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Content

Notes from the Editor-in-Chief

Welcome to our first issue of the 2023 ASEAN Journal of Rehabilitation Medicine. This issue has articles that relate directly to rehabilitation medicine treatment and diagnostic methods that are becoming popular among rehabilitation physicians. There are also researches on factors related to the therapeutic effects of various diseases. The readers can have more information for decision-making in the practices. In addition, research on medical education topics has also been exciting from residency training programs.

In the first article, Keesukphan A and her colleagues study the effect of peripheral magnetic stimulation in patients with knee osteoarthritis. The authors looked specifically at the short-term effects of repetitive peripheral magnetic stimulation on pain reduction in knee osteoarthritis. Their findings indicate that adding this treatment intervention provides no significant additional therapeutic effect in a short-term improvement of pain in primary knee osteoarthritis patients compared with sham treatment. They suggested that future studies include multiple treatment sessions and investigate an appropriate treatment protocol.

In the second article, Eurcherdkul P and her colleagues examine the efficacy of high-intensity lasers combined with muscle training in patients with patellofemoral pain syndrome. Unfortunately, adding these interventions did not yield better outcomes than muscle training alone.

In the third article, Vorawanthanachai T and her colleagues compared the effects of three soreness reduction methods after dry needling for a patient with upper trapezius trigger points. They suggested that diclofenac spray combined with contract-relax stretching might be the intervention of choice to reduce post-dry needling soreness at the upper trapezius muscle effectively.

In the fourth article, Poolpipat P and her colleagues carried out their cross-sectional study about thermoplastic ankle-foot orthoses in patients with foot drop to identify factors related to AFO use and develop a more efficient way to determine an appropriate AFO prescription. They found that Sixty percent of their patients continued using an AFO after three months. The factors contributing to good compliance are; being unable to do ankle dorsiflexion, wearing clogs, and having practiced walking with a physical therapist.

In the fourth article, Lewsirirat S and her colleagues evaluated the relationship between evertor muscle function and recurrence of deformity in pediatric idiopathic clubfoot after two years or more after treatment. They found that the severe deformity at presentation was a significant proportion of the recurrence.

The sixth article is about the diagnosis study. Charussuriyong P and Suksathien found that

a shoulder ultrasound by a trained physiatrist showed high sensitivity and specificity for detecting supraspinatus tears diagnosed by MRI. They suggested that trained clinicians new to musculoskeletal ultrasound could use this method to evaluate supraspinatus tendon tears for initial diagnosis and management.

In the seventh article, Suksathien R and her colleagues evaluated the reliability and acceptability of using the multiple mini-interview (MMI) for Physical and Rehabilitation Medicine in the residency admission selection process. They found that the MMI was highly accepted among both candidates and interviewers, especially in fairness and decreased bias, allowing efficient evaluation of the candidate's performance and strengths.

The last article is a case report by Pattanasuwanna P. She presents her case about Riche-Cannieu anastomosis in patients with suspected carpal tunnel syndrome. She emphasized that this anastomosis should be excluded if no compound muscle action potential response is obtained from the abductor pollicis brevis with median stimulation without supportive evidence, such as motor weakness and muscle atrophy. Stimulation of the ulnar nerve with recording at the APB muscle can help avoid misdiagnosis.

We continue to invite and welcome works from our rehabilitation medicine field in South East ASEAN countries colleagues. We look forward to your submissions of individual papers and special-themed issues and forums. Thank you for joining us

Assoc. Prof. Kingkaew Pajareya
Editor-In-Chief
The ASEAN Journal of Rehabilitation Medicine

Original Article

Comparison of Effectiveness, Patient Satisfaction, and Durability between 3D-Printed Customized Insoles and Conventional Custom-Made Insoles for Flat Feet: A Randomized Controlled Trial

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ABSTRACT

Objectives: To compare foot and ankle function, patient satisfaction, and insole durability between 3D-printed customized insoles and conventional custom-made insoles for the treatment of flat feet.

Study design: A randomized controlled trial.

Setting: Siriraj Hospital, Mahidol University, Bangkok, Thailand.

Subjects: Sixty Thais with bilateral flat feet.

Methods: Participants were randomized into either the 3D-printed insole group (study) or the conventional insole group (control). The effectiveness of both types of insoles was compared using the visual analog scale foot and ankle (VAS-FA) score to evaluate foot and ankle function, navicular height, and participant insole use to evaluate insole durability. Patient feedback was used to evaluate patient satisfaction.

Results: Patient characteristics and baseline VAS-FA score were comparable between groups. The median change (range) in VAS-FA score from baseline to the third month score was 1.5 (-6.3, 68.0; $p = 0.002$) in the study group and 4.0 (-6.5, 35.0; $p < 0.001$) in the control group. Mean and standard deviation change in the deformation of insoles in the third month were as follows: right side in the study group: 0.2 (0.3) cm ($p = 0.010$) and in the controls: 0.2(0.3) cm ($p < 0.001$); left side among study group 0.1 (0.2) cm ($p = 0.005$) and in the controls: 0.3 (0.4) cm ($p = 0.001$). In addition, the study group overall satisfaction score was significantly higher than the control group: 3.8 (0.4) vs. 3.3 (0.6), respectively ($p < 0.001$).

Conclusions: The VAS-FA scores significantly improved at three months in both groups. There was no statistically significant difference between the groups. Deformation of insoles was found in both groups with no significant difference between the groups. Measured durability and patient-reported satisfaction were both statistically significantly higher in the study group than in the control group.

Keywords: flat feet, foot orthoses, 3D-printed customized insoles, conventional custom-made insoles, patient satisfaction

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Introduction

A medial arch collapse characterizes a flat foot during weight bearing.[1] Flat foot may result from malalignment of the tarsal bone or impaired function of the plantar fascia.[1] Individuals with flat feet often suffer from pain, discomfort, instability, and limited foot and ankle function, in addition to malalignments of the foot, such as calcaneovalgus alignment and forefoot abduction.[2] Flat foot patients struggle with decreased impact absorption capacity of the foot, reduced foot control force, and excessive foot rotation.[3,4] The prevalence of flat foot is approximately 3% and 25% in healthy participants.[5] One study reported that the prevalence of flat foot determined by footprint was 52.5% in the Thai military population.[6]

The primary conservative treatment includes orthotics and footwear management. Custom-made insoles support the foot, normalize calcaneovalgus alignment, support the medial longitudinal arch to decrease foot overpronation, and distribute the weight under the foot.[2,7]

Three-dimensional (3D) printing, or additive manufacturing, is constructing a 3D object from a digital model. This technology has been widely introduced in the medical field, including in the development of prostheses and orthoses. Three-dimensional fabrication of foot orthosis has mostly been performed using continuous filament of a thermoplastic material or fused deposition modeling (FDM) method, selective laser sintering (SLS), or stereolithography (SLA). One study reported the FDM method to be more cost-effective; than the other available methods; however, the quality of the orthoses produced using this method has yet to be determined.[8]

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The cost of 3D printing foot orthoses is comparable to fabricating conventional custom-made foot orthoses.[9,10] Few studies have investigated the short- or long-term clinical effects of 3D-printed insoles on foot conditions. One study evaluated the efficacy of 3D-printed insoles in patients with rheumatoid arthritis and recreational runners.[11] Moreover, our literature review revealed only one study that examined the effect of 3D-printed insoles on people with flat feet. That study reported that a 3D-printed insole could adjust the lateral center of pressure during walking.[12]

Although 3D printing technology has been adopted for the fabrication of insoles in many countries, data specific to foot and ankle function (VAS-FA), insole durability, and user satisfaction/quality of life compared to custom-made conventional insoles (vacuum forming) are scarce. Accordingly, this randomized controlled trial aimed to investigate foot and ankle function score, insole durability/deformation, and patient satisfaction compared between 3D-printed customized insoles and conventional custom-made insoles in Thai people with flat feet.

Methods

Study design

This randomized controlled study was approved by the Siriraj Institutional Review Board (SIRB) (COA no. 753/2019) and registered as an RCT, no. TCTR20211215008 in the Thai clinical trials registry.

Participants

Patients treated at the Sirindhorn School of Prosthetics and Orthotics Outpatient Clinic of the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, from 2019 to 2021, were screened before enrolment. Patients older than 12 years with bilateral flat feet and prescribed custom-made insoles were eligible for inclusion. Patients having one or more of the following were excluded: 1) history of surgery of the foot or ankle, 2) negative result of heel raise test, 3) fixed foot deformities, 4) leg length discrepancy, 5) neurological conditions that could affect walking ability, 6) active wound at foot or ankle, 7) impaired cognitive function, or 8) use of 3D-printed foot orthoses within the past year. Sixty participants were randomly allocated to either the 3D-printed insole group (study group, n = 30) or the custom-made conventional insole group (control group, n = 30) by using the randomization.com (http://www.randomization.com) website.

Sample size calculation

The sample size was calculated based on our assumption that a large effect size (0.8) for the mean difference would be detected between the study and control groups. The number of participants was 26 per group to achieve a statistical power of 80% at a significance level of 5%. Assuming an estimated loss to follow-up rate of 10%, we increased the sample size to 30 participants per group. Moreover, a sample size of 30 participants per group was calculated to have sufficient statistical power to detect a medium effect size (0.53) corresponding to the minimal clinically significant difference (MCID) within the group.

Study procedures

At the baseline visit (visit 1), patient characteristics, self-report questionnaire, visual analog scale foot and ankle (VAS-FA) score, and navicular height were collected in both groups. An experienced certified orthotist performed foot assessment and foot capturing. Participants in the study group had their feet scanned using a 3D foot scanner with the patient in a partial weight-bearing sitting position. Patients in the control group underwent foot casting using foam impression casting in a partial weight-bearing sitting position. Then the insoles were made (Figure 1 and Figure 2).

During the second visit (visit 2), a certified orthotist fitted and adjusted the insoles according to the fitting standard and collected the navicular height in centimeters (cm). In addition, all participants were asked to record their daily insole use in a logbook provided to each participant.

Participants in both groups were followed-up at one and three months (visits 3 and 4). At both follow-up time points, insoles were adjusted as needed, and VAS-FA, navicular height, and daily use of insoles from the logbook were collected and recorded. At the 3-month follow-up, all participants were also asked to rate their satisfaction with their insoles.

Materials

The customized 3D-printed insoles were fabricated using the 3D digital model from the 3D scanner and computer-aided design (CAD) software and the Ultimaker 3 fused deposition modeling (FDM) type 3D printer. The 3D-printed insoles were printed in three-quarter-length rigid foot orthoses. The shell was made from acrylonitrile butadiene styrene (ABS) polymer-based filament and thermoplastic polyurethane (TPU). Layers of ethylene-vinyl acetate foam (EVA) shore A30 and polyure thane foam shore A5 were used for the top layer. At the bottom of the toe part, a non-woven chemical sheet was applied to reinforce and connect the foam layers to the plastic shell (Figure 1).

The conventional custom-made insoles in the control group were fabricated from the negative foot model that was obtained from the foam box casting. A vacuum-forming machine produced the semi-rigid foot orthoses. The three layers of foam included surface EVA shore A22, middle layer PU shore A5, and base EVA shore A60 (Figure 2).

