438, P. R. China

[2]*Faculty of Health, Arts and Design, Swinburne University of Technology*
Hawthorn, VIC 3122, Australia

[3]*School of Health and Rehabilitation Sciences*
The University of Queensland, St. Lucia QLD 4072, Australia

[4]*Research Institute for Sport and Exercise*
University of Canberra, Bruce, ACT 2617, Australia

a.jones15@uq.edu.au; alice.jones.hk@gmail.com

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Background: Since the outbreak of the SARS-CoV-2 virus in December 2019, the COVID-19 pandemic continues to threaten global stability. Transmission of SARS-CoV-2 is mostly by respiratory droplets and direct contact but viral RNA fragments have also been detected in the faecal waste of patients with COVID-19. Cleanliness and effective sanitation of public toilets is a concern, as flushing the toilet is potentially an aerosol generating procedure. When the toilets are of the squatting type and without a cover, there exists a risk of viral contamination through the splashing of toilet water and aerosol generation.
Objective: This study aims to determine whether the cleanliness of public toilets was a concern to the general population during the COVID-19 pandemic, and whether a squatting toilet was preferred to a seated design.

*Corresponding author.

Methods: A questionnaire was designed and posted on "WeChat" contact groups of the investigators.
Results: The survey showed that 91% of participants preferred squatting toilets, but that 72% were apprehensive of personal contamination when using public toilets. Over 63% of the respondents had encountered an incidence of water splash and would prefer public toilets to be covered during flushing and 83% of these respondents preferred a foot-controlled device.
Conclusion: This survey suggests that consideration should be given to the installation of a simple foot-controlled device to cover public squatting toilets to help restrict potential COVID-19 contamination and to meet hygienic expectations of the public.

Keywords: Public toilets; squatting; toilet cover; splashing.

Background

The COVID-19 pandemic demanded an urgent response from healthcare systems worldwide, challenging the management of patients with this novel disease and the adequacy of health service provision. In the early phase of the outbreak, strategies which limited the spread of the virus were fundamental considerations, together with the logistical provision of personal protective equipment, diagnostic kits and mechanical ventilators.[1] SARS-CoV-2 is the virus responsible for COVID-19, and the main routes of transmission of this virus are through infected respiratory droplets and close contact with an infected individual.[2] About 2–10% of patients with confirmed COVID-19 presented with diarrhea[3–5] and COVID-19 viral RNA fragments were detected in the fecal waste from patients with COVID-19.[6,7] Appropriate management of excreta and wastewater disposal in sewerage systems is considered essential to public health policy.[8] Squatting toilets are common in Asian countries, and a squatting posture has been shown to widen the anorectal angle and facilitate defecation.[9] However, use of a squatting toilet may be a concern if the toilet is left uncovered. Up to 145,000 droplets can be generated per flush[10] and microorganisms can be entrained into "droplet nuclei toilet plume aerosols" and remain viable for extended periods while airborne.[11] The toilet flush is an "aerosol generating procedure" and without a cover there is a potential risk of viral contamination of the user.

All health professions have a role in promulgating disease prevention strategies to the general public. With the intention of increasing student engagement in public health education, physical therapy students in China were invited to participate in a campaign to increase awareness of public toilet hygiene. One student group surveyed community observations of public toilet facilities. Information gathered from this survey may contribute to future design perspectives for squatting public toilets. This paper describes the findings of this survey of public toilet use in China.

Method

Ethics approval was sought prior to the launch of an online survey on views of the general public on their use of public toilet facilities in China. As this was an online survey, replies from participants were voluntary and implied consent to participate in the survey. Formal ethics application was waived by the ethics committee of the Shanghai University of Sport.

Design of the questionnaire

A 16-question questionnaire was designed by the investigators (L. Pan, S. Chen, Y. Guo, Y. Du and X. Wu) to determine whether the potential to spread COVID-19 in public squatting toilets was of concern to the general public. The preferences for squatting or sitting type of toilet, hand-controlled or foot-controlled toilet cover and flushing mechanism were sought. The questions were posted on the "WeChat" contact groups of the investigators. The WeChat platform is a mobile communication App extensively used in China. Friends and relatives of the investigators were invited by phone messages to complete the survey on the WeChat platform. Return of a completed questionnaire implied consent to participate in the survey. Descriptive data from completed questionnaires were analyzed.

Table 1. Number of participants by gender, age and province.

	Males	Females	Provinces/Municipalities
Under 18 years	0	4	Hunan: 1, Shanghai: 2, Sichuan: 2
18–45 years	35	88	Anhui: 2, Beijing: 3, Chongqing: 2, Guangdong: 3, Guizhou: 76, Hainan: 1, Hebei: 3, Henan: 1, Hubei: 3, Jiangsu: 1, Shaanxi: 1, Shandong: 2, Shanghai: 10, Shanxi: 2, Sichuan: 5, Xinjiang: 3, Yunnan: 1, Zhejiang: 4
45–65 years	1	3	Guangdong: 1, Shanghai: 3
Over 65 years	2	1	Guizhou: 1, Shanghai: 2
Total	38	96	16 provinces and three municipalities

Results

A total of 134 participants (38 males and 96 females) completed the online questionnaire from 16 provinces and three municipalities (similar administrative status as provinces). The majority of the participants (95%) were in the age group of 18–45 years, four aged between 45 years and 65 years and three over 65 years old (Table 1). Results showed that 91% of the participants preferred a squatting toilet, and that 72% of the participants worried about personal contamination by water splash during toilet use. Also, 63% reported encountering a splashing incidence during toilet use and a similar percentage preferred the toilet to have a cover. Besides, 93% of participants would like the flushing conditions in public toilets

Table 2. Questions and responses of the 134 participants: Data as number (%).

	Questions	Responses				
		1	2	3	4	5
1	Are you worried about public toilet hygiene because of the recent COVID disease? 1 = Worried 2 = Not particularly 3 = Not worried	72 (53.7)	46 (34.3)	16 (11.9)		
2	During the COVID period, are you satisfied with the condition of public toilets in hospitals? 1 = Satisfied 2 = Not sure 3 = Not satisfied	39 (29.1)	81 (60.4)	14 (10.4)		
3	During the COVID period, are you satisfied with the condition of public toilets in commercial complexes and public entertainment areas? 1 = Satisfied 2 = Not sure 3 = Not satisfied	41 (30.6)	74 (55.2)	19 (14.2)		
4	Do you prefer squatting toilets or sit-down toilets in public places? 1 = Squatting toilet 2 = No preference 3 = Sitting toilet	122 (91)	11 (8)	1 (1)		
5	Are you satisfied with the current hygienic condition of public "squatting" toilets? 1 = Satisfied 2 = Not sure 3 = Not satisfied	41 (30.6)	57 (42.5)	36 (26.9)		
6	Are you satisfied with the convenience of use of current public squatting toilets? 1 = Satisfied 2 = Neutral 3 = Not satisfied	61 (45.5)	50 (37.3)	23 (17.2)		
7	During the use of public squatting toilets, did you encounter any incidence of water splashing? 1 = Yes 2 = Do not remember 3 = No	85 (63.4)	18 (13.4)	31 (23.1)		
8	When using public squatting toilets, were you worried about personal contamination by water splashing? 1 = Yes worried 2 = Not really 3 = Not worried	97 (72)	29 (22)	8 (6)		
9	Do you wish public toilets had some type of cover to improve the level of cleanliness? 1 = Yes 2 = No strong view 3 = No	83 (62)	31 (23)	20 (15)		

Table 2. (*Continued*)