Outcomes

Visual analog scale foot and ankle (VAS-FA) score

The modified visual analog scale foot and ankle (VAS-FA) score Thai version was used to measure foot and ankle function.[13] The modified version consists of 18 questions from the 20 questions in the original version. In addition, two irrelevant questions relating to weakness and impaired sensation were

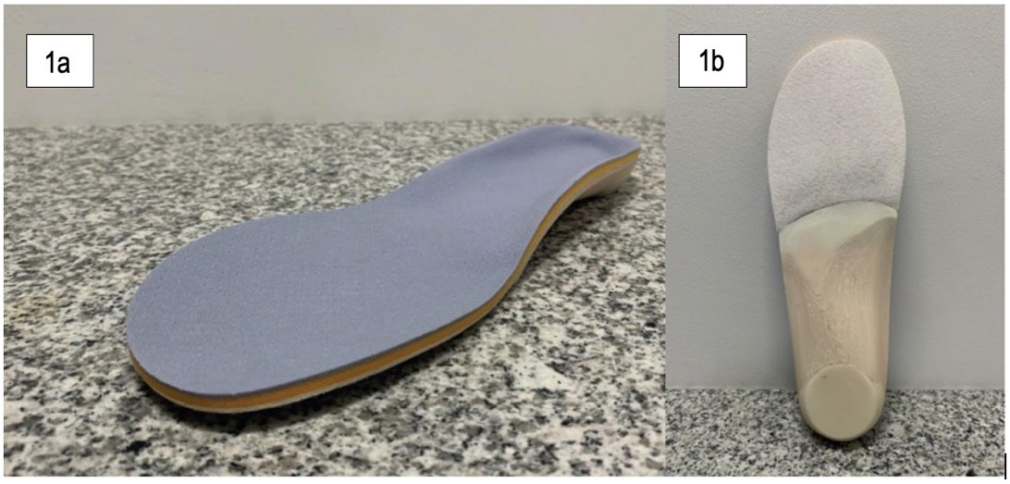

Figure 1. Customized 3D-printed insoles: 1a, top view showing a top layer of EVA shore A30 and a middle layer of PU shore A5; and 1b, bottom view showing a base layer of polyurethane polymer
EVA, ethylene-vinyl acetate foam; PU, polyurethane foam

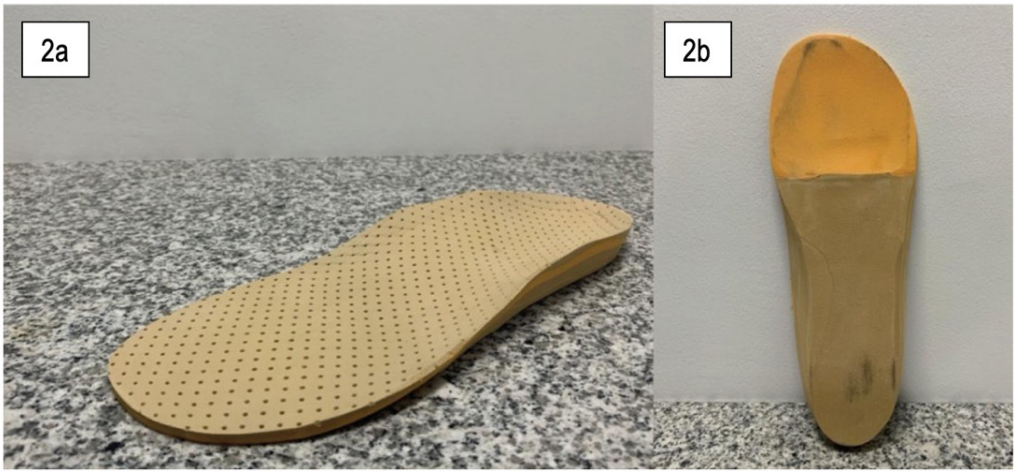

Figure 2. Conventional custom-made insoles: 2a, top view showing a top layer of EVA shore A 22 and middle layer: PU shore A 5; and 2b showing bottom view base layer: EVA shore A 60
EVA, ethylene-vinyl acetate foam; PU, polyurethane foam

excluded from the study. Participants were asked to rate each of the 18 questions on a visual analog scale from 0-100, with 0 indicating no symptom at all and 100 indicating the worst symptom.

Patient satisfaction

The insole satisfaction survey consisted of four domains (1 question for each domain): comfort, maintenance, durability, and overall satisfaction. The participants were asked to rate their level of insole satisfaction using a 5-point Likert scale (0 = not satisfied, 4 = very satisfied).To assess the satisfaction of participants relative to the quality of their insoles.

Insole durability/deformation

The reduction in navicular height (cm) from baseline to the 1- and 3-month post-intervention follow-ups were used to evaluate insole deformation or durability. Navicular height was measured using a steel ruler. The distance between the top of the navicular tuberosity and the floor was recorded when the participant stood on the insoles. Daily use of insoles recorded in the study logbook and navicular height to evaluate insole deformation or durability.

Statistical analysis

Data were prepared and analyzed using PASW Statistics for Windows, version 18.0 (SPSS, Inc., Chicago, IL, USA). Descriptive statistics were used to describe patients and their clinical characteristics. Number and percentage were used to describe qualitative data, while mean and standard deviation (SD) or median and range were used to describe normally and non-normally distributed quantitative data, respectively. Inferential statistics were used to test hypotheses. The Shapiro-Wilk test was used to evaluate the normality of quantitative data. Pearson's chi-square test, Fisher's exact test, or Yates' continuity correction test was used to compare the proportions of baseline characteristics of participants between the study and control groups. Independent t-test or Mann-Whitney U test was used to compare mean or median differences of VAS-FA score, satisfaction score, insole durability/ deformation, and baseline characteristics of participants between groups, as appropriate. A dependent t-test or Wilcoxon signed-rank test was used to compare mean or median changes of insole durability and VAS-FA score from baseline

to the 1- and 3-month follow-ups within groups, as appropriate. All tests were two-sided, and a *p*-value of less than 0.05 was considered statistically significant.

Results

Study participants

Sixty Thai patients with bilateral flat feet were recruited for the study. Participants were randomly allocated to receive either 3D-printed insoles (study group) or conventional insoles (control group) (Figure 3).

The mean age of overall patients was 33.8 (15.4) years, and 37 (61.7%) were females. Participant baseline characteristics compared between the study and control groups (all variables $p > 0.05$) are shown in Table 1.

Visual analog scale foot and ankle (VAS-FA) score

VAS-FA scores were compared within and between groups at baseline and at the 1- and 3-month follow-ups (Table 2).

Participants in the study group had a slightly higher baseline VAS-FA score than controls ($p = 0.858$). VAS-FA scores were reduced from baseline to 1 month in both groups. The reduction in the VAS-FA score in the control group was statistically significant, with a median score of 1.5 (range: -11.8, 37.5; $p = 0.030$). In contrast, the VAS-FA score in the study group was not significantly reduced, with a median VAS-FA score of 0.5 (range: -20.0, 71.5; $p = 0.084$). However, the VAS-FA score in both the study and control groups was significantly reduced from baseline to 3 months post-intervention, with a median reduction in the VAS-FA score in the study

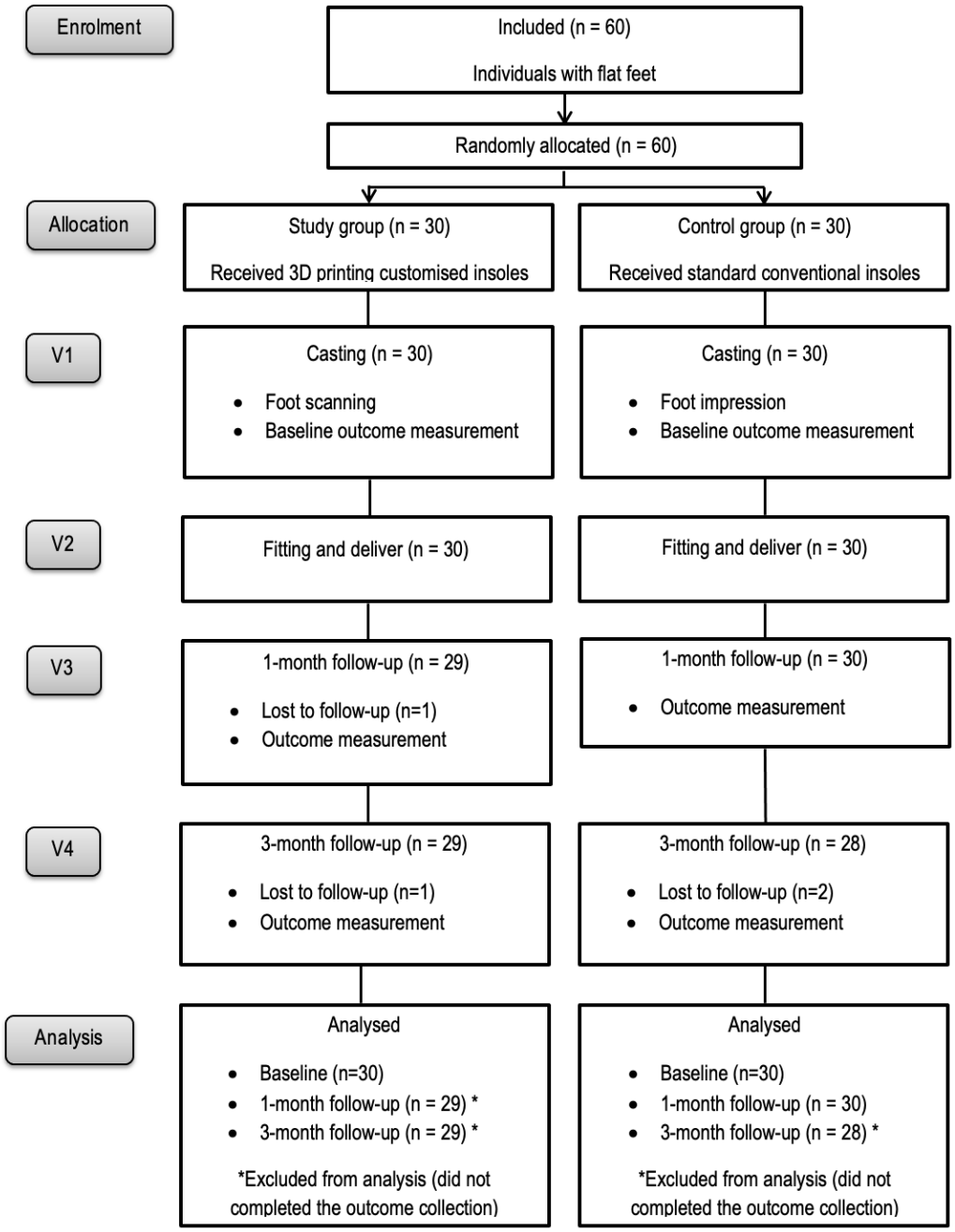

Figure 3. Flow diagram of the study protocol
V, visitation; n, sample size

Table 1. Participant baseline characteristics of the study and control groups

Characteristics	Study group (n = 30)	Control group (n = 30)	*p*-value*
Age (years)[1,2]	30.7 (13.3); 25 (12, 63)	36.9 (16.9); 32 (12, 66)	0.139
Gender, female[3]	20 (66.7)	17 (56.7)	0.595
Body mass index (BMI) (kg/m^2)[1]	24.5 (4.9)	23.5 (3.8)	0.398
Previous use of foot orthoses[3]	14 (46.7)	17 (56.7)	0.605

[1]Mean (standard deviation), [2]median (range), [3]number (%)

*$p < 0.05$ indicates statistical significance

Table 2. The comparison of VAS-FA score between the study and the control groups, and between baseline and each follow-up time point in each group

VAS-FA Scores	Study group (n = 30)	Control group (n = 30)	*p*-value*,a
Baseline	12.2 (0, 76)	9.0 (0, 62.5)	0.858
Post-intervention	(n = 29)[c]	(n = 30)	
- 1 month	5 (0, 53)	5.9 (0, 55)	0.897
- Δ 1 month	0.5 (-20.0, 71.5)	1.5 (-11.8, 37.5)	0.773
p-value[b]	0.084	0.030	
	(n = 29)[c]	(n = 28)[c]	
- 3 months	1.0 (0, 81.8)	4.8 (0, 66)	0.358
- Δ 3 months	1.5 (-6.3, 68.0)	4.0 (-6.5, 35.0)	0.791
p-value[b]	0.002	< 0.001	

Median (range)

Δ Median change in VAS-FA score from baseline to each follow-up time point in each group

[a]Comparison between the study and control groups using an independent t-test or Mann-Whitney U test.

[b]Comparison between baseline and each follow-up in each group using dependent t-test or Wilcoxon signed-rank test.

[c]Some participants did not complete the questionnaire, so their data was not included in the analysis

*p-value < 0.05 indicates statistical significance

VAS-FA, Visual analog scale foot, and ankle score

group of 1.5 (range -6.3, 68.0; $p = 0.002$), and in the control group of 4.0 (range: -6.5, 35.0; $p < 0.001$). There was no significant difference in VAS-FA score reduction from baseline to each follow-up time point between groups ($p > 0.05$).

Satisfaction score

Patient satisfaction scores of four domains, including comfort, maintenance, durability, and overall satisfaction of/ with the insoles compared between the study and control groups and between baseline and each follow-up time point in each group, are shown in Table 3. There was no significant difference in the satisfaction score for the comfort and maintenance domains between groups. The mean comfort score in the study and control groups was 3.6(0.6) and 3.4(0.6), respectively ($p = 0.173$). The mean maintenance score in the study group and the control group was 3.5(0.7) and 3.3(0.7), respectively ($p = 0.238$). In contrast, the satisfaction scores for the durability and overall satisfaction domains differed significantly between groups. The durability score in the study group was significantly higher than in the control group, with a mean of 3.9(0.4) versus 2.8(1.0), respectively ($p < 0.001$). The overall satisfaction score in the study group also was significantly higher than in the control group, with a mean of 3.8(0.4) versus 3.3(0.6), respectively ($p < 0.001$).

Insole durability/ deformation

The change in navicular height (centimeter) from baseline to one and three months post-intervention was used to evaluate the durability/deformation of the insoles. Daily use of insoles and navicular height of the study and the control groups at baseline and each follow-up time point in each group are shown in Table 4.

The change in navicular height in both the left and right sides at one and three months from baseline within the group was analyzed. The mean navicular height on both feet in both groups was noticeably lowered at each of the two follow-ups. Thus, there was significant deformation of insoles within the group at 1- and 3- months of intervention in both groups. However, there was no significant difference in insole deformation between groups at either post-intervention time point ($p > 0.05$).

Regarding the daily use of insoles, the median daily use of insoles at one and three-month follow-ups was slightly higher in the study group. However, there was a significant difference in daily use of insoles between groups at three months, with a median daily use of insoles in the study group of 5.4 (range: 0.5, 11.6) hours per day versus 3.7 (range: 1.0, 7.0) hours per day in the control group ($p = 0.038$).

Table 3. Patient satisfaction with the insoles compared between the study and control groups

Scores	Study group (n = 29)[c]	Control group (n = 28)[c]	*p*-value[*]
Satisfaction score			
Comfort	3.6 (0.6)	3.4 (0.6)	0.173
Maintenance	3.5 (0.7)	3.3 (0.7)	0.238
Durability	3.9 (0.4)	2.8 (1.0)	< 0.001
Overall	3.8 (0.4)	3.3 (0.6)	< 0.001

Mean (standard deviation)

Level of satisfaction with the insoles using a 5-point Likert scale (0 = not satisfied, 4 = very satisfied)

[*] $p < 0.05$ indicates statistical significance,

[c] Some participants did not complete the questionnaire, so their data was not included in the analysis

Table 4. The comparison of navicular height and daily use of insoles between the study and the control groups, the comparison of navicular height at baseline and each follow-up

Parameters	Study group (n = 30)	Control group (n = 30)[c]	*p*-value[*,a]
Navicular height (cm)[1]			
●Left side			
Baseline	3.78 (0.74)	3.78 (0.72)	0.997
Post-invtervention	(n = 29)[c]	(n = 30)	
- 1 month	3.69 (0.67)	3.58 (0.62)	0.539
- Δ 1 month	0.09 (0.20)	0.19 (0.33)	0.161
p-value[b]	0.023	0.004	
	(n = 29)[c]	(n = 28)[c]	
- 3 months	3.64 (0.67)	3.49 (0.70)	0.395
- Δ 3 months	0.13 (0.24)	0.29 (0.42)	0.087
p-value[b]	0.005	0.001	
●Right side			
Baseline	3.83 (0.79)	3.80 (0.76)	0.882
Post-invtervention	(n = 29)[c]	(n = 30)	
- 1 month	3.73 (0.69)	3.64 (0.72)	0.640
- Δ 1 month	0.10 (0.26)	0.16 (0.23)	0.386
p-value[b]	0.047	0.001	
	(n = 29)[c]	(n = 28)[c]	
- 3 months	3.67 (0.68)	3.56 (0.76)	0.568
- Δ 3 months	0.16 (0.31)	0.24 (0.29)	0.298
p-value[b]	0.010	< 0.001	
Daily use of insoles (hrs)[2]			
- 1 month	(n = 29)[c]	(n = 30)	
	5.5 (1.0, 11.0)	4.3 (0.5, 10.0)	0.072
	(n = 29)[c]	(n = 28)[c]	
- 3 months	5.4 (0.5, 11.6)	3.7 (1.0, 7.0)	0.038

[1]Mean (Standard deviation), [2]median (range)

Δ Mean change/reduction of the navicular height from the baseline to each follow-up time in each group

[*] $P < 0.05$ indicates statistical significance

[a]Comparison between the study and control groups using an independent t-test or Mann-Whitney U test.

[b]Comparison between baseline and each follow-up in each group using dependent t-test or Wilcoxon signed-rank test.

[c]Some participants lost to follow-up, so their data was not included in the analysis

Discussion

Our study found the VAS-FA score to be significantly improved from baseline to 1-and 3-months post-intervention within both groups. However, there was no statistically significant difference in the VAS-FA score at 1-month and 3-months post-intervention between the study and control groups. This finding means that 3D-printed and conventional insoles have the same ability to significantly improve foot and ankle function in patients with flat foot conditions because custom-made foot orthoses or insoles help cushion the heel, relieve pain, increase stability in the foot, and correct flexible deformities of the foot.[14,15] In addition, the 3D-printed insole method showed a similar arch height index when compared to the conventional insole fabricating method.[9]

Besides evaluating the foot and ankle function, our study evaluated the durability of the two types of insoles by assessing the deformation of the insole as measured by navicular height changes. We found insole deformation in both groups,

but more deformation was observed in the control group. However, the difference between groups did not reach statistical significance. A foam base combination layer was used to form the insole in the control group, whereas the study group used thermoplastic elastomer (TPE) as a ¾ base and top with EVA and PU foam. Although TPE maintains its structure well, the deformation likely occurred in the foam layer. A previous study on the durability of insoles in diabetic feet reported no significant difference in peak pressure at 12 months after the start of insole use, and most compression was observed during the first six months. The authors concluded that the visual compression of insoles did not reflect the effectiveness of insoles relative to the plantar pressure effect.[16]

Moreover, our study found significantly higher scores of patient satisfaction with insole durability and overall satisfaction in the study group than in the control group, which was in line with significantly increased daily use of insoles at the 3-month follow-up in the study group than in the control group. These two findings support evidence for the customized 3D-printed insoles over conventional insoles.

However, this study has some limitations. First, the 3-month follow-up to evaluate insole durability is relatively short. A longer follow-up period might reveal essential differences between these insoles. Secondly, our study recruited participants with different degrees of flat feet that were not recorded and compared between the two groups. Although randomization was done, the baseline VAS-FA score was higher in the study group than in the control group. Lastly, our study did not include concern about shoes which might affect outcomes and patient satisfaction with the insoles. For further study, a longer-term study in a larger population with different degrees of flat feet and cost-effectiveness should be determined.

Conclusions

To our knowledge, this is the first study to evaluate the effectiveness of 3D-printed insoles relative to foot and ankle function, insole durability, and patient satisfaction compared with conventional, custom-made insoles for treating patients with flat feet. While the VAS-FA scores significantly improved in both groups, there was no significant difference between groups. Deformation of insoles was observed in both groups but without significant between-group differences. There was significantly more excellent durability and overall satisfaction with 3D orthoses than with conventional insoles. We conclude that 3D-printed insoles are associated with significantly greater patient satisfaction.

Disclosure

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Original Article

Correlation between Cervical Spondylosis and Myofascial Pain Syndrome: A Retrospective Study

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ABSTRACT

Objectives: To determine the prevalence and characteristics of myofascial pain syndrome (MPS) in people diagnosed with cervical spondylosis and the correlation between these two conditions.
Study design: Retrospective study.
Setting: Outpatient Rehabilitation Clinic, Saraburi Hospital.
Subjects: Patients diagnosed with cervical spondylosis between March 1, 2019 and February 28, 2022.
Methods: Patient characteristics and general information were obtained from medical records. The level and severity of cervical spondylosis were determined from radiographic findings. Muscles of the neck, shoulder, arm, and hand areas diagnosed with MPS were used to determine the prevalence of MPS and to analyze correlations with cervical spondylosis and other related factors.
Results: Of the 281 patients with cervical spondylosis recruited, 71.5% were diagnosed with MPS and the average number of MPS-affected muscles was 2.29 per person. The severity of cervical spondylosis was statistically significantly associated with a diagnosis of MPS (p = 0.003). Those with a minimal degree of cervical spondylosis on radiographic study were approximately 13 times more likely to have a diagnosis of MPS than those with a gross degree; however, severity had a weak negative correlation with the number of MPS-affected muscles (r = -.224, p < 0.001). Multivariable logistic regression analysis demonstrated that less severe cervical spondylosis, female gender and lower body mass index were independent factors correlated with a diagnosis of MPS (p < 0.05).
Conclusions: Patients diagnosed with cervical spondylosis have a high prevalence of concomitant MPS. Physicians need to be aware of the possibility of MPS when treating cervical spondylosis, especially if the patient is female, has a low BMI, and has less severe cervical spondylosis.

Keywords: cervical spondylosis, myofascial pain syndrome, pain, prevalence, risk factors

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Introduction

Cervical spondylosis is the medical term for the degeneration of the cervical spine and its associated components. The pathophysiology involves the vertebral bodies, intervertebral discs, facet joints, joints of Luschka, ligamentum flava, and vertebral laminae.[1] Since cervical spondylosis is related to degenerative processes, it is more prevalent in those over 50 years old.[2] Clinical manifestations of cervical spondylosis include neck pain as well as stiffness of the neck. When an adjacent nerve root is compressed, radicular pain presents.[3] In addition to aging, other causes of cervical spondylosis include mechanical overload on the cervical spine and spinal trauma from certain sports activities such as rugby playing, football competition, and horseback riding.[4,5] The severity of cervical spondylosis could be assessed and graded using a plain radiographic study of the cervical vertebrae in a lateral view.[6,7]

Cervical spondylosis is treated depending on the severity of the signs and symptoms. However, other diagnoses mimicking cervical spondylosis should be further investigated and adequately treated.[8] Physicians have to check the red flag signs, such as fever, weight loss, and lymph node enlargement. If there is no red flag sign, the goal of treatment is to relieve pain, increase the patient's ability to do daily activities, and prevent nerve root damage. The pharmacological therapies include nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, antidepressants, and opioids. The non-pharmacological therapies are physical modalities, soft cervical collars, and therapeutic exercises.[1] Epidural steroid injections and facet joint injections could be a choice for patients with intractable neck or radicular pain that resists other non-invasive treatments.[9,10]

Myofascial pain syndrome (MPS) is a common diagnosis in patients with regional pain related to a trigger point in an affected muscle.[11] Approximately 25%-90% of patients who present with musculoskeletal pain in general medical practices are diagnosed with MPS.[12-16] Pain from the trigger point could be referred to distant regions,[17] so-called referred pain, a pathognomonic sign of MPS. Trigger points can be distinguished from tender points that cause pain only at the pressure-applying area.[18] Also, patients with MPS may complain of paresthesia and numbness, which may not be confirmed with the sensory examination. To be noted, MPS can mimic

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various diseases[18] and can be secondary to pathologic neuromusculoskeletal lesions such as enthesopathy, arthritis, spinal disc lesion, and radiculopathy.[19]

Although the prevalence is high, general practitioners have low awareness of MPS. An underdiagnosis caused a missed opportunity for the patient to receive appropriate treatment.[20-22] Muscle stretching, trigger point injections, dry needling, deep pressure massage, and physical modalities, including diathermy, shock wave, or laser therapy, are treatment options for MPS.[23,24] In chronic pain, depression, or stress, antidepressants and anxiolytics may also be required.[25] There is inadequate evidence for using NSAIDs as a treatment for MPS because MPS is a non-inflammatory pain syndrome.[26] In addition, eliminating perpetuating factors, such as poor posture at work, is essential for preventing the recurrence of MPS.[19]

The researcher, a physiatrist, has observed when treating patients with cervical spondylosis in the rehabilitation outpatient department of Saraburi Hospital that MPS trigger points in the neck, arms, and hands are frequently detected together. Given that cervical spondylosis and MPS are treated differently. Therefore, failure to diagnose MPS in patients with cervical spondylosis may result in inadequate treatment and unsatisfactory treatment outcomes. The observed data from routine practice contributed to the aim of this research, which was to determine the prevalence and characteristics of MPS in patients diagnosed with cervical spondylosis. The knowledge may help to increase awareness of co-diagnosis of MPS or secondary MPS and lead to appropriate treatment and rehabilitation programs for patients with cervical spondylosis.

Methods

Study design

This was a retrospective study. The protocol of this study was approved by the Saraburi Hospital Research Ethics Committee (Research Project No. SRBR65-015, Certificate No. EC015/2565).

Participants

The target population was patients diagnosed with cervical spondylosis who visited the outpatient rehabilitation department of Saraburi Hospital between March 1, 2019, and February 28, 2022.

The researcher screened electronic medical records, which were retrieved if cervical spondylosis ICD-10 codes (M4712, M4722, M4782, and M4792) were applied. Data would be excluded if one of the following conditions was found: 1) no cervical radiography done within five years before the diagnosis; 2) no medical records or missing data resulting in an uncertain diagnosis of cervical spondylosis; 3) no hospital visitations during the study period, such as receiving medicine by mail due to the COVID-19 pandemic situation.