	Questions	Responses 1	2	3	4	5
10	If more time is necessary for proper sanitization of public toilets, how long would you be prepared to wait? 1 =< 5 s 2 = Up to 10 s 3 = Up to 20 s 4 = Up to 30 s 5 = Others	13 (10)	27 (20)	23 (17)	59 (44)	12 (9)
11	If a foot- or hand-controlled device was installed to improve sanitization, would you be willing to use it? 1 = Yes 2 = Not sure 3 = No	117 (87)	12 (9)	5 (4)		
12	Would you prefer the sanitization device be hand-controlled or foot-controlled? 1 = Foot-controlled 2 = Either 3 = Hand-controlled	107 (83)	17 (13)	5 (4)		
13	Do you wish the water flushing condition in public toilets to be improved? 1 = Yes 2 = Not sure 3 = No	125 (93)	8 (6)	1 (1)		
14	If a foot- or hand-controlled device was installed to reduce water splashing, would you be willing to use it? 1 = Yes 2 = Not sure 3 = No	120 (90)	11 (8)	3 (2)		
15	Would you prefer this device to be foot-controlled or hand-controlled? 1 = Foot-controlled 2 = Either 3 = Hand-controlled	110 (83)	16 (12)	7 (5)		
16	What is your first-choice mechanism for toilet flushing? Automatic flushing Foot-controlled flushing Press-button Turn button Pull string	73 (54.5)	45 (33.6)	13 (9.7)	2 (1.5)	1 (0.7)

improved, and over 83% preferred a foot-controlled device to cover the toilet or minimize water extrusion. Responses to the 16 questions are displayed in Table 2.

Discussion

This is the first survey which explores the general view of toilet use in China and a preference for a squatting or seated arrangement, and whether there was any apprehension of contamination via splashing of toilet water. This paper addresses an important public health concern, particularly during the COVID-19 pandemic. SARS-CoV-2 is the virus responsible for COVID-19 and is transmitted via infected respiratory droplets[2] but also may be transmitted via the fecal–oral route.[5] The majority of public toilets in China are of the uncovered squatting type.

Toilet flushing is potentially an "aerosol generating procedure". Johnson *et al.* reported about 145,000 droplets per flush in high-energy flushometer toilets, and 95% of droplets were $< 2\mu$m in diameter.[10] SARS-CoV-2 aerosol droplets found in the hospitals in Wuhan were reported to be 0.25–1 μm in diameter.[12] The toilets used in Johnson *et al.*'s study were of seated type and quite possibly the water flow was higher than that in squatting toilets in China. However, over 63% of the participants in our survey encountered an incidence of splashing during toilet flushing. Clearly, flushing an uncovered toilet poses a risk of viral spread to the user. This survey showed that while a third of the participants considered the hygienic condition of public toilets satisfactory, many would prefer the flushing conditions to be improved. While only about half of the participants reported they were worried about public toilet hygiene during the COVID-19 pandemic, 72% of them admitted they were worried about personal contamination and all participants were willing to spend extra waiting time for any necessary sanitization procedure. If an improved sanitizing procedure were in place which required extra time for the cleaning process, the majority of our survey participants expressed a willingness to spend an extra 30 s, and some even more than 5 min of waiting for the sanitizing process.

Upgrading public toilets in China is a considerable task because almost all public hospitals, schools, universities and the majority of commercial buildings have squatting public toilets without covers. In 2019, there are 147,466 independent and movable public toilets,[13] these figures do not include public toilets in hospitals, schools, universities or commercial malls. In 2019, the Chinese government allocated 7 billion RMB in upgrading rural toilet facilities.[14] The Chinese government actively supported the concept of a "Toilet Revolution" originally proposed by UNICEF in 1997.[15] China is a major industrialized country and most probably has the largest squatting toilet market in the world.[15] Squatting toilets with covers are available in some commercial malls in major cities, however most of these covers are hand-controlled (Fig. 1) and cleaning and disinfection procedures need further refining. Figure 2 shows an integrated toilet with a foot-controlled lid, but currently only available for domestic use. Designing covers for a large number of public toilets must obviously take into consideration the production costs. Rather than a sophisticated device, simple step-to-open and step-to-close mechanisms might be considered. Factors that affect the ease of cleaning and disinfection are also essential considerations and must be carefully contemplated in a pandemic. Investment in effective public health disease prevention strategies in a pandemic is easily offset by a reduced healthcare spending treating the people infected by COVID-19. The risk of splashing must be eliminated, and the maneuver for operation of the cover should be foot-controlled, to avoid direct physical contact of the toilet.

Fig. 1. A multigrid hand-controlled toilet cover to prevent objects from dropping into the toilet when not in use.

Fig. 2. Domestic squatting toilet with a foot-controlled cover.

This survey reveals that 91% of the participants prefer a squatting toilet compared to a sitting one. Although a sitting toilet may be more convenient, a squatting toilet has some advantages over a seated toilet. First, no physical contact with a squatting toilet is necessary. Second, the squatting position facilitates relaxation of the muscles around the anal canal and widens the anorectal angle to allow a straighter passage for defecation.[9] This theory led to the use of a "Defecation Posture Modification Device" (DPMD) with the seating type of toilet. The DPMD brings the hips and knees in a pseudo-squatting position thus facilitates relaxation of the pelvic floor muscles during defecation.[16] It was also reported that the squatting action during use of squatting toilets improved blood flow velocity in the lower extremities,[17] and the user is subjected to squatting, as a form of exercise for strengthening of the quadriceps muscles. Quadriceps strength is associated with a lower cardiovascular mortality in patients with coronary artery disease.[18] However, not everyone can squat,[19,20] especially those with restricted lower limb joint mobility and older people with poor balance and muscle weakness.

Irrespective of the type of toilet, limiting toilet flush water splash may reduce oral–fecal contamination and save on sanitation costs. The current COVID-19 pandemic provides opportunities for strengthening public health systems globally, and

it is time to consider long-term optimal environmental plans beyond disaster response.[21]

There are several limitations in this survey. Our questionnaire did not explore why our participants favored squatting toilets. It is therefore not clear whether squatting toilets were preferred on a cultural or a zero-physical-contact hygienic basis. Further, while we inquired about an improved sanitizing process, we did not explore whether our participants were willing to pay for a higher level of sanitization. Understanding the level of commitment of the general public can help with the planning and future design of public toilets. Lastly, our sample size was relatively small and not randomized, nonetheless the results provide useful information for improvement of public toilets in China.

Conclusions

This survey showed that the general public cohort questioned in China preferred a squatting to seated type of public toilet. The majority of people had encountered splashing of toilet flush water and many were worried about personal contamination through this process. The majority of the participants hoped for improved public toilet cleanliness and were willing to spend more time to trade for an improved toilet sanitizing process associated with use of the public toilet. This survey suggests that consideration should be given to the installation of a simple foot-controlled device to cover public squatting toilets to help restrict potential COVID-19 contamination.

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Conflict of Interest

The authors declare that there are no conflicts of interest related to this article.

Author Contributions

All authors have read and approved the paper. The specific contribution of each author is as follows: Alice Y. M. Jones, Jia Han, Li Pan, Shuang-lan Chen, Yi-sha Guo, Yu-xiang Du and Xiao-di Wu conceptualized the study question and design. Alice Y. M. Jones, Jia Han and Li Pan designed the questionnaire. Li Pan, Shuang-lan Chen, Yi-sha Guo, Yu-xiang Du, Xiao-di Wu and Alice Y. M. Jones participated in data collection, data analysis, data interpretation and preparing the first draft of the paper. Alice Y. M. Jones and Jia Han reviewed and advised on analyses and interpretation of data.