Variables for statistical analysis

The following data were retrieved from the patient's medical records: 1) demographic and medical characteristics, including gender, age, and body mass index (BMI); 2) the most affected level and severity of cervical spondylosis; 3) muscles affected by MPS at the neck, shoulder, arms, and hand. The severity of cervical spondylosis was determined based on a lateral view of cervical radiography and the Kellgren-Lawrence grading scale: minimal (grade 1), mild (grade 2), moderate (grade 3), and gross (grade 4).[6,7]

Statistical methods

Descriptive statistics including percentage, frequency, mean and standard deviation (SD) were used to describe the variables. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to analyze whether the variable was normally distributed. The association or correlation between variables was analyzed as follows: 1) between the severity of cervical spondylosis, gender, and the presence of MPS using a chi-square test for significance testing and using logistic regression to obtain crude odds ratio (OR) with a 95% confidence interval (CI) for detecting the direction and the magnitude of the association; 2) between the severity of cervical spondylosis as well as age and BMI and number of the muscles diagnosed with MPS, using Spearman's rank correlation; 3) between gender, and the number of the muscles diagnosed with MPS, as well as between age, BMI and the diagnosis of MPS using Point-biserial correlation. If $r^2 < 0.4$, 0.4-0.6, > 0.6, then the strength of the correlation is weak, moderate, and strong respectively.[27] Lastly, the multivariable logistic regression analysis was used to adjust the confounding factors and prove the independent association of interested factors and the diagnosis of MPS. A p-value of less than 0.05 was considered to be clinically significant.

Results

According to data extraction from the hospital medical records between March 1, 2019, and February, 28 2022, 389 cases were diagnosed with cervical spondylosis. Among these retrieved data, 108 cases were excluded due to having one of the exclusion criteria (Figure 1). Of the remained 281 patients, 27.8% were men, the mean (SD) age was 57.12 (10.22) years, the mean (SD) BMI was 24.37 (3.58) kg/m^2, and 71.5% were diagnosed with MPS. The average number of MPS-affected muscles in those co-diagnosed with MPS and cervical spondylosis was 2.29 (Table 1), and the trapezius was the most frequently affected muscle, followed by paracervical muscles and infraspinatus, respectively (Table 2).

Of the 281 cervical spondylosis cases, 125 (44.5%) had moderate severity. The most common level was C5/C6 (136 cases, 48.4%).

Figure 2 shows the highest percentage of MPS (95.5%) in those with a minimal degree and the lowest percentage (61.0%) in those with a gross degree of cervical spondylosis. Table 3 shows the association between the severity of cervical spondylosis and the diagnosis of MPS (p = 0.003). For

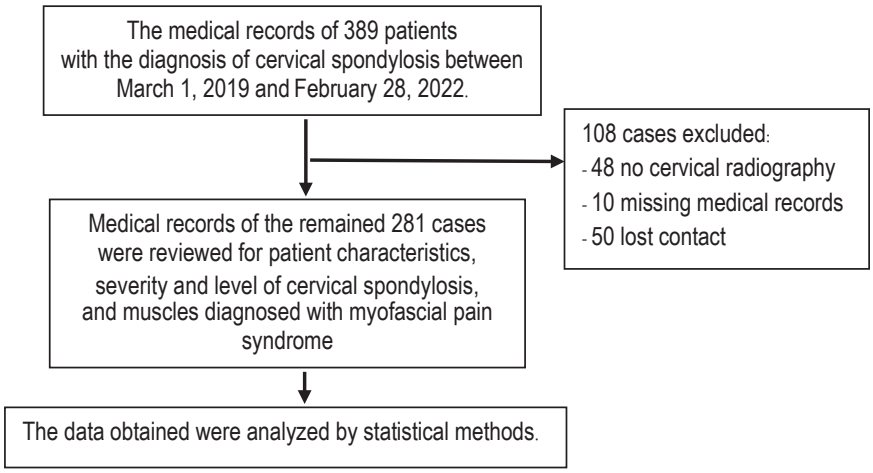

Figure 1. Flow chart of the study

Table 1. Demographic and clinical data of the patients diagnosed with cervical spondylosis (N = 281)

Parameters	
Gender, male[1]	78 (27.8)
Age, years [2]	57.12 (10.22)
Body mass index, kg/m^2 [2]	24.37 (3.58)
MPS, present[1]	201 (71.5)
Number of MPS-affected muscles per patient[2]	2.29 (1.05)

[1]Number (%), [2]mean (standard deviation)
MPS, myofascial pain syndrome

instance, the patients with minimal cervical spondylosis were 13 more likely to have MPS than those with a gross degree of cervical spondylosis. The patients with mild cervical spondylosis were 3 times more likely to have MPS than those with a gross degree of cervical spondylosis.

Regarding the effect of gender on the presence of MPS, MPS was found more in females than in males. Furthermore, statistical analysis revealed a significant relationship between gender and the diagnosis of MPS ($p < 0.001$).

Table 2. Muscles diagnosed with myofascial pain syndrome (MPS) (N = 201)

Muscles	Right	Left
Trapezius	110 (54.7)	107 (53.2)
Paracervical muscles	52 (25.9)	41 (20.4)
Levator scapulae	7 (3.5)	13 (6.5)
Rhomboideus	3 (1.5)	13 (6.0)
Infraspinatus	29 (14.4)	38 (18.4)
Teres muscles	-	1 (0.5)
Deltoideus	19 (9.5)	21 (10.4)
Biceps brachii	-	3 (1.5)
Triceps brachii	2 (1.0)	3 (1.5)
Wrist extensors	5 (2.5)	4 (2.0)
Intrinsic hand muscles	-	1 (0.5)

Number (%)

The correlations between variables analyzed by Spearman's rank correlation and point-biserial correlation are shown in Table 4. The severity of cervical spondylosis, age, and BMI had a weak but statistically significant negative correlation with the number of MPS-affected muscles. In contrast, females

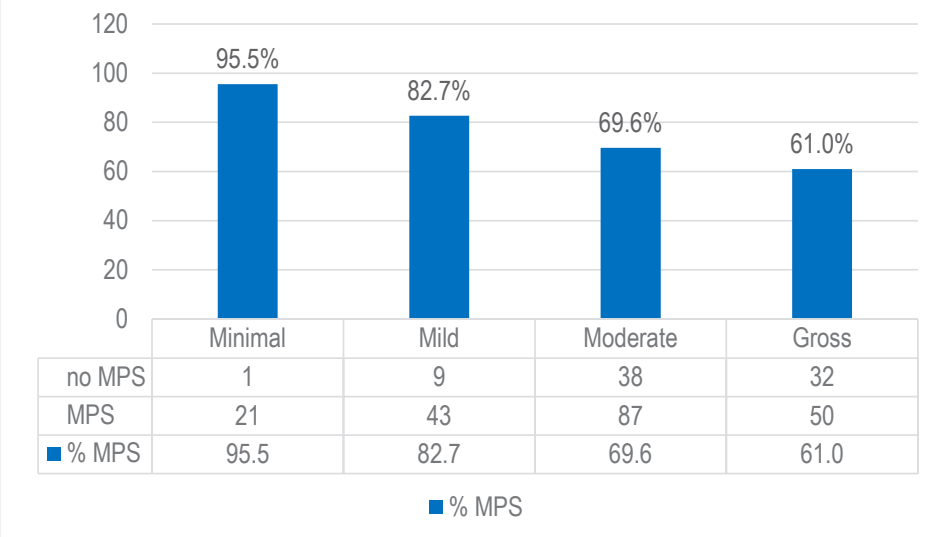

Figure 2. The distribution of myofascial pain syndrome (MPS) in each severity of cervical spondylosis

Table 3. Association between severity of cervical spondylosis and the diagnosis of myofascial pain syndrome (MPS)

Muscles	Diagnosis of MPS		Odd ratio[1]	95% CI		*p*-value
	Absent	Present		Lower	Upper	
Minimal	1	21	13.440	1.722	104.879	0.013
Mild	9	43	3.058	1.314	7.114	0.009
Moderate	38	87	1.465	0.816	2.630	0.200
Gross	32	50	-	-	-	0.009

[1]Crude odd ratio

Table 4. Correlation between variables and numbers of muscles with myofascial pain syndrome (MPS), diagnosis of MPS, and severity of cervical spondylosis

Interesting factors	Number of muscles with MPS		Diagnosis of MPS	
	Coefficients	*p*-value	Coefficients	*p*-value
The severity of cervical spondylosis	-0.224[1]	< 0.001	-	-
Age	-0.321[1]	< 0.001	-0.189[2]	0.002
BMI	-0.187[1]	0.002	-0.193[2]	0.002
Gender, female	0.285[2]	< 0.001	-	-

[1] = Spearman's Rank Correlation Coefficients; [2] = Point Biserial Correlation Coefficients
BMI, body mass index; MPS, myofascial pain syndrome

Table 5. Summary of multiple logistic regression analysis for the diagnosis of myofascial pain syndrome (MPS)

	B[1]	SEB[2]	Odds ratio	95% CI		*p*-value
				Lower	Upper	
Gender, female	1.647	0.336	5.190	2.686	10.029	< 0.001
BMI	-0.138	0.048	0.871	0.793	0.956	0.004
The severity of cervical spondylosis	-0.643	0.219	0.526	0.342	0.808	0.003
Age	-0.012	0.017	0.988	0.956	1.021	0.472

[1]B, unstandardized regression weight; [2]SEB standard deviation to a mean
BMI, body mass index

had a weak but statistically significant positive correlation. A weak but statistically significant negative correlation was found between age and BMI and the diagnosis of MPS.

Using the enter method of multivariable logistic regression analysis, female gender, low BMI, and less severity of cervical spondylosis were independent correlating factors for the diagnosis of MPS. At the same time, age was not an independent correlating factor for diagnosing MPS (Table 5). For instance, when another factor is held constant, female patients diagnosed with cervical spondylosis are approximately 5 times more likely than male patients to have the diagnosis of MPS (OR 5.190, 95% CI = 2.686-10.029). Compared to patients with a one-unit lower BMI, those with a one-unit higher BMI had a 12.9% lower likelihood of having the diagnosis of MPS (OR 0.871, 95% CI = 0.793-0.956). In addition, patients with gross degree cervical spondylosis had a 47.4 percent lower probability of having the diagnosis of MPS than those with moderate degree cervical spondylosis. Patients with moderate degree cervical spondylosis had a 47.4 percent lower probability of having the diagnosis of MPS than those with mild degree cervical spondylosis (OR 0.526, 95% CI = 0.342-0.808).

Discussion

There were 281 patients with cervical spondylosis who met the inclusion criteria for this study. The prevalence of MPS was 71.5%, and the mean number of MPS-affected muscles was 2.29 per person. In this study, the high prevalence of MPS in patients with cervical spondylosis may be due to the investigator's specialist, who seems more concerned about MPS than other medical specialists. On the other hand, treating physicians who are general practitioners may misdiagnose MPS, or MPS may be underdiagnosed.

Interestingly, this study found a negative correlation between the degree of cervical degeneration and the diagnosis of MPS and a negative correlation between the degree of cervical degeneration and the number MPS affected muscles. The possible explanation may be that MPS in those with a less severe degree of cervical spondylosis may be primary MPS. Alternatively, cervical spondylosis can be an incident finding as radiographs frequently reveal some degenerative changes in asymptomatic individuals.[28-30]

Moreover, the result of this study demonstrated that females diagnosed with cervical spondylosis were approximately five times more likely to be diagnosed with MPS and have a higher number of MPS than males. This finding is in

line with the results reported by Fricton JR et al.[12] and Sabeh AM et al.[31] Both found that females experience MPS more often than men, which may be the result of an altered level of female hormones during the menstrual phase and may increase pain sensitivity, particularly during the second week of the menstrual cycle.[32]

In addition, this study found a negative correlation between age and the diagnosis of MPS and between age and the number of MPS-affected muscles in the univariable analysis. This finding may be because younger patients are in their working years and have more significant muscle activity with poor ergonomic postures, a risk factor for MPS[19] leading to the upper cross syndrome.[33] Also, younger females are more likely than older females to experience the altered hormone levels discussed previously.[32] However, the correlation was not significant by using the multivariable analysis.

Surprisingly, this study found an unexpectedly negative correlation between BMI and the diagnosis of MPS, which is inconsistent with a previous study[34] Agung I et al. reported no correlation between BMI and MPS, meaning that MPS can be found in both thin and obese people. Possible explanations for these results include that BMI is calculated based on height and weight, indicating poor body composition.[35,36] Some studies have found that a low BMI is associated with low muscle mass.[37,38] This may make them more prone to muscle overload and fatigue, which are important risk factors for MPS.[19,39-41] However, this study lacks information regarding body composition. Future research should collect the data required to determine the cause of this correlation.

Other findings of cervical spondylosis from this study are in line with other studies.[28,42] The most common vertebral levels affected by cervical spondylosis were C5/6[42].

Besides the findings mentioned above, this study had some limitations. First, it is a retrospective study. There were no pre-specified diagnostic criteria for MPS. Therefore, physiatrists in the department might not strictly follow the diagnostic criteria of MPS[11] and not be concerned about whether MPS is primary or secondary. A future study should be prospectively conducted to avoid this limitation. Next, the data were recruited from the patients who visited the rehabilitation outpatient department, resulting in a selection bias that may overestimate the prevalence of MPS. So, randomization of the study population from various departments such as orthopedic surgery, neurosurgery, or neuro-medicine should be conducted to confirm whether the diagnosis of MPS is not specialist-dependent. In addition, data for this study were collected during the COVID-19 pandemic, and many patients were excluded from the study. During this time, confounding factors such as poor ergonomics while working from home, psychological stress, and long COVID syndrome may exist but were not explored. Lastly, outcomes of combined treatment of cervical spondylosis and MPS should be further studied to demonstrate the benefit of diagnosis of MPS in those with cervical spondylosis.

This study suggests that individuals with cervical spondylosis have a relatively high likelihood of having MPS for clinical application.

Conclusions

Patients with cervical spondylosis have a high incidence of MPS in the neck, shoulder, arm, and hand regions. It is important to raise the treating physician's awareness of the concomitant MPS, especially if the patient is female, has a low body mass index (BMI), and has less severity of cervical spondylosis.

Disclosure

The authors declare that there is no conflict of interest.

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Original Article

Adaptation of The Stroke Driver Screening Assessment (SDSA) to Malaysian Version (MySDSA) and its Validation for Fitness to Drive after Stroke

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ABSTRACT

Objectives: To adapt the Stroke Drivers Screening Assessment (SDSA) to the Malaysian version (MySDSA) and to establish its criterion validity and predictive ability in assessing fitness to drive after a stroke in Malaysia.

Study design: A universal sampling method.

Setting: A tertiary hospital in an urban setting in Malaysia.

Subjects: Stroke survivors referred for assessment of fitness to drive.

Methods: The MySDSA was adapted from the original SDSA. An expert panel of doctors, occupational therapists, and representatives from the Malaysia Road Transport Department and the Malaysia Institute of Road Safety Research was formed and a consensus decision was made to substitute all road signs in the SDSA Road Sign Recognition section with the Malaysian equivalent. No further changes to the SDSA were made, and the original English language was maintained. After that, stroke patients who had been referred for driving fitness assessment were recruited. The patients were tested using MySDSA and were classified as pass or fail using a discriminant equation. The patient's performance on the MySDSA was then compared with their performance on a computerised driving simulator using Receiver Operating Characteristic (ROC) analysis. The assessor for the driving simulator was blinded from the MySDSA results.

Results: Twenty stroke survivors (mean age 50 years ±10) of the initial 35 stroke survivors recruited completed both the MySDSA and the driving simulator assessment. There was no statistically significant association between either demographic or stroke characteristics and MySDSA performance. MySDSA predicted driving performance on the simulator with 74% adjusted accuracy and above moderate effect size (Cohen's d=0.661).

Conclusions: MySDSA has acceptable accuracy for predicting driving performance on the driving simulator test after a stroke, but it is not recommended to be used alone as a replacement for a driving simulator.

Keywords: driving, rehabilitation, stroke, assessment

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Introduction

In Malaysia, the stroke incidence rate has been increasing among the younger adult population in recent years, both globally and locally.[1,2] This increases the socioeconomic burden because stroke survivors still have immense social responsibilities and obligations at such an age range. As the patients gradually recover and return to premorbid function, return to driving becomes an important goal. The ability to drive represents independence and facilitates social reintegration.[3]

In Malaysia, a valid driving license duration ranges from 1 to 5 years, and the license must be renewed before the expiry date. Per sections 30.1 and 30.2 of the Road Transport Act 1987 (Laws of Malaysia - Act 333, 2013), physicians have the overall legal responsibility to certify if a person with significant medical conditions is fit to drive. For example, a stroke patient with a valid driving license is required to obtain a physician's certificate to confirm his fitness to drive and if any car modifications are required. However, there is no policy to officially withdraw the existing driving license after someone is diagnosed with a stroke.

Returning to driving after a stroke is not without any risk. It has been reported to have an increased risk of serious traffic injuries regardless of the laterality of vascular lesions.[4] This may be explained by Groeger's cognitive theory, which states that driving involves multilevel cognitive and psychological processes.[5] Fitness to drive after stroke may be compromised by stroke consequences such as visual field deficit, inattention, memory deficits, motor sensory impairments, apraxia, and language difficulties. Stroke survivors returning to driving without clinician evaluation is not uncommon.[6] However, to ensure the safety of all road users, an objective assessment of driving fitness is essential.

An on-road driving assessment is considered a gold standard evaluation and is available in most developed countries.

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However, it is not done routinely in Malaysia due to the lack of resources and expertise. This problem is also actual with a computerised driving simulator test. Unfortunately, there are less than five healthcare centres with a computerised driving simulator in the country, and only two centres performed the on-road driving assessment for a minimal population. In addition, the waiting time for these tests is highly long. Coupled with a lack of a registered policy for compulsory testing, most stroke survivors started driving despite the advice from their physicians. For this reason, we need a portable, easily administered, and valid screening assessment tool to determine driving fitness after a stroke. This tool is hoped to ensure the patient's best interest and, at the same time, safeguard road users by identifying unsafe drivers.

One of the established assessment batteries for predicting stroke survivors' driving performance with high accuracy is the Stroke Drivers Screening Assessment (SDSA).[7-9] It is available in the European, United States, and Nordic versions, with accuracy ranging from 62% to 87%.[10-13] SDSA seems to measure predominantly attention and executive abilities,[14] of which have previously been shown to be essential determinants of safe driving.[15] Therefore, in this study, we aimed to adapt the SDSA for use in the Malaysian population and to determine whether it is a suitable screening instrument for stroke patients to return to driving. This adaptation is intended for healthcare professionals already involved with return-to-drive assessment and training.

Methods

This study was approved by the Medical Research and Ethics Committee in UMMC (ID No. 201944-7291) and the Malaysia Ministry of Health (NMRR-20-593-53696). All subjects have given their written informed consent for the study.

Participants

Stroke patients who were referred for driving assessment in the Department of Rehabilitation Medicine, University Malaya Medical Center (UMMC) from May to October 2020 were screened. Using the G power calculator, the desired sample size for the correlation point biserial model with a moderate effect size is 21 patients.

The inclusion criteria were diagnosis of haemorrhagic or ischemic stroke verified by a physician or neuroimaging, having a full driving license, actively driving for at least three times a week; 3 months prior to the stroke, no significant cognitive impairments (Mini-Mental State Examination [MMSE] ≥ 24 or Montreal Cognitive Assessment [MOCA] ≥ 18), and independent or mildly independent in basic activities of daily living (Modified Barthel Index [MBI] ≥ 75). In addition, those aged ≤ 18 and ≥ 70 or with a history of any other neurological conditions like Parkinson's disease, psychiatric disorder, or conditions that legally preclude driving conditions according to Malaysia Ministry of Health guidelines were excluded, such as epilepsy and any form of visual field defect.

Materials

The data was collected using a self-constructed questionnaire specifically designed based on the objectives of this study. The questionnaire has four sections: the first three consist of patients' demographic data, disease-specific characteristics, and driving exposure, respectively, while the fourth section explores the return to the driving experience.

Development of MySDSA

The development of MySDSA was done via adaptation of the original SDSA. An expert panel was formed for this purpose, which comprised relevant healthcare professionals from a few hospitals in Malaysia, including doctors and occupational therapists involved in return to driving assessments and representatives from the Malaysia Road Transport Department and Malaysia Institute of Road Safety Research.

The original SDSA consists of 4 subtests - Dot's cancellation test, Square Matrix Direction, Square Matrix Compass, and Road Sign Recognition. A consensus was achieved among the expert panels to retain all three subtests as the original version except for Road Sign Recognition. The Road Sign Recognition test was modified, in which all the road signs were changed to Malaysia equivalents (Figure 1).

For the language medium, the panel members agreed to maintain the English language for MySDSA, and no translation is needed. The reasons are: English on the SDSA was only used in the instruction guide the healthcare professionals, whereas the patients do not have to read any statement or sentences in English. All healthcare professionals in Malaysia use English as the medium of academic study and communication. They have also been using the original SDSA for the past few years.

Study protocol

This protocol involves a few steps: the index test and the reference test. For the index test, the clinicians tested every subject referred for the driving assessment using MySDSA. The total duration to complete the assessment was about 30 minutes. In order to determine the subject's performance with MySDSA, the discriminant equation of the original SDSA battery was used. Using this formula, two scores - pass score, (a), and fail score, (b), were obtained for each subject. Finally, the MySDSA total score was derived by subtracting the fail score (b) from the passing score (a). With zero as the cut-off point, a positive MySDSA score indicated that the subject passed the MySDSA test. Meanwhile, a negative MySDSA score indicated that the subject failed the MySDSA test.

(a) Pass score = (Dot's Cancellation time x 0.012 + Dot's Cancellation false positive x 0.216 + Square Matrices Direction x 0.409 + Road Sign Recognition x 1.168) - 13.79

(b) Fail score = (Dot's Cancellation time x 0.017 + Dot's Cancellation false positive x 0.035 + Square Matrices Direction x 0.185 + Road Sign Recognition x 0.813) - 10.042

(c) MySDSA total score = (a) - (b)

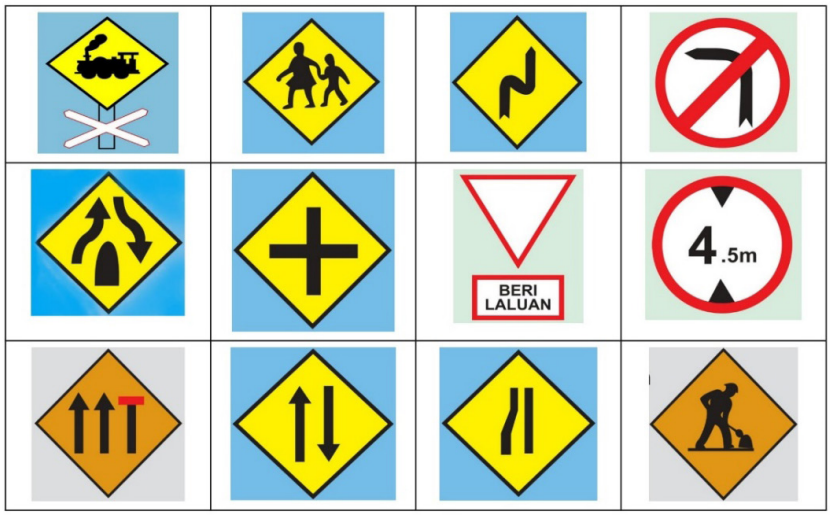

Figure 1. The Road Sign Recognition test has been substituted with the Malaysian equivalent.

For the reference test, all subjects who have been tested with MySDSA were then evaluated on a computerised driving simulator (Jayonik SIMULASIA-SA-3500-R) as the standard criterion. This test was conducted by an occupational therapist trained in the simulator, and subjects were categorised as pass or fail. The previous study has shown that adapting to an unfamiliar car is associated with an increased cognitive load which could affect the assessment validity.[16] Thus, four sessions of free driving practice were allowed to get the subject accustomed to the simulator.

The final session (the fifth) consisted of a basic driving course and a defensive driving course. The basic driving course mainly assessed the driver's behaviour for safety measure compliance, for example, wearing a seat belt, maintaining driving in the same lane, giving a signal, and maintaining safe distance from another car. The defensive driving course assessed the driver's brake reaction speed and brake distance when they encountered sudden obstacles for example, an animal crossing the road or another car blocking the road. Each session was one hour long. The assessor was blinded from the subject's MySDSA outcome.

Statistical analysis

In view of the small sample size, Shapiro-Wilk was used for the normality test. Subjects' demographic and stroke characteristics were compared using Independent t-tests or the Mann-Whitney U test and Chi-square or Fisher's exact tests as applicable. For statistical analysis purposes and due to the small sample size, the MOCA score is converted to MMSE scores using the validated conversion by Roalf et al.[17] to enable us to get one uniform score.

The correlation between the MySDSA score (MySDSA total score, which was calculated using the formula explained under the Methods section - index test) and the continuous variable was measured using Spearman and Pearson test. The agreement between MySDSA and driving simulator performance was measured using MedCalc Receiver Operating Characteristic (ROC) analysis.

Results

Thirty-five stroke survivors were initially recruited with a mean age of 52 ± 10.9 years and a mean stroke duration of 6.9 ± 9.08 months. Fifteen subjects (43%) dropped out of the study due to a sudden lockdown in the country; thus, they could not complete the driving simulator assessment. As a result, only 20 subjects (57%) completed the driving simulator assessment (Table 1).

The average interval between MySDSA and driving simulator assessment was 19.7±12.4 weeks. There was no significant association between the demographic or stroke characteristics and MySDSA performance. Spearman test showed a moderate positive correlation (p = 0.552, p = 0.001).

Those who completed both MySDSA and driving simulator assessment (n = 20) were included in the ROC analysis. For ROC analysis, the positive test and 'disease present' referred to subjects who were unfit to drive based on MySDSA and computerised driving simulator performance, respectively (Table 2).