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Lumbopelvic sagittal standing posture associations with anthropometry, physical activity levels and trunk muscle endurance in healthy adults

George A. Koumantakis[1,2,*], Antonios Malkotsis[2], Stefanos Pappas[2], Maria Manetta[2], Timotheos Anastopoulos[2], Apollon Kakouris[2] and Eleutherios Kiourtsidakis[2]

[1]*Department of Physiotherapy, 401 General Army Hospital of Athens*
Panagioti Kanellopoulou 1, Athens, Greece

[2]*School of Physiotherapy, Faculty of Health Sciences*
Metropolitan College (Affiliated to Queen Margaret University, Edinburgh, UK)
Athens, Greece

[*]*g.koumantakis2@gmail.com*

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Background: Various factors, inherited and acquired, are associated with habitual spinal postures.
Objective: The purpose of this study was to identify the relationships between trunk muscle endurance, anthropometry and physical activity/inactivity and the sagittal standing lumbopelvic posture in pain-free young participants.
Methods: In this study, 112 healthy young adults (66 females), with median (IQR) age of 20 years (18.2–22 years), without low back pain, injury or trauma were included. Lumbar curve (LC) and sacral slope (SS) angles were measured in standing with a mobile phone application (iHandy level). Anthropometric, physical activity/inactivity levels (leisure-time sport involvement and sitting hours/day) and abdominal (plank prone bridge test) and paraspinal (Sorensen test) isometric muscle endurance measures were collected.
Results: LC and SS angles correlated significantly ($r = 0.80$, $p < 0.001$). Statistically significant differences for both LC ($p = 0.023$) and SS ($p = 0.013$) angles were identified between the male and female participants. A significant negative correlation was identified between the abdominal endurance time and LC ($r = -0.27$, $p = 0.004$); however, the power of this result (56%) was not sufficiently high. The correlation between

[*]Corresponding author.

abdominal endurance and SS was non-significant ($r = -0.17$, $p = 0.08$). In addition, no significant associations were identified between either of the sagittal lumbopelvic angles (LC–SS) in standing and the participants' body mass index (BMI), paraspinal endurance, leisure-time sport involvement or sitting hours/day. **Conclusion:** The potential role of preventive exercise in controlling lumbar lordosis via enhancement of the abdominal muscle endurance characteristics requires further confirmation. A subsequent study, performed in a larger population of more diverse occupational involvement and leisure-time physical activity levels, is proposed.

Keywords: Muscle fatigue; physical activity; abdominal; lumbar; spine.

Introduction

Neuromuscular control of spinal postures and movements is key, contributing in parallel to load minimization and injury or degeneration prevention of passive spinal structures.[1] Pelvic and spinal alignment in the sagittal plane is crucial for maintaining a balanced stance, forming the basis for many functional activities.[2] Postural deviations are considered to be among the factors progressively leading to or associated with the presence of painful spinal musculoskeletal disorders.[3–6] and degeneration.[7] However, this is still a matter of debate, as not all relevant studies have clearly demonstrated detrimental effects on spinal structures or symptoms development linked to postural deviations.[8]

Previous studies have substantiated that sagittal spinal posture is influenced by age progression,[9] sex[9,10] and increased body mass index (BMI).[2,11] Additionally, spinal posture has been significantly associated with the paraspinal muscle endurance levels,[12–14] although other researches have not substantiated such a relationship for the lumbar curve (LC), with a significant relationship only demonstrated between abdominal performance and pelvic inclination in women.[15] Furthermore, different types of occupational demands,[16] physical activity levels for asymptomatic men only[15] and specific long-term athletic training[17] may influence standing posture. However, no associations between lumbar lordosis and physical activity levels[18] and lifestyle or occupational demands have also been reported.[19] Postural assessment has also been studied in adolescent populations,[20,21] as adolescence may be an opportune time period to influence improvements in spinal posture via certain postural exercise interventions[17,22] and possibly prevent musculoskeletal pain episodes in the future. A predictive role of adolescent spinal non-neutral posture at 14 years for back pain development at 17 years of age in the same population has been established, however, among a multitude of other factors collectively contributing to the pain experience.[23] On the other hand, apart from environmental and lifestyle factors, familial predisposition seems to be also influential, at least for certain hyperlordotic postures.[24]

The "core" muscles are considered to consist of transversus abdominis (TrA) and multifidus (MULT) muscles, providing mainly stability to the low back and pelvis, in coordination with the more superficial trunk musculature. A significant decrease in thickness measurements of TrA has been identified in 20 healthy adults when assuming a swayback compared to a neutral lumbopelvic posture, denoting better activation of TrA in the latter standing posture.[25] Similar results of decreased activation in the internal oblique/TrA muscles have been recently reported in 37 adults, when a slouched sitting posture was assumed.[26] The muscle tone of the deep trunk muscles has been lately described as predictive of both positive (TrA) and negative (MULT) outcomes among the low back pain (LBP) sufferers.[27] A history of LBP in a mostly young mixed-sex cohort has also been shown to affect the thickness of TrA more than the MULT one.[28] Therefore, except LBP presence, also extreme flexion (flatback) or extension (lordotic) lumbar spine postures affect the activation of deep trunk muscles, rendering the relevant spinal segments "unprotected" in the case of prolonged or increased spinal loading.

The purpose of this study was to identify certain factors that correlate with standing lumbopelvic posture in healthy participants, with the aim to focus on those factors that are considered to be modifiable. For instance, advice on BMI reduction or adopting more active physical activity lifestyles (increasing exercise frequency in general or

increasing trunk-specific exercise) could then be proposed as preventive measures against spinal pain. Such factors can be targeted by physical therapists, to promote the adoption of more optimal spine standing postures, documented to be less frequently related with non-specific LBP episodes.

Methods

Study design

Cross-sectional correlational design is used to explore the associations between sagittal lumbopelvic posture in standing and anthropometric, leisure-time activity/inactivity habits and trunk muscle endurance performance variables.

Participants

The study took place at Metropolitan College with volunteers being students of one of the campuses of this institution. The exclusion criteria for the participation of this study were any injury-trauma and/or active LBP and menstruation or pregnancy (females) to avoid any influence of those factors on habitual standing posture. Recruitment of participants took place from November 2016 to January 2017 and was achieved via e-mail notifications of the purposes of the study, sent to 450 students of the School of Health. E-mail notifications were sent out twice, in the beginning of November and a reminder at the beginning of December 2016. Totally 125 students responded to the research call. However, 10 students finally were not able to make their assessment appointments and three had a fairly recent incident of back pain, therefore were excluded. Finally, 112 healthy adults (46 males and 66 females) participated voluntarily in this research study. The descriptive statistics of participants are presented in Table 1. A written informed consent, presenting the purposes and aims of this study and the inclusion–exclusion criteria, was signed by all participants prior to their inclusion to the study. The study protocol was approved by the Ethics Committee of Metropolitan College. All rights of participants were protected at all times, according to the Declaration of Helsinki.

Lumbopelvic sagittal standing postural assessment

Lumbar posture can be clinically assessed with the Bubble inclinometer which is a device with a good reliability and validity or with a wide variety of other measurement instruments such as pantograph, kyphometer, flexible curve and lately, the smartphones.[29] Sagittal lumbopelvic posture in standing was assessed in two previous studies with the use of a smartphone (iHandy free application).[29,30] The first of those studies verified the inter-rater within-day (ICC = 0.96) and intra-rater between-day (ICC = 0.81, SEM = 3° and $MDC_{90\%} = 7°$) reliabilities of the lumbar curve in 30 healthy participants, with the smartphone measurement displaying comparable accuracy to the one with a Bubble inclinometer (ICC = 0.85, SEM = 3° and $MDC_{90\%} = 6°$).[29] The within-day intra-rater reliability of this postural assessment method was further confirmed, measuring two angles in quiet standing posture, the sacral slope (SS; $ICC_{2,1} = 0.97$, SEM = 1.61° and $MDC_{95\%} = 4.46°$) and the lumbar curve ($ICC_{2,1} = 0.96$, SEM = 2.13° and $MDC_{95\%} = 5.9°$), in a larger group of asymptomatic participants ($n = 183$).[30] The validity of the method to differentiate between male and female participants' SS and LC angles has also been established in the latter study.[30]

Table 1. Descriptive statistics of ratio-type variables (anthropometric, two posture measures and two trunk muscle endurance test measures) from all participants ($n = 112$).

	Min	Max	Mean	Standard deviation
Height (cm)	150	198	173	9.5
Body mass (kg)	45	115	69.7	14.3
BMI (kg/m^2)	17.6	39.8	23.1	3.5
Lumbar curve (°)	9.9	52.9	24.2	8.1
Sacral slope (°)	5.2	34.5	17.6	6.1
Plank prone bridge endurance test (s)	16	245	88.6	47.4
Modified Sorensen endurance test (s)	34	370	126.3	54.6

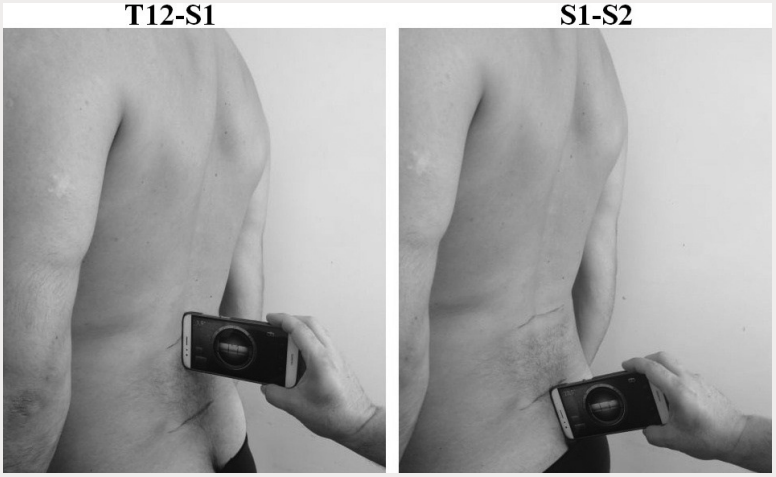

Fig. 1. Lumbar curve and sacral slope measurement technique with the smartphone placed at T12–L1 and S1–S2 interspaces.

Therefore, the use of smartphones as measurement tools of spinal angles has adequate evidence-base to be used further.

The iHandy level application was used to measure the SS and LC angles in standing (Table 1). The angle readings from the smartphone, when placed with its upper vertical side at T12–L1 and S1–S2 spinous processes, were recorded (Fig. 1). The sacral slope value corresponded to the reading from S1–S2 and the lumbar curve value corresponded to the sum of the absolute readings from T12–L1 and S1–S2. Additional measurement details of SS and LC parameters are presented analytically elsewhere.[29,30]

Trunk muscle endurance assessment

As core stability is linked to a continuous role of the trunk muscles in the maintenance of mid-range neutral-zone postures,[1] the endurance capacity of those is commonly assessed.[13,31]

For the purposes of this study, the timed endurance to complete exhaustion of the abdominal muscles was measured via the performance of the plank prone bridge test [Table 1 and Fig. 2(a)]. According to a recent study, the application of the prone bridge test (plank test) is a valid and highly reliable method (ICC = 0.87 – 0.89) for the measurement of abdominal muscle endurance,[32] although muscles of the entire anterior aspect of the body are activated in this test. The plank test can be considered a functional endurance test, as it requires simultaneous isometric muscle activation of all the anterior chain muscles.[32,33]

Also, the timed endurance to complete exhaustion of the paraspinal muscles was measured via the performance of a modification of the Sorensen test [Table 1 and Fig. 2(b)]. The Sorensen test is a valid and reliable method to evaluate the

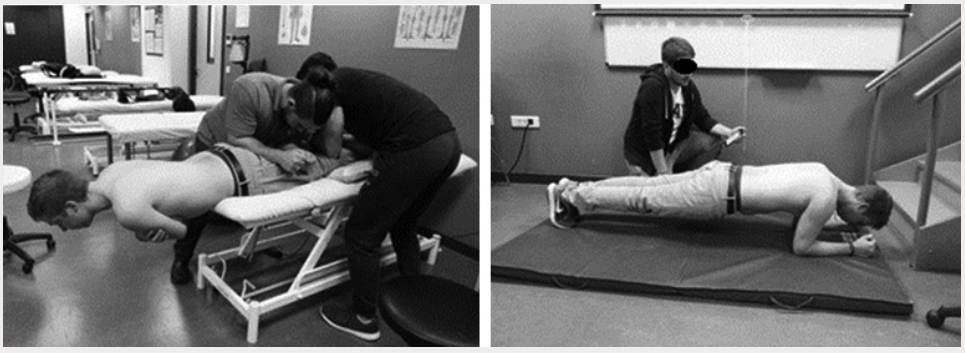

Fig. 2. Procedures for (a) plank prone bridge endurance test and (b) modified Sorensen endurance test to complete exhaustion.

endurance capacity of the trunk extensors, with the additional posterior chain muscles also active (gluteals, hamstrings), during a timed isometric activation of those muscles to complete exhaustion while maintaining the unsupported upper body in the horizontal position, with the buttocks and legs firmly held by three canvas straps and arms folded across the chest.[34,35] The Modified Trunk Extension Testing method (modification of the Sorensen test) follows the same principles as the original test, with the only difference from the standard procedure being the replacement of straps with the participation of a clinician who should firmly hold the subjects' lower extremities onto the examination table. This procedure is also a very reliable variation of Sorensen test method.[31,36]

Anthropometric and self-report physical activity/inactivity characteristics

A questionnaire compiled by the research team was given to participants to fill in, comprising factors that could potentially be associated with their lumbopelvic sagittal standing posture. The questionnaire included items on sex, anthropometric characteristics (age, body mass index), exercise frequency and intensity characteristics (the Baecke Sport Activity subscale),[37] as well as the time spent sitting daily expressed in three categories (less than 3 h/day, 3–5.9 h/day and more than 6 h/day).[38]

Experimental procedures

A pilot study was conducted between the members of the research team, to familiarize with and finalize all measurement procedures. All participants read and completed a form before the beginning of measurements concerning the purposes and the aims of the study, anthropometric and physical activity pattern details. All participants then assumed the standing position with their lower limbs parallel to each other and arms by their side. Three measurements were sequentially conducted by two members of the team for the measurement of SS and LC. One investigator placed the phone in the back of participants, according to anatomical landmark identification for the measurement of the two angles of interest (Fig. 1) viewing the phone from its posterior aspect, without looking at its screen, and another noted the angles in a blinded fashion to avoid biasing results between the three measurements. Additionally, between the three measurements of SS and LC, participants were requested to relax and walk a short distance (10 steps) in order to alter their body posture between measurements. Moreover, one investigator was involved with palpation of anatomical landmarks and skin-marking and another two investigators coordinated the plank test and the Modified Trunk Extension test (modified Sorensen test) procedures (Fig. 2). Prior to the beginning of fatigue testing, participants performed adequate warm-up, under the supervision of the investigators, which included stretches and mild spine mobilizing exercises in order to avoid any muscle strain injury during fatigue testing.

Data analysis

All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 20. The variables collected corresponded to different levels of measurement: sex was nominal-type measurement, number of hours spent in sitting/day was ordinal-type measurement and age, BMI, the Baecke Sport Index and the abdominal and paraspinal muscles endurance tests data corresponded to ratio-type measurements. The corresponding normality of distribution tests per variable were initially performed; sex was assessed with the Binomial test, hours spent sitting/day were assessed with the chi-square test and all variables related to ratio type were assessed with the Kolmogorov–Smirnov test.