Fourteen and six subjects were correctly and incorrectly categorized by MySDSA, respectively. No significant differences

Table 1. Demographic data and stroke characteristics (n = 20)

Variables	
Sex[1] (male/female)	15 (75) / 5 (25)
Race[1] (Malay/Indian/Chinese)	9 (45) /2(10) / 9 (45)
Stroke Event[1] (first/recurrent)	18 (90)/ 2 (10)
Stroke Type[1] (ischemic/hemorrhagic)	15 (75)/5 (25)
Stroke Side[1] (dominant/non-dominant)	12 (60) /8 (40)
Employment Status[1] (yes/no)	6 (30) /14 (70)
Education[1] (primary/secondary/tertiary)	1 (5) /8 (40) /11 (55)
Age (years)[2]	50 (10.17)
Stroke duration (months)[2]	6.9 (9.08)
MMSE[2]	28.40 (1.73)
MBI[2]	90.10 (9.49)
Daily Driving Distance (km)[2]	34.81 (17.07)
MySDSA-simulator interval (weeks)	19.65 (12.37)

[1]Number (%), [2]mean (standard deviation, SD)

Table 2. MySDSA versus driving simulator performance

	Driving simulator		Total
MySDSA	Fail	Pass	
Fail[1]	True positive = 5 (25)	False positive = 3 (15)	8
Pass[1]	False negative = 3 (15)	True negative = 9 (45)	12
Total	8	12	20

[1]Number (%)

Table 3. Demographic and stroke characteristics of the stroke survivors in the "True" and "False" groups

Variables	True (n = 14)	False (n = 6)	*p*-value
Age[1]	49 (10.4)	53 (9.9)	0.45[a]
Gender[2] (male/female)	11/3	4/2	0.62[b]
Ethnicity (Malay/Chinese/Indian)	7/6/1	2/3/1	0.71
Education level (primary/secondary/tertiary)	1/6/7	0/2/4	0.69
Employment status Yes/No	3/11	3/3	0.30
Daily driving distance (km)[1]	37 (15)	30 (21)	0.40
First/recurrent stroke	13/1	5/1	0.52
Stroke type (ischemic/hemorrhagic)	10/4	5/1	1.00
Stroke location (subcortical/cortical)	9/5	4/2	1.00
Stroke side (dominant/non-dominant)	8/6	4/2	1.00
Stroke duration (months)[3]	2 (0.7-6.5)	10 (0.8-14.8)	0.28
MMSE[3]	29 (27-30)	28.5 (26.8-30)	0.89
MBI[3]	93 (82.3-97.8)	93.5 (80-97.8)	0.97
MySDSA-simulator interval (weeks)[3]	26 (7.8-32.5) 2.1	12 (6.8-24.8)	0.41
MySDSA sum score[3]	(-0.4-3.9)	0.2 (-4.3-1.5)	0.08

[1]Mean (standard deviation, SD), [2]number, [3]median (interquartile range, IQR)
[a]independent t test, [b]Fisher's exact test, cChi-square test, dMann-Whitney U test
MMSE, Mini Mental State Examination; MBI, Modified Barthel Index; MySDSA, Malaysian version of Stroke Driver Screening Assessment

between the true and false groups were found in the demographic or stroke characteristics (Table 3). In addition, the differences in the MySDSA-driving simulator assessment interval and MySDSA sum score between both groups were also not statistically significant.

By computing this disease prevalence into the ROC analysis, the adjusted accuracy of MySDSA to predict driving performance on the driving simulator was 74%. This adjustment method is applicable when the sample sizes in the positive and the negative groups do not reflect the actual prevalence of the disease.[18]

MySDSA sensitivity was 62.5%, indicating that the proportion of probability for MySDSA to detect a subject who was unfit to drive is 62.5%. MySDSA specificity was 75%, indicating that the proportion of probability for MySDSA to detect a subject who was fit to drive is 75%. The negative predictive value (NPV) and positive predictive value (PPV) for MySDSA were 96.4% and 15.6%, respectively. The area under the ROC curve (AUC) is 0.688 (p = 0.095) (Figure 2).

Discussion

The best determinant of fitness to drive are Road Sign Recognition, Square Matrices Compass, and Trail Making Test Part B with 84%, 85%, and 80% accuracy, respectively.[15] In stroke survivors, only visual-cognitive skills have typically been identified as predictors of fitness-to-drive of stroke survivors because of the typical pattern of motor impairment involving only one side of the body.[15] Thus, it is possible for them to drive with some modification to accommodate their weaknesses. One test battery that was previously developed for this purpose is the SDSA.[7,8]

In the present study, we adapted the UK version of SDSA to make our Malaysian version (MySDSA). MySDSA showed a superior result in its specificity compared to its sensitivity

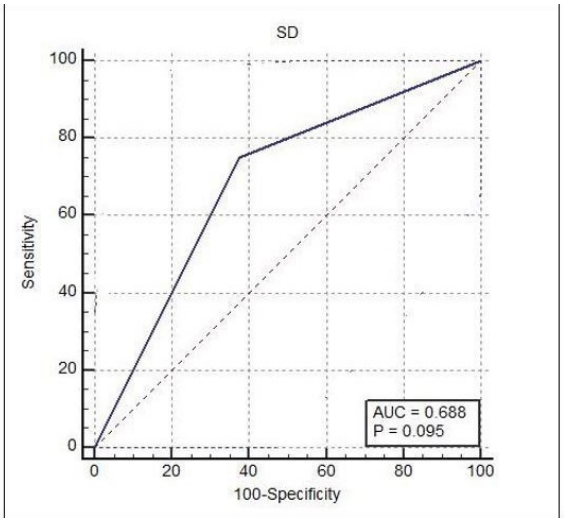

Figure 2. Receiver operating characteristic curve
AUC = Area under the curve

(75% versus 62.5%). It also has NPV of 96.4%, which signifies the probability of a subject being truly fit to drive if he passes MySDSA assessment. However, although sensitivity and specificity measure the intrinsic accuracy and do not depend on the prevalence rate, they do not provide information on the diagnostic accuracy of a particular patient.[18] To obtain this information, we used positive predictive value (PPV) and negative predictive value (NPV), which depend on the disease prevalence.[19,20] The disease prevalence was 6.9%, which was derived by measuring the proportion of stroke survivors who was deemed unfit to drive from driving assessments conducted in UMMC and the total stroke cases referred for driving assessment.

The overall accuracy of MySDSA in predicting the driving performance of stroke patients referred for driving assessment is 74%, comparable to previous studies involving SDSA adaptation.[11-13] The area under the ROC curve (AUC) is 0.688 (0.7) with *p*-value of 0.095, which is not statistically significant at a five percent type I error. Again, this can be due to the small sample size of this current study. However, it is statistically significant when we set the alpha level (α) at 10%, which means the result is generalisable with 90% confidence. In general, an AUC of 0.5 suggests no discrimination, 0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent, and more than 0.9 is considered outstanding.[21,22] In this study, the AUC value is acceptable with the above medium effect size (d = 0.661).

Another study using a driving simulator as a reference test was Akinwuntan et al.[13] They tested the US version of the SDSA battery and reported a high accuracy rate (87%) in predicting the driving performance of stroke patients. The Nordic version of SDSA (NorSDSA) was tested with on-road driving performance. The result was similar to MySDSA, with specificity being superior to sensitivity. However, it has a lower discriminant analysis which can only correctly classify 62% of the stroke patients to pass.[12]

The parameters found in this study indicate that MySDSA tends to identify safe rather than unsafe post-stroke drivers with a specificity of 75% vs. a sensitivity of 62.5%. This finding implies that MySDSA is not suitable as a stand-alone test to substitute driving simulator assessment as it may risk inaccurate approval for fitness to drive, especially for those with a MySDSA sum score closer to zero. Our advice is for clinicians to use it with other cognitive tests, for example, Trail Making Test Part A and the Snellgrove Maze Task if the clinician does not have access to a computerised driving simulator. This combination was shown to be a good predictive model for on-road test failure after a stroke.[23]

Overall, MySDSA is a valid screening tool that has the potential to be used widely in Malaysia. Similarly, as SDSA, it can be used by any clinician and does not need extensive training.[24] The two major drawbacks of this study are the small sample size due to the high dropout rate and the long interval between MySDSA and the driving simulator test, which can affect accuracy since neurological recovery may occur over such a prolonged duration. During the COVID-19 pandemic, this study was halted for three months due to the local government movement control order, explaining the long interval between MySDSA and the driving simulator assessment. Moreover, the centre involved in this study was designated as one of the COVID-19 hospitals during the pandemic, rendering further recruitment impossible within the set time frame.

Another limitation is using a local computerised driving simulator as a reference standard compared to on-road assessment. Despite the lower face validity than on-road assessment, it enables repeatable assessment in various controlled driving environments. It has established relative validity.[25,26] The simulator in this study is the best contextual driving assessment available in the country and has been acknowledged by the National Road Transport Department. It uses a virtual reality concept that simulates the local traffic and weather. The demerit marking system is also similar to the system used for on-road driving test in Malaysia.

Conclusions

This study showed that MySDSA has an acceptable accuracy for predicting driving performance on the driving simulator test. In clinical practice, MySDSA can serve as a screening assessment prior to sending the stroke patients to the driving simulator test. Due to the slightly higher sensitivity, MySDSA should not be used as a stand-alone battery in the decision making on fitness to drive without a driving simulator. The decision should be made collectively from results of multiple established cognitive tests, experience of the driver and judgment of the clinicians. Larger studies are needed to further establish the criterion validity of MySDSA in predicting driving performance.

Disclosure

The authors declare no conflict of interest of any kind.

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Original Article

Factors Associated with Immediate Post-Needling Soreness after Dry Needling at Upper Trapezius Muscle in Patients with Myofascial Pain Syndrome

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ABSTRACT

Objectives: To investigate the factors associated with immediate post-needling soreness after dry needling at the upper trapezius muscle in patients with myofascial pain syndrome.
Study design: Prospective study.
Setting: Department of Rehabilitation Medicine, Phetchabun Hospital, Phetchabun province, Thailand.
Subjects: The participants were 265 patients with myofascial pain syndrome at the upper trapezius muscle who were treated by dry needling between January and September 2022. The inclusion criteria comprised ages 18-65 years and a numeric rating scale (NRS) of muscle pain intensity ≥ 3 scores.
Methods: The participants were interviewed regarding their demographic data, including gender, age, BMI, affected side, and NRS of initial muscle pain intensity. Dry needling at the upper Trapezius was performed by using an acupuncture needle. Data recorded during needling included needle size, the number of needle insertions, the total number of needles, responses during needling, and the number of muscle twitching. Data recorded immediately after dry needling, included the bleeding size, presence of hematoma, duration of ischemic compression, NRS of muscle pain, and NRS of soreness. The demographic data are shown as frequency, percentage, means, and standard deviations. The relationship of factors associated with post-needling soreness was analyzed by chi-square test, and potential associated factors of post-needling soreness were analyzed by multiple binary logistic regression, Forward Wald test.
Results: Two hundred sixty-five patients were 19.2% of males and 80.8% of females, with a mean age of 44 years, and average BMI of 23.7 kg/m^2, and average initial muscle pain intensity of 5.8. The most frequently affected side was the right side (54.3%). Most patients had post-needling soreness (54.0%), with a mean soreness score of 3.3. Chi-square analysis identified seven variables that involved post-needling soreness: needle size, number of needle insertions, total number of needles, number of muscle twitching, bleeding size, presence of hematoma, and duration of ischemic compression. However, multivariate analysis identified only three factors that were statistically significantly associated with post-needling soreness, including needle size (OR_{adj} 4.38, 95%CI 2.40-8.04, $p < 0.001$), number of muscle twitching (OR_{adj} 1.19, 95%CI 1.08-1.36, $p = 0.007$), and number of needle insertions (OR_{adj} 1.07, 95%CI 1.03-1.11, $p = 0.001$)
Conclusions: The associated factors with immediate post-needling soreness in patients after upper trapezius dry needling were needle size, number of muscle twitching, and number of needle insertions.