The main analysis of this study included unrelated t-tests, Kruskal–Wallis and bivariate correlations. To explore possible differences in LC and SS angles between the categories of nominal (sex) and ordinal variables (sitting hours/day), unrelated t-tests were run for sex and Kruskal–Wallis tests for sitting hours/day. To explore possible associations between LC and SS angles and ratio-type variables (age, BMI, Baecke Sport Index subscale, modified Sorensen endurance and abdominal plank endurance tests), Pearson's bivariate correlations were run. Pearson's correlation values that were significant were considered as weak if $r < 0.25$, fair if $0.25 < r < 0.50$, moderate-to-good if $0.50 < r < 0.75$ and good-to-excellent if $r > 0.75$.[39] The significance level for all comparisons was initially set at 0.05. However, due to several correlation tests performed, the significance

level was adjusted according to the Holm–Bonferroni method.[40] *A priori* sample size estimation suggested that for the nine correlations of interest (four explanatory variables × two lumbopelvic upright standing variables — SS and LC, plus one correlation between SS and LC), the adjusted a-level would be 0.00625; therefore, to achieve 80% power with a fair correlation of $R = 0.33$ the required sample size would be $n = 112$ participants. Also, upon completion of recruitment, an achieved power calculation was performed. Should sufficient power been not achieved, the sample size in a new study required to achieve an 80% power was additionally calculated. An online program for computing power and sample size for correlational designs (https://sample-size.net/correlation-sample-size/).[41] was utilized to perform all relevant calculations.

Results

Nearly all variables conformed to a normal distribution, apart from sitting hours and age. For sitting hours, the distribution of participants into the set categories were: 38 participants for less than 3 h/day, 60 for 3–5.9 h/day and 14 for more than 6 h/day. For age, the median [inter-quartile range (IQR)] values were 20 years (18.25–22 years). Since participants were of a rather narrow age range, no correlations between age and lumbopelvic sagittal posture variables were performed. The descriptive statistics of the remaining ratio-type variables are analytically presented in Fig. 1.

Statistically significant male–female differences for both angles were identified with unrelated t-tests; specifically, for LC, the mean (SD) values were 25.6° (8.1°) for females and 22.1° (7.7°) for males, $p = 0.023$, and for SS, the mean (SD) values were 18.8° (6°) for females and 15.9° (5.8°) for males, $p = 0.013$. However, there were no statistically significant differences either for SS ($p = 0.056$) or for LC ($p = 0.345$) between the three levels of the "sitting hours/day" variable, analyzed with the Kruskal–Wallis non-parametric test. Similarly, no significant associations were identified between BMI or physical activity levels (Baecke Sport Index) or paraspinal endurance and the lumbopelvic (LC or SS) standing posture (Table 2). On the contrary, significant correlations between lumbar curve and sacral slope angles ($r = 0.80$, $p < 0.001$) and between lumbar curve and abdominal isometric endurance ($r = -0.27$, $p = 0.004$) were identified (Table 2). To account for the multiple correlations performed (nine Pearson's correlations in total), adjustment of the level of significance was performed according to the Holm–Bonferroni method, with the a-level being lowered for the correlation between LC and SS to $a = 0.0056$ and that between LC and abdominal endurance to $a = 0.00625$. Therefore, these two latter correlations remained significant after this adjustment.

For the correlation between LC and abdominal endurance ($r = -0.27$), with a sample size of $n = 112$ participants and a significance level of $a = 0.00625$, the statistical power achieved was 56%. Based on the observed correlation value and the adjusted significance level, a sample size of 170 participants would have been required to achieve an adequate power level of 80%.

Table 2. Correlations of lumbopelvic angles with ratio-type variables.

		Sacral slope	Lumbar curve
Lumbar curve	R	**0.80****	1
	Sig. (two-tailed)	0.0001	
BMI	R	−0.05	0.10
	Sig. (two-tailed)	ns	ns
Leisure-time sport activity (Baecke Sport Index)	R	0.03	0.02
	Sig. (two-tailed)	ns	ns
Plank prone bridge endurance test	R	−0.17	**−0.27****
	Sig. (two-tailed)	ns	0.004
Modified Sorensen endurance test	R	0.04	−0.07
	Sig. (two-tailed)	ns	ns

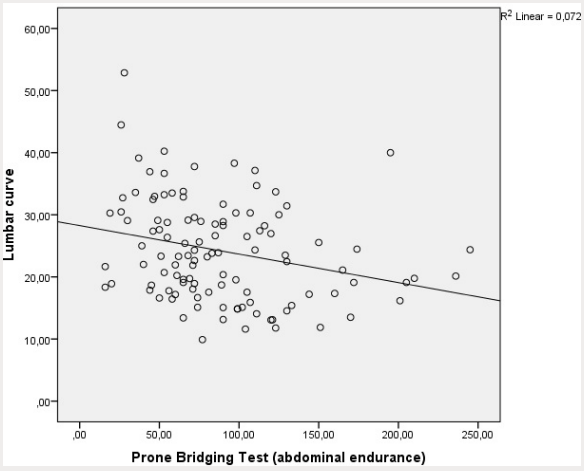

Fig. 3. Scatterplot of lumbar curve angle in upright standing against the plank prone bridge endurance test performed to complete exhaustion ($n = 112$).

Discussion

Previous studies have reported that extremes of posture in either direction may potentially increase the prevalence of spinal pain.[2,21] and lead to relatively earlier spinal degeneration in the long term.[7] The purpose of this study was to examine whether a list of modifiable anthropometric, lifestyle and muscle physical performance factors were associated with sagittal standing lumbopelvic posture (LC–SS) and one non-modifiable factor (sex). To this end, the effect of sex and an inactivity level index (sitting hours/day) on LC–SS, as well as the associations between BMI, a leisure-time sport activity index, abdominal and paraspinal muscles isometric endurance levels and LC–SS were examined in a mixed sample of 112 male–female college students.

Lumbopelvic posture variables (LC and SS) have been determined via placement of a smartphone operating the iHandy goniometer application, onto T12–L1 and S1–S2 spinous processes, under previously validated methodology.[29,30] The surface palpation methods utilized to identify the anatomical bony landmarks of interest present a limitation of our study, as palpatory methods usually have poor reliability and validity due to the difficulty in landmark identification,[42] as well as the reported between-subject anatomical landmark differences.[43]

Participants of this study were mostly between 18 years and 25 years old ($n = 103$, 92%); therefore, due to their limited age range the effect of age on lumbopelvic sagittal alignment was not examined. However, BMI did not demonstrate a significant correlation with lumbopelvic posture variables in our study and this is a matching finding only to one previous study.[9] This finding is most likely justified by the inclusion of only 18 (16%) overweight and five obese (4.5%) individuals in the sample of this study. In contrast, several other studies have confirmed significant associations between BMI and sagittal standing postures in children[11] and adults.[2,44] In particular, a cohort study with adult participants ($n = 489$) reported a strong relationship between overweight and obese participants and the types of non-neutral postural lumbopelvic variations in the sagittal plane, according to the Roussouly four-type classification.[2]

Conversely, significant relationships between sex and LC/SS were present. Several previous studies in adult[2,9,30] and adolescent[10] populations confirm this finding; therefore, the natural variation in standing posture between male and female participants should be taken into account when interpreting postural data in the standing position.

Concerning physical activity/inactivity levels, neither inactivity (sitting hours/day) nor leisure-time sport activity (Baecke Sport Index) was related to lumbopelvic posture in participants of this study. These physical activity/inactivity variables were based on self-report and therefore inadvertently relying on participants' recall.[45] Results of this study concur with two previous studies conducted in adults that had reported no association between lifestyle[2,19] or occupational demands on lumbar lordosis.[19] In contradistinction, a study of older-age industrial workers with flexion-related LBP reported that physical inactivity was associated with more posterior pelvic tilt.[6] However, participants of this study were younger and pain-free individuals, therefore these studies cannot be directly compared. Therefore, the effect of activity/inactivity levels in sagittal lumbopelvic posture may require further examination, as these variables may be linked to BMI or muscle performance state[13] or prolonged static postures under a variety of work-based environments.[45,46]

Finally, only the plank prone bridge test (abdominal endurance) demonstrated a significant fair negative association with LC ($r = -0.27$, $p = 0.004$). However, the power achieved for this finding was 56%, lower to a standard acceptable

level of power (80%). Furthermore, the cause-and-effect relationship between abdominal endurance and LC is not clear. Immediate variations in the recruitment of the deep abdominal muscles related to postural alterations have been demonstrated in studies with healthy participants,[25,26] with more mid-range postures favoring better activation of the abdominal muscles. Three previous cross-sectional research studies examining abdominal muscle performance utilizing other performance tests (leg-lowering test or four abdominal endurance tests of progressive difficulty from crook lying) to the one used in this study (plank test), have reported no[14,47] to very weak relationships[15] with lumbopelvic posture in standing. Differences in testing methods between this and previous studies as well as population differences may have accounted for this variation in results. Furthermore, in order to monitor whether increased or decreased abdominal muscle endurance through training/de-training may progressively contain or increase LC, studies of prospective rather than cross-sectional design may be required.