Keywords: post-needling soreness, dry needling, upper trapezius muscle, myofascial pain syndrome

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Introduction

Myofascial trigger points (MTrPs) are hypersensitive nodules in taut bands in skeletal muscles. Active trigger points are symptom-producing by triggering local or referred spontaneous pain,[1] contributing to autonomic phenomena, motor dysfunction, and impaired range of motion.[1,2] The upper trapezius muscle is the common site of myofascial pain syndrome (MPS),[3] presenting in 93.75% of chronic neck pain patients.[4] The patients usually feel uncomfortable and have limited neck and shoulder movement, which affects their job, socialization, and quality of life.[5]

Dry needling is a very effective and widely used treatment for myofascial trigger points.[6,7] It has been shown not only to have a similar efficacy at alleviating myofascial pain as lidocaine injection[8] but also no adverse effects like lidocaine injections, including allergic reactions, muscle infarction, skin depigmentation, tendon atrophy, or more serious side effects such as fainting, palpitations, and apnea.[9] Thus, dry needling is the safer alternative treatment for patients with myofascial pain syndrome.[10]

However, soreness is a frequent complication after myofascial trigger point dry needling.[11,12] It was reported to range between 50-100% in most studies[13] however, Myburgh et al.'s study[14] reported lower percentages of post-needling soreness (29.4%). The patients who exhibited post-needling soreness describe it as quite different from the pain caused by MTrPs. The quality of soreness is described as constant pressure

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or dull aching, which is distinguishable from the sharp and tight aching they experience before needling.[8] Post-needling soreness has shown to be higher immediately[12] or a few hours after needling 8 and lasts less than 72 hours in most studies in which filiform needles were used. [13] The intensity was reported to be between 3.5-5.6 of the VAS score.[8] The patients with post-needling soreness have reported reduced treatment adherence as a consequence[15] and may result in refusing further stretching, which negatively affects treatment. Regarding the researcher's observation, the patients refused to continue dry needling when immediate post-needling soreness occurred. Consequently, the treatment outcome was ineffective, and soreness might overwhelm the initial muscle pain from myofascial pain syndrome, making the clinical symptoms look worse than baseline.

From the literature review, they considered post-needling soreness as being a result of the tissue injury produced by the needling and the following inflammatory reaction.[1] The tissue injury and inflammation factors may influence post-needling soreness. Martin-Pintado's study[12] found that women exhibited higher intensity in post-needling pain than men, and pain during needling and the number of needle insertions significantly correlated with post-needling soreness. They studied only patients with a latent myofascial trigger point. Since the post-needling soreness influenced the treatment outcome of myofascial pain syndrome, so the researcher would like to investigate the factors associated with immediate post-needling soreness after dry needling at the upper trapezius muscle in patients with an active myofascial trigger point. This important finding will further develop the clinical practice guideline for post-needling soreness prevention.

Method

This study was approved by the Institutional Ethic Committee of Phetchabun Hospital (Approval number 05/2565).

Study design

Prospective study.

Participants

Patients diagnosed with acute, subacute, or chronic cases of myofascial pain syndrome (MPS) at the upper trapezius muscle were based on Travel and Simon's clinical criteria. The subjects were those who visited the Rehabilitation outpatient clinic at Phetchabun Hospital and were treated by dry needling between January and September 2022. They were invited to participate in the study. After giving their informed consent, they were recruited into the study. The inclusion criteria consisted of ages between 18-65 years, myofascial pain intensity using a numeric rating scale (NRS) at least three out of ten. Patients with any of the following were excluded from the study: coagulopathy, thrombocytopenia, receiving the antiplatelet/ anticoagulant, a history of trigger point dry needling/ injection in the target region during the previous seven days, fibromyalgia, cervical disc herniation, cervical stenosis, cervical radiculopathy or radicular pain, cervical myelopathy, a history of neck surgery or trauma during the previous six months, numbness at the upper trapezius region, and poor perception or communication.

The sample size was analyzed by binary logistic regression and calculated using 20 times of variables (13 factors), 260 patients, and an additional 2% to prevent dropouts (5 patients). Thus, the sample size of this study was 265 patients.

Procedure

The assessor was a nurse who interviewed participants regarding their demographic data, including gender, age, BMI, and affected side. Then, asked the patient to evaluate the initial muscle pain using a numeric rating scale (NRS) in the paper record, where 0 means no pain and 10 means the most severe pain. Dry needling (fanning technique) at the upper Trapezius was performed using an acupuncture needle with one physiatrist in all patients. The needle size was selected depending on the trigger point depth and toughness. The number of needle used in each patient depended on the number of palpated active trigger points and patient tolerance. The number of needle insertions in each needling depended on responses during needling (e.g.no response, dull sensation, sharp sensation, radiating pain, muscle twitching), patient intolerance, and the physiatrist's judgment. Typically, the physiatrist performed until the muscle responses were observed and stopped needling, whether there were no muscle responses or patient intolerance. The needling procedure should be finished within 10 minutes in each case. During needling, the physiatrist observed muscle responses and twitching to determine the number of needle insertions in each case. When needling finished, ischemic compression was performed for at least 10 seconds, and if presenting any bleeding, the skin was continued compressed until the bleeding disappeared. The physiatrist recorded data during needling, including needle size, the number of needle insertions, the total number of needles, responses during needling, and the number of muscle twitching. Then, the researcher immediately recorded the data after dry needling where the bleeding size and hematoma occurred and evaluated the NRS of muscle pain and soreness (where 0 means no pain and 10 means the most severe pain) immediately in the paper record by the assessor. The quality of soreness is described as constant pressure or dull aching, which is distinguishable from the sharp and tight aching they experience before needling.[8]

Statistical analysis

SPSS statistical software system version 16.0 was used for statistical analysis. Demographic data, NRS of initial muscle pain, NRS of post-needling muscle pain, and NRS of post-needling soreness were analyzed with descriptive statistics. The quantitative data were shown as means and standard deviations, while qualitative data were shown as frequencies and percentages. The Chi-square test analyzed

the relation of variables with post-needling soreness. The univariate factors affecting post-needling soreness with a statistical significance level of less than 0.2 were selected for statistical analysis by multiple binary logistic regression and forward Wald test. A statistically significant confidence level was set at 0.05.

Results

The baseline characteristics of the study population

There were 333 patients during the study period. Sixty-eight of them were excluded due to 22 were aged above 65 years, 4 had NRS of pain intensity < 3, 24 had cervical diseases (disc herniation, stenosis, cervical radiculopathy or radicular pain), 10 had a history of trigger point dry needling in target region during the previous seven days, and 8 received the antiplatelet/ anticoagulant. The baseline characteristics of 265 patients enrolled in the study were summarized in Table 1. Most of the patients had post-needling soreness, 143 subjects (54.0%), which a mean soreness score was 3.3 (SD 2.5). After dry needling, most patients had muscle pain relief (97.4%), and the mean muscle pain score was 3.2 (SD 1.6).

Factors associated with post-needling soreness

From the Chi-square analysis, seven factors associated with post-needling soreness were statistically significant. These factors were needle size ($p < 0.001$), number of needle insertions ($p < 0.001$), total number of needles ($p = 0.043$), number of muscle twitching ($p < 0.001$), bleeding size ($p = 0.008$), presence of hematoma ($p = 0.003$), and duration of ischemic compression ($p = 0.047$).

In univariate analysis, factors that revealed statistically significant associated with post-needling soreness were seven factors including, initial muscle pain intensity (ORadj 1.25, 95%CI 1.06-1.47, $p = 0.007$), needle size (OR_{adj} 3.22, 95%CI 1.94 - 5.32, $p < 0.001$), number of needle insertions (OR_{adj} 1.08, 95%CI 1.05 - 1.11, $p < 0.001$), total number of needles (OR_{adj} 1.79, 95%CI 1.32 - 2.43, $p < 0.001$), number of muscle twitching (OR_{adj} 1.34, 95%CI 1.20 - 1.48, $p < 0.001$), bleeding size (OR_{adj} 6.35, 95%CI 1.53 - 26.40, $p = 0.011$) and presence of hematoma twitching (OR_{adj} 12.1, 95%CI 1.56 - 93.89, $p = 0.017$) as shown in Table 2.

Table 1. The baseline characteristics of the study population (N = 265).

Baseline characteristics	Study population (N = 265)
Age (years)[1]	44.0 (1.2)
BMI (kg/m^2)[1]	23.7 (3.5)
Initial muscle pain intensity (score)[1]	5.8 (1.6)
Gender[2] n (%)	
Male	51 (19.2)
Female	214 (81.8)
Affected side[2]	
Left	121 (45.7)
Right	144 (54.3)

[1]Mean (standard deviation), [2]number (%)

In multivariate analysis, factors that revealed statistically significant associated with post-needling soreness were only three factors. These three factors were needle size (ORadj 4.38, 95%CI 2.40-8.04, $p < 0.001$), number of muscle twitching (OR_{adj} 1.19, 95%CI 1.08-1.36, $p = 0.007$), and number of needle insertions (OR_{adj} 1.07, 95%CI 1.03-1.11, $p = 0.001$) as shown in Table 2.

Discussion

This study found post-needling soreness in 54.0% of patients similar to the previous study.[11,16] The soreness intensity was about 3.3, indicating a moderate level of severity, which is similar to the previous studies (3.5-5.6 scores).[8,17,18] Nearly all of the patients in this study had muscle pain relief and muscle pain scores dropped by 45%. In regard to the result, the participants in this study had the effective outcome of dry needling trigger points.

The baseline characteristics, including gender, age, BMI, affected side and initial muscle pain intensity, were no significant

Table 2. Univariate and multivariate analysis to examine the association between the variable factors and post-needling soreness.

Associated factors	Univariate analysis		Multivariate analysis	
	Crude odds ratio: OR (95% confidence interval)	*p*-value	Adjusted OR: OR_{adj} (95% confidence interval)	*p*-value
Age (years)	1.01 (0.99-1.03)	0.437	1.01 (0.99-1.03)	0.447
BMI (kg/m^2)	1.07 (0.99-1.15)	0.056	1.02 (0.94-1.12)	0.597
Initial muscle pain intensity (score)	1.25 (1.06-1.47)	0.007*	1.02 (0.84-1.25)	0.817
Needle size (mm)	3.22 (1.94-5.32)	< 0.001*	4.38 (2.40-8.04)	< 0.001*
Number of needle insertions (times)	1.08 (1.05-1.11)	< 0.001*	1.07 (1.03-1.10)	0.001*
Total number of needles (numbers)	1.79 (1.32-2.43)	< 0.001*	0.75 (0.39-1.42)	0.377
Responses during needling	0.94 (0.70-1.27)	0.701	1.08 (0.74-1.58)	0.705
Number of muscle twitching (times)	1.34 (1.20-1.48)	< 0.001*	1.19 (1.05-1.36)	0.007*
Bleeding size (mm)	6.35 (1.53-26.40)	0.011*	1.79 (0.25-12.64)	0.560
Presence of hematoma	12.1 (1.56-93.89)	0.017*	1.78 (0.14-22.58)	0.657
Duration of ischemic compression	0.00 (0.000)	0.999	0.00 (0.000)	0.999

*statistically significant confidence level at $p < 0.05$

relation with post-needling soreness. This result was similar to Agung et al.'s study,[19] which found that BMI was unrelated to pain intensity. While, for gender, Martín-Pintado et al.[12] found that women exhibited higher intensity of post-needling soreness than men. In multivariate forward stepwise regression analysis, the statistically significant factors associated with post-needling soreness were only needle size, number of needle insertions, and number of muscle twitching. Similarly, previous studies[12,13] found that the number of needle insertions was positively correlated with post-needling soreness intensity, thus confirming the relationship between the amount of tissue damage produced during needling and the intensity of post-needling soreness. In addition, Simon et al.[1] and Hong[8] mentioned the association of soreness with capillary hemorrhage and the consequent irritation of muscle. As a result, the needle size and number of needle insertions were also associated with post-needling soreness, in which a larger needle size and more needle insertions might cause more capillary hemorrhage.

In considering needle sizes, there are many sizes, such as 0.16x25 mm, 0.22x40 mm, 0.25x25 mm, 0.25x40 mm, and 0.25x 75 mm in Phetchabun Hospital. However, in this study, the needle size used only 0.16x25 mm and 0.22x40 mm of needles which are the common and appropriate sizes for upper trapezius dry needling. In clinical practice, if we use too small a needle diameter, the needles may kink and need more repeated needle insertions. While we use a too-short needle, the needle may not reach the trigger points, especially in obese patients with high-thickness skin folds. For this reason, using the smallest possible needle size is better to reduce the risk of post-needling soreness.

The dry needling to elicit local twitch responses (LTRs) is a commonly used technique to treat MTrPs for managing MPS.[20] According to the recent review,[21] there is a consensus that elicitation of LTR provides more significant immediate and long-term pain relief with needling therapy than no LTR. From this study, the number of muscle twitching was associated with post-needling soreness. As well as several studies found that the repeated needle insertion required to elicit LTRs often leads to added microtrauma and post-needling soreness, which can increase patients' resting pain levels instead of reducing them.[12,22,23]

The bleeding size and presence of hematoma, representing capillary hemorrhage, did not correlate with post-needling soreness as well as the recent study, which did not find significant correlations between the presence of blood in the cotton swab after hemostasis and the intensity of post-needling soreness after dry needling of latent myofascial trigger points.[12] Controversially, some studies observed that patients presenting with visible ecchymosis or swelling after needling presented with more significant post-needling soreness.[1,8] Emphasizing ischemic compression, the previous study found that it reduces post-needling soreness intensity and duration.[17] So, in this study, the physiatrist compressed the patient's skin at least 10 seconds after dry needling and increased duration of compression only in patients with bleeding or hematoma. There might be a bias of duration of ischemic compression due to case selection.