The lack of association between lumbopelvic posture and trunk extensor endurance (Sorensen test) in the sample of this study, consisting mostly of young participants, may be due to the fact that the majority of subjects did not present with flatback and/or posterior pelvic tilt, as verified by the lumbar curve mean (SD) data (Fig. 1). Trunk kyphotic[13] or lumbar lordotic[12] angles have been related to lower trunk extensor muscle endurance in past studies. Also, trunk extensor muscle endurance of adolescents and young adults has been predicted to a rather high percent (14.4%) by their mothers' trunk muscle endurance capacity.[48] In addition, a recent study examining the cross-sectional area of multifidus and erector spinae in relation to lumbopelvic posture also reported no correlation between the cross-sectional area of those muscles and the angles of SS or LC in a group of healthy asymptomatic participants.[49] Finally, according to the phasic and tonic muscles' categorization, the lumbar extensor muscles tend to develop muscle spasm with fatigue, therefore maintaining the position of the lumbopelvic passive structures, whereas fatigue-prone abdominal muscles tend to elongate, therefore not able to adequately control the lumbopelvic sagittal position.

There is moderate-quality evidence supporting the effectiveness of exercise alone or in combination with appropriate education in LBP prevention in previously asymptomatic populations.[50] Whether the positive effect of exercise for LBP prevention is more general or if it is mediated by maintaining more mid-range postures still remains unresolved, with some studies demonstrating associations between specific postures and LBP development, while most prospective studies demonstrating no effect.[8] As far as secondary prevention of back pain is concerned, a relevant pilot randomized–controlled trial has demonstrated that using motion sensors technology as biofeedback to improve movement and postural patterns in the treatment of subacute and chronic LBP was significantly more effective than clinical guidelines-based management.[51] Also, specific exercise may be required in contradistinction to more general, to instigate the targeted postural improvements.[17]

Among the limitations to this study, our results are restricted to only healthy young college students (undergraduate mostly and postgraduate) that were measured in a comfortable standing position. Additionally, cross-sectional studies, like the present one, could be vulnerable to reverse causality, with the cause-and-effect direction of effect between posture and all other variables difficult to establish with certainty.[52] Also, significant differences have been identified between the average 24-h lumbar lordosis measurement and static measurement in standing,[53] perhaps denoting the non-functional nature of static measurements followed in this study.

Future research work in this field can be performed in a larger sample of participants with and without LBP of working age range (18–65 years old), occupational and leisure-time physical activity involvement, to examine further the association between trunk muscle performance characteristics (endurance, strength and flexibility) and spinal posture.

This study identified a significant correlation between the lumbar curve in standing and abdominal endurance, as well as the influence of sex in standing lumbopelvic posture. The association of abdominal endurance with lumbar curve was fair and the power achieved was not sufficient, therefore, no clear recommendations can be provided for the factors that could act preventively against end-range lumbosacral postures. However, better isometric abdominal endurance was associated with less lumbar lordosis curve in young pain-free adults. The effect of sex in interpreting lumbopelvic posture should also be taken into account.

Conflict of Interest

The authors have no conflict of interest relevant to this paper.

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Author Contributions

George A. Koumantakis had an executive role in supervising this project, performed the statistical analysis and helped to design the manuscript. All authors designed and drafted the manuscript, have read and approved the final version of the manuscript and agreed with the order of presentation of the authors.

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Indian (Marathi) version of the Shoulder Pain and Disability Index (SPADI): Translation and validation in patients with adhesive capsulitis

Apeksha Jayesh Pahade[1], Surendra K. Wani[1,*], Rajani P. Mullerpatan[2] and Kathryn Elizabeth Roach[3]

[1]*Dr. Vithalrao Vikhe Patil Foundation's College of Physiotherapy*
Vadgaon Gupta (Vilad Ghat) PO. MIDC., Ahmednagar, 414111, Maharashtra, India

[2]*MGM School of Physiotherapy, MGM Center of Human Movement Science*
MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

[3]*Division of Physical Therapy, School of Medicine, University of Miami, Miami, Florida, USA*

[*]*wanisuren@gmail.com*

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Background: The Shoulder Pain and Disability Index (SPADI) is the most commonly used self-administered questionnaire which is a valid and reliable instrument to assess the proportion of pain and disability in shoulder disorders. There is no evidence of SPADI questionnaire being translated into regional Indian language (Marathi).
Objective: This study aims to translate and culturally adapt and validate the Marathi version of the SPADI questionnaire. This was done as per the AAOS outcomes committee guidelines.
Methods: Cross-cultural adaptation and psychometric testing of SPADI was done in the Outpatient Physiotherapy Department of Tertiary Care Hospital, Ahmednagar, India.
Results: The internal consistency was assessed by calculating Cronbach alpha value for the pain score (0.908), disability score (0.959), and total SPADI (0.969) which were all high. The Test–retest reliability was assessed using the intraclass correlation coefficient (ICC) values for the pain score (0.993), disability score (0.997), and total SPADI (0.997) which showed excellent reliability. The criterion validity was assessed using Pearson correlation coefficient. In Males, weak to strong negative correlation was observed except for shoulder

[*]Corresponding author.

extension and in females, moderate negative correlation was observed between baseline shoulder range of motion and initial total SPADI scores and individual pain and disability except for shoulder internal rotation. The internal consistency of the Marathi SPADI (Cronbach's alpha >0.99) was higher than the original English version. The reliability of the total Marathi SPADI and its subscale (Intraclass correlation coefficient >0.90) were found to be higher than that of the English SPADI and were consistent with the German, Brazilian, Slovene and Greek versions.
Conclusion: The translated and culturally adapted Marathi version of the SPADI questionnaire is a reliable and valid tool for the assessment of pain and disability in Marathi population.

Keywords: Cross cultural adaptation; Marathi version; psychometric; reliability; SPADI; validity.

Introduction

Shoulder pain or dysfunction is the third most common musculoskeletal condition among the general population with a lifetime prevalence of 70%.[1,2] Periarthritis, subacromial impingement, rotator cuff injury, acromioclavicular arthritis, etc. are some of the common causes of shoulder pain and disability which interferes in the social & working aspects of living of patients, affecting the overall quality of life.[3,4]

Adhesive capsulitis is one of the common causes of shoulder pain & disability, with a prevalence of around 43.1% among the shoulder cases reported.[3] This condition is characterized by pain, stiffness and limited range of motion of glenohumeral joint due to chronic inflammation of capsule which affects the upper extremity function and performance.[5]

A comprehensive evaluation of the shoulder joint generally involves the assessment of pain, clinical evaluation of shoulder range of motion, strength and joint play using standard protocols. Besides, shoulder specific self-reported questionnaires or patient-reported outcome measures (PRO) and performance-based outcome measures are also some of the simplest ways to obtain information about musculoskeletal pain and were used to evaluate disability associated with it.[4] The appropriate selection of outcome parameter is essential to confirm the efficacy of specific treatment protocol for shoulder pain & disability.[6]

More than 30 different questionnaires are available in the literature to assess pain and function of shoulder.[7] The clinometric properties of the 16 shoulder questionnaires which were designed to measure physical functioning in individuals with shoulder problems were analyzed and its clinometric properties were identified and evaluated in a systemic review[8] and they found that the Shoulder Pain and Disability Index (SPADI),[9] Disability of the Arm, Shoulder and Hand Questionnaire (DASH),[10] and the American Shoulder and Elbow Surgeons Questionnaire (ASES)[11] were the most extensively used questionnaires to assess disability associated with shoulder dysfunction.

SPADI is the most commonly used instrument in research around the shoulder joint to assess the proportion of disability. It is easy to administer, responsive, agreeable, and interpretable with objectivity with good construct validity and a minimum ceiling and flooring effects which have been tested in many clinical settings. It is self-administered and assesses both shoulder pain and disability during the important functional tasks of daily living.[9]

Roach and colleagues developed the original SPADI questionnaire in 1991. The initial validation of the questionnaire was done on 37 men with shoulder pain. They reported high internal consistency (0.86 to 0.95), and moderate test–retest reliability (interclass correlation coefficient (ICC = 0.65) on a subgroup of 23 patients. Principal components factor analysis was conducted which supported two subscales: pain and disability. The validity of the questionnaire was established by correlating SPADI total and subscale scores with shoulder ROM.[9]

Although enough evidence supports the reliability and the validity of the English language SPADI, these properties do not extend to a translated version used in a different cultural context.[12] The SPADI questionnaire has been translated and culturally adapted into many other languages but there very few published studies on its validity either in Asia or specifically in India.

Patients in India experience difficulties in understanding English questionnaires due to the language barrier. Before using any outcome

measure, which quantifies the impact of shoulder pain and disability on patients and assesses the efficacy of treatments in Indian scenario, it should be validated for their use in the Indian socio-cultural context for more accurate interpretation. Therefore, cross-cultural adaptation, reliability testing and validation of the questionnaire, which is translated in Indian regional languages, is essential for the questionnaire to be used use in that particular region. Moreover, there is no evidence of the SPADI questionnaire being translated into Marathi, which is a widely used language in the Maharashtra state of India. Therefore, this study aimed to translate and culturally adapt the Marathi version of the SPADI questionnaire and to validate it in Indian patients with Adhesive capsulitis.

Materials and Methods

Shoulder Pain and Disability Index (SPADI) (English version)

The SPADI is a self-administered questionnaire that assesses shoulder pain and dysfunction.[10] It consists of 13 items. The first five items measure the pain, and the next eight items assess patients' disability.[14] This version of the SPADI questionnaire has a ten-point numerical rating scale (NRS).[15] The patient has to answer the questions according to the level that corresponds to their pain and difficulty in movement, on a numerical rating scale ranging from 0, i.e., no pain and difficulty to 10, i.e., maximum pain and such difficulty so that the patient needs help.[10,15] The calculation of final score was done by summing the individual responses and converting them into a percentage (%).[15]

Procedure

The commencement of study was done after obtaining approval by the Institutional Ethics Committee. The linguistic validation process was initiated after prior permission was obtained from the original developer of the questionnaire through the mail, to acquire their consent.

Steps Followed for Translation & Validation

As per the guidelines provided by the American Association of Orthopaedic Surgeons (AAOS) outcomes committee, translation and cross-cultural adaptation of the SPADI questionnaire was performed.[15]

(1) First, forward translation of the questionnaire from English to Marathi was done by an informed (T1) and uninformed translator (T2).
(2) In the second step, the two translations (T1 and T2) were taken into consideration and the discrepancies were resolved, and a final form of the Marathi questionnaire was made (version T-12).
(3) In the third step, Back-translation (Marathi to English) of the version T-12 was obtained from the two back-translators (BT1 and BT2).
(4) Then Expert committee consisting of all four translators (T1, T2, BT1, BT2), one methodologist (researcher), and one language professional (having a good knowledge of both English and Marathi languages) reviewed the two back translated questionnaire (BT1 & BT2) to find out any discrepancies in interpretation/meaning and established a prefinal Marathi version of the questionnaire.
(5) Pretesting of prefinal Marathi version of the questionnaire was done by administering in 31 patients with adhesive capsulitis selected with a purposive sampling method attending our physiotherapy outpatient department of Tertiary Care Hospital, Ahmednagar.

While testing the cross-culturally adapted version in Marathi for its validity, written informed consent was obtained from each patient who satisfied the inclusion criteria for this study. The patients of both the genders aged between 40–60 years and medically diagnosed with adhesive capsulitis were included in the study. Patients reported gradual onset and progressive worsening of pain (VAS ranging in between 3 and 8) and stiffness at shoulder at least from three months duration affecting functional activities related to shoulder. Patients having history of trauma, surgery or fracture of affected shoulder, Shoulder joint instability or dislocation, systemic illness like rheumatoid arthritis, Reiter's syndrome, osteoarthritis of the affected shoulder joint, Shoulder pain of cervical origin, patients with neurological diseases or other severe medical or psychiatric disorders, inability to read and understand Marathi were excluded from the study.

After a brief clinical examination, patients were explained about the procedure to fill the questionnaire before responding. The patients were seated comfortably and the questionnaire was given to them and they were asked to mark the point on the scoring system, which best represented their status of shoulder pain and disability.

The researcher noted the layout and wording of the questionnaire, its ease of understanding, and ease of completion of the questionnaire during the administration of questionnaire among patients. The patients stated no trouble in understanding and answering the questions effectively, therefore without making major alterations the SPADI questionnaire — Marathi version was then validated further to ensure consistency between the source (English) and target version of the questionnaire (Marathi).

(6) The documentation of the above steps was submitted to the developers of the original questionnaire so as to ensure that the process has been carried out properly and that a reasonable translation has been achieved.[16]

After the patients completed the Marathi version of the questionnaire (Step 5), the active ROM of the shoulder was measured using a standard universal goniometer in the standard test positions.[17] These ROM values were then used to analyze the criterion validity of the questionnaire. The test–retest reliability was also assessed by taking a second assessment session which was at least 24 hours after the first session (ICC).

Statistical analysis: Statistical analysis was done using SPSS version 20.0. Unpaired *t*-test was used for comparison of the baseline characteristics of males and females. The internal consistency was determined using Cronbach alpha value. The test–retest reliability of the Marathi total SPADI, pain and disability subscales were assessed using intraclass correlation coefficient (ICC). The criteria validity was assessed using Pearson correlation coefficient.

Results

The sample consisted of 17 male and 14 female participants with the right shoulder being affected in 16 participants and left shoulder being affected in 15 participants. The mean age of males and females was 46.29 and 50.5 years, respectively. There was no statistical significant difference between males and females at baseline ($p > 0.05$) (Tables 1 and 2).

Reliability

The ICC values for the pain score (0.993), disability score (0.997), and total SPADI (0.997) were all high, showing excellent reliability (Table 3).

Internal consistency

The Cronbach alpha value for the pain score (0.908), disability score (0.959), and total SPADI (0.969) was all high. Removal of any question except questions 1, 10 and 13 would lead to lower Cronbach alpha compared to that of the total

Table 1. Descriptive statistics.

Gender	Male	17 (54.83%)
	Female	14 (45.16%)
Affected side	Right	16 (51.61%)
	Left	15 (48.38%)
Comorbidities	Diabetes	10 (32.25%)
	Hypertension	8 (25.80%)
	Hypertension and diabetes	5 (16.12%)

Table 2. Patient baseline characteristics.

Characteristics	Male Mean ± SD	Female Mean ± SD	*p*-value
Age (Years)	46.29 ± 7.47	50.5 ± 5.57	0.092
Shoulder flexion (degree)	115.64 ± 27.38	116 ± 23.10	0.96
Shoulder extension (degree)	31.76 ± 5.76	33.21 ± 3.33	0.41
Shoulder abduction (degree)	91.11 ± 19.2	93.92 ± 15.67	0.66
Shoulder internal rotation (degree)	51.23 ± 11.46	53.64 ± 13.52	0.59
Shoulder external rotation (degree)	36 ± 8.73	33.71 ± 8.95	0.47
SPADI pain score (%)	63.64 ± 14.92	65.28 ± 14.79	0.76
SPADI disability score (%)	53.48 ± 19	58.77 ± 16.10	0.42
Total SPADI score (%)	57.36 ± 17.2	61.21 ± 15.22	0.51

Table 3. Reliability of Marathi language SPADI.

SPADI[c] scale	ICC[b] value	95%CI[a]	
		Lower bound	Upper bound
Pain score average measure	0.993	0.985	0.996
Disability score average measure	0.997	0.995	0.999
Total score average measure	0.997	0.994	0.999

Notes: [a]CI = Confidence Interval; [b]ICC = Intraclass Correlation Coefficient; [c]SPADI = Shoulder Pain and Disability Index.

Table 4. Redundancy of each individual item (by computing Cronbach alpha if item was deleted).

Questions	Cronbach alpha if item deleted
Question 1	0.972
Question 2	0.965
Question 3	0.965
Question 4	0.966
Question 5	0.965
Question 6	0.965
Question 7	0.963
Question 8	0.964
Question 9	0.965
Question 10	0.973
Question 11	0.964
Question 12	0.964
Question 13	0.972

SPADI score. Removal of questions 1, 10, 13 leads to small improvement in the Cronbach alpha (Table 4).

Validity

The face validity of the questionnaire was established with the original English version of the SPADI and was considered adequate for the Marathi SPADI after discussions within the expert committee, i.e., the content of the translated items was understandable and could be used in the assessment of shoulder pain and function as they depict activities of the shoulder in daily living (stage 4).

Criterion validity between the initial total SPADI score, individual pain score, and individual disability score and the baseline active range of motion of shoulder for males and females was assessed using Pearson correlation (Tables 5 and 6). For males, there was a weak to strong negative correlation between shoulder range of motion and pain score (Correlations ranged from 0.309 to 0.850) except for shoulder extension; shoulder range of motion and disability score correlation ranged from 0.474 to 0.869 except for shoulder extension, indicating weak to strong negative correlation; shoulder range of motion and total SPADI correlation scores ranged from 0.426 to 0.874) except for shoulder extension indicating weak to strong negative correlation (Table 5). For females, there was a moderate to strong negative correlation between shoulder range of motion and pain score (Correlations ranged from 0.639 to 0.770), except for shoulder internal rotation; shoulder range of motion and disability score correlation ranged from 0.611 to 0.692 except for shoulder internal rotation, indicating negative correlation; shoulder range of motion and total SPADI correlation scores ranged from 0.648 to 0.697) except for shoulder internal rotation, indicating moderate negative correlation (Table 6).

Table 5. Relationship between SPADI scale and shoulder ROM in males.

$N = 17$	Pain score	Disability score	Total score
Shoulder flexion	−0.851**	−0.869**	−0.874**
Shoulder extension	−0.263	−0.241	−0.251
Shoulder abduction	−0.832**	−0.814**	−0.829**
Shoulder internal rotation	−0.309	−0.475	−0.426
Shoulder external rotation	−0.777**	−0.820**	−0.816**

Notes: ROM = Range of motion; SPADI = Shoulder Pain and Disability Index.
**Correlation is significant at 0.01 level (2-tailed).
*Correlation is significant at 0.05 level (2-tailed).

Table 6. Relationship between SPADI scale and shoulder ROM in females.

$N = 14$	Pain score	Disability score	Total score
Shoulder flexion	−0.675**	−0.611*	−0.649*
Shoulder extension	−0.718**	−0.646*	−0.684**
Shoulder abduction	−0.770**	−0.629*	−0.697**
Shoulder internal rotation	+0.015	−0.086	−0.042
Shoulder external rotation	−0.639*	−0.693**	−0.684**

Notes: ROM = Range of motion; SPADI = Shoulder Pain and Disability Index.
**Correlation is significant at 0.01 level (2-tailed).
*Correlation is significant at 0.05 level (2-tailed).

Discussion

The SPADI is a self-administered questionnaire that assesses shoulder pain and dysfunction. The reliability and validity of the English language SPADI were established earlier and had enough documented evidence.[9] But patients in Maharashtra (India) experience difficulties in understanding the English version of the questionnaire due to the language barrier. Therefore, this questionnaire was administered in patients by translating questions in the local language. So, there may be some variations in administration and interpretation of this questionnaire among different researchers in the Maharashtra region. Therefore, there is a need for translation of the SPADI questionnaire in the local language — Marathi in our set up.

Most widely used language in the Maharashtra state of India is Marathi, and hence we have translated the English version of SPADI questionnaire into Marathi version for ease in administration among patients. The SPADI questionnaire was Translated and culturally adapted into Marathi language according to the guidelines of the AAOS outcome committee for cross-cultural adaptations.[15] The pre-final version of the SPADI Marathi version was administered to 31 patients with Frozen shoulder. Most of the patients understood every item from the questionnaire except the 1st and the 9th item of the questionnaire, which was then reformulated accordingly. During translation, some words in the questionnaire were adapted, keeping in mind the clothing differences of the patients in India and also according to gender. For example, "Putting on a shirt that buttons down the front" and "Putting on your pants". In Indian culture, as women mostly wear sarees with a blouse piece that hooks in the front or at the back and instead of pant they wear underskirt under sarees, so the Marathi version of the questionnaire was slightly modified accordingly.

On comparing the internal consistency of Marathi version with the original English version of SPADI (Roach KE), we observed that the Cronbach alpha values for pain subscale (0.908) were higher than the pain subscale score for English version (0.86) and the Cronbach alpha value for disability (0.959) was almost similar to disability score (0.93) of English version and the Cronbach alpha value for the total SPADI score (0.969) was also similar to that of the original English version (0.95), and also previous literature reported that the values greater than 0.7 is considered reliable having good internal consistency.[17] Therefore, the Marathi version is considered a reliable tool. These results are also comparable to the previous study of translation in another Indian language — Tamil version.[24]

Further, the reliability of the Marathi version was also analysed and the intraclass correlation coefficient (ICCs) was >0.90 for the pain score, disability score, and total SPADI showing excellent reliability indicating that the questionnaire is suitable for individual assessment of patients.[8] These results are similar to those which were obtained when the original English version of the questionnaire was tested for reliability.[14,18,19]

Additionally, when our results of reliability were compared with the original author's study (Roach E), the reliability of the total Marathi SPADI had an ICC value (0.997), which was higher than the total English SPADI (ICC = 0.6552).[9] Comparison of the ICC values for the pain and the disability subscale score and the total Marathi SPADI score with the values obtained by testing the questionnaires in German, Brazilian, Slovene and

Greek versions showed consistent results.[20–23] Our results also demonstrated a good face and criterion validity of the Marathi version of the SPADI questionnaire analysed by calculating the correlation between the initial total SPADI score, individual pain score, individual disability score and the baseline degree of active range of motion of shoulder using Pearson correlation.

There was gender difference observed in the correlation between the initial total SPADI score, individual pain, disability score and baseline shoulder range of motion. The hypothesized mechanism behind these findings may be as the pain threshold level and pain tolerance is lower in females than in males which would affect the achieved shoulder range of motion.[25]

This study demonstrated that the Marathi version of an SPADI Questionnaire had a satisfactory test–retest reliability, internal consistency, and face and criterion validity. Therefore, it is a reliable and valid tool to record the quality of life affected due to pain and disability in the Maharashtrian population.

Study Limitation

The main limitation of our study is that the sample size was small, and factor analysis of individual items of the questionnaire was not done.

Conclusion

The results of our study concluded that the translated and culturally adapted Marathi version of the SPADI questionnaire is a reliable and valid tool for the assessment of pain and disability in Marathi population.

Conflict of Interest

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

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Author Contributions

All the authors contributed to the conception and design of study and approval for the submission to publication. A J Pahade & Wani S K contributed to the data analysis and interpretation. Mullerpatan R P contributed to the manuscript drafting. Roach K E contributed to the manuscript revision.

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