Thus, the researcher recommends choosing the smallest needle size for effective dry needling to reduce post-needling soreness. Necessarily, the physiatrist should practice using a small needle (e.g., 0.16 mm in diameter) instead of the large one, performing minimal repeated needle insertions (not more than 20 needle insertions), and also eliciting a small number of LTRs (not more than 5 LTRs) in any trigger point dry needling technique. Then compress the skin after dry needling for at least 10 seconds, according to this study. These recommendations can apply as a clinical practice guideline to prevent post-needling soreness after dry needling at any muscle.

The limitations of this study, first, there was only one dry needling technique (fanning technique) used in this study. Nowadays, many dry needling techniques are used in clinical practice, such as pistoning, fanning (redirection), single insertion, needle winding (rotation), and needle tenting. Further study is needed to investigate the association between these techniques and post-needling soreness. Second, the researcher recorded NRS of soreness only immediately after dry needling, but the onset of post-needling soreness can occur immediately[12] or a few hours after needling.[8] This study might not include all patients with post-needling soreness. Third, in this study, dry needling was performed by only one physiatrist. So, it might differ from the variety in technique, needle size used, judgment in needle insertions, and the total number of needles. Lastly, this research did not study psychosocial factors that may influence post-needling soreness perception.[24]

In conclusion, the associated factors with immediate post-needling soreness in patients after upper trapezius dry needling were needle size, number of needle insertions, and number of muscle twitching.

Disclosure

The authors declare no conflicts of interest.

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Original Article

Effectiveness of High-Intensity Laser Therapy in Combination with Conventional Conservative Treatment for Carpal Tunnel Syndrome Compared with Conventional Conservative Treatment Alone in Clinical Outcomes and Electrophysiologic Parameters: An Experimental, Non-Randomized Clinical Trial Single-Blind Study

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ABSTRACT

Objectives: To determine the effectiveness of the combination of high-intensity laser therapy (HILT) with conventional conservative treatment for individuals with carpal tunnel syndrome (CTS) compared to conventional treatment alone.

Study design: An experimental study using non-randomized clinical trials in a single-blind study.

Setting: Outpatient Rehabilitation Clinic, Saraburi Hospital.

Subjects: Patients diagnosed with CTS classified as minimal, mild, or moderate, based on the modified neurophysiologic grading system.

Methods: The 60 participants were divided equally into two groups, a HILT treatment (experimental) group and a conventional conservative treatment (control) group. The participants freely choose their own treatment group. Clinical outcomes and electrophysiological parameters were measured before treatment and five weeks after treatment. Results were compared between the groups.

Results: At baseline, none of the demographic, clinical, or electrophysiologic parameters were statistical significantly different between the two groups with the exception of the chief complaint and the sensory nerve action potential amplitude (SNAP amp). Repeated-measures analysis of variance found a significant group-by-time interaction among the numeric rating scale of numbness (NRS numbness), the numeric rating scale of pain (NRS pain), the Boston questionnaire symptom severity score (BQSSS), the Boston questionnaire functional severity score (BQFSS), sensory nerve action potential peak latency (SNAP PL), sensory nerve conduction velocity (SNCV), median-ulnar sensory latency difference to the ring finger (Median vs. Ulnar), and compound motor action potential onset latency (CMAP OL).

Conclusions: This study demonstrated that the addition of HILT to conventional conservative treatment is an effective and noninvasive treatment method for minimal, mild, and moderate CTS.

Keywords: high-intensity laser therapy, carpal tunnel syndrome, numbness, pain, electrophysiologic parameters

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Introduction

Carpal tunnel syndrome is the most common peripheral nerve entrapment, accounting for 90% of all neuropathies and a clinical prevalence of 3.8% in the general population.[1,2] It is most prevalent in women and frequently bilateral, but dominant-side symptoms tend to be more severe.[3,4] The typical symptoms of this condition include numbness and pain in the index and middle fingers, as well as the thumb and ring finger.[5] Electrodiagnostic testing can confirm the diagnosis and determine the severity of the disease, ranging from minimal to extremely severe, using the modified neurophysiologic grading system.[6]

The treatment consists of the use of non-steroidal anti-inflammatory drugs (NSAIDs), vitamin B to enhance nerve regeneration, intracarpal tunnel steroid injection, as well as the wearing of wrist support with the wrist extended between 0 and 10 degrees, including wrist posture education for the workplace and daily life, avoiding flexing the wrist.[5,7-9] Other treatments, including nerve gliding, ultrasound, extracorporeal shockwave, and laser therapy, are considered conservative treatments for CTS.[7,8,10,11] Carpal tunnel release surgery is often reserved for patients whose symptoms are severe or unresponsive to conservative treatment.[12,13]

Light Amplification by Stimulated Emission of Radiation (laser) is a device that emits a single wave-length with coherent, constant phases and one direction. The range of wavelengths that affect human tissue is between 650 and 1100 nanometers (nm). The human body absorbs light energy that varies with each wavelength of light (chromophores).[14,15] The power of laser light can also be used to classify the type of laser. Class 3B and above is for therapy, meaning the energy is less than 500 mW, referred to as “low-intensity laser therapy” (LILT). In contrast, class 4, greater than 500 mW, is referred to as “high-intensity laser therapy” (HILT), and the energy is transferred more deeply.[15-17]

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Laser therapy has the potential to produce biophysical effects within tissues, which can accelerate the wound-healing process and reduce inflammation, pain, and scarring in the tissues.[18-23] The previous study in rats demonstrated that laser could promote axonal sprouting in axonotmesis lesions and more severe trauma, such as neurotmesis.[24]

There have been a limited number of studies on using HILT in CTS patients, and the sample sizes of these studies have been small.[16,17,25] While the preliminary results of these studies have shown promising treatment outcomes in both clinical and electrophysiologic parameters, there are significant differences in the protocols used. These differences include the duration, energy, method of treatment, and techniques for utilizing HILT, which vary greatly or lack specificity. As a result, the physiatrist cannot follow along effectively. From the experience of using a HILT on individuals diagnosed with carpal tunnel syndrome at Saraburi Hospital, most treatment outcomes were favorable with no adverse effects. However, no data were collected for statistical analysis, and there was no control group. Consequently, the purpose of this study was to compare the effectiveness of HILT to conventional conservative treatment in patients with carpal tunnel syndrome. In the future, the outcomes of this study will likely inform the decision to prescribe treatment for CTS patients.

Methods

Study design

This research was an experimental study (non-randomized clinical trials) single-blind study. The post-treatment electrodiagnosis study will be conducted by a physiatrist who is not involved in the research and will be blinded. The Saraburi Hospital Research Ethics Committee approved the protocol of this study (Research Project No. SRBR65-013, Certificate No. EC018/2565) and was registered in the Thai Clinical Trials Registry (TCTR20230103002).

Participants

Study participants were adults (age ≥ 20 years) who presented with hand pain or numbness and underwent electrodiagnosis. The result was minimal, mild, or moderate CTS levels based on the modified neurophysiologic grading system.[6] The definition is 1) "Minimal CTS" is abnormal only for the median-ulnar sensory latency difference to the ring finger (Median vs. Ulnar); 2) "mild CTS" is slowing of sensory nerve action potential peak latency (SNAP PL) and normal compound motor action potential onset latency (CMAP OL); 3) "moderate CTS" is slowing of SNAP PL and CMAP OL. The patient would be excluded if any of the following conditions were found: 1) contraindication to laser such as undergoing cancer treatment, having had radiation therapy within the past six months, and the patient had bleeding from the arm to the finger;[26] 2) underlying disease that may disturb experimental measurements such as polyneuropathy, cervical radiculopathy, brachial plexopathy, ulnar neuropathy, radial neuropathy, and rheumatoid arthritis; 3) receiving conservative treatment within the past six months such as physical modality, orthosis, and intracarpal tunnel steroid injection; 4) History of carpal tunnel release; 5) Numeric rating score of pain ≥ 8

Sample size

The sample size was determined using the equality design formula to compare the two independent groups in terms of the mean difference. The sample size calculation was based on a study by Casale et al.[16] The primary outcome is the numeric rating scale of numbness (NRS numbness), the calculated variable using the largest sample size. For an alpha level of 0.05, a power of 80%, and an estimated drop-out rate of 20%, the target sample size was 64 hands. (32 hands per group)

Randomization

There was no randomization in this study. Patients with confirmed minimal, mild, or moderate CTS were given a description of the research. Then, they were allowed to voluntarily choose a treatment group, divided into 32 laser hands and 32 control hands.

Intervention

The control group was treated with suggested behavioral modifications by the researcher. The suggestion included wrist posture education for the workplace and daily life, avoiding flexing or moving the wrist, taking only a vitamin B complex tablet three times daily, and using wrist support with a 10-degree wrist extension during sleeping time.

The experimental group maintained the treatment on the same basis as the control group. In addition, the researcher will add the HILT using Mectronic healthcare iLux Triax, power 15 watts (The device simultaneously released three wavelengths: 810 nm, 980 nm, and 1,064 nm, which equally distributed the power over the three wavelengths, 5 watts for each wavelength) with intensity dosage of 20 J/cm^2, the laser was applied to 10 cm proximal from the wrist crease to palmar crease (refer to number 1 of figure 1), and cover the specific finger area where the patient has numbness or pain (refer to number 2 of figure 1). The calculated intensity dosage was distributed evenly in all areas, place the probe no more than 1 centimeter away from the skin and move the probe at a speed of approximately 30-40 cm/sec. During treatment, the researcher will periodically touch the patient's skin and pause the laser if he or she feels too hot or the skin temperature is equal to or higher than 38 degrees Celsius. Once the patient feels comfortable and the temperature is lower than 38 degrees Celsius, the treatment will resume until completion. The HILT was applied twice weekly (Tuesday and Thursday) for ten treatment sessions.

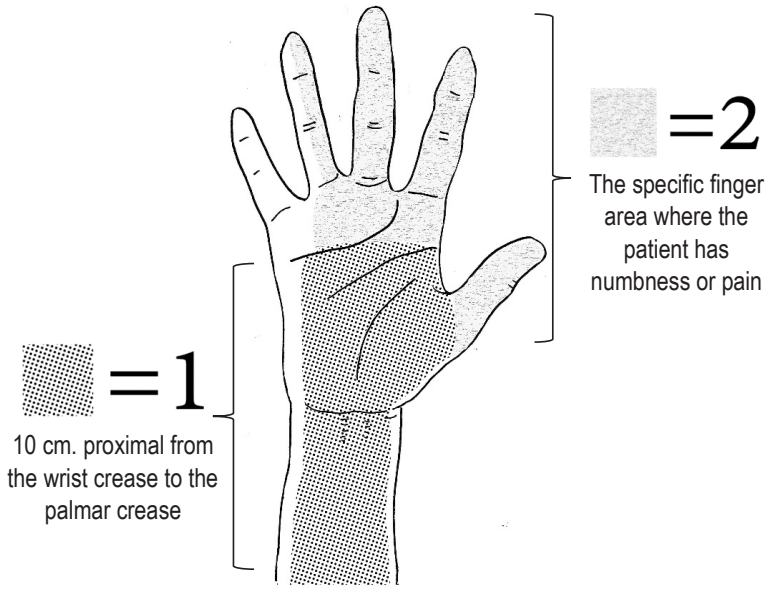

Figure 1. The location of a HILT was applied

Outcome

The variables listed below were recorded twice, first collected before therapy, then again five weeks following treatment completion.

The primary outcome measure was the NRS numbness, ranging from 0 to 10. The secondary outcome measures were the numeric rating scale of pain (NRS pain), which ranges from 0-10, the Boston questionnaire (Thai version),[27] which consists of eleven items of symptom severity (BQSSS), and eight items of functional severity score (BQFSS), each item on a scale of 1-5, and the electrophysiologic parameters as follows: 1) sensory nerve action potential peak latency (SNAP PL); 2) sensory nerve conduction velocity (SNCV); 3) sensory nerve action potential amplitude (SNAP amp); 4) median-ulnar sensory latency difference to the ring finger (median vs. ulnar); 5) compound muscle action potential onset latency (CMAP OL); 6) compound muscle action potential amplitude (CMAP amp); 7) compound muscle action potential area under the curve (CMAP area).

Nicolet EDX® electrodiagnosis is performed by stimulating a surface electrode on the skin to examine 1) sensory study of the median and ulnar nerves at the wrist 13 cm from the ring electrode. 2) motor study of the median and ulnar nerves at the wrist, 7 cm from the disc electrode point, and at the elbow. 3) comparative study (median-ulnar sensory latency difference to the ring finger), by using a ring electrode on the ring finger, stimulation median and ulnar nerve at the wrist 13 cm proximal to ring electrode. Using the normal electrophysiologic parameters as follows: 1) SNAP PL ≤ 3.5 ms. 2) CMAP OL ≤ 4.4 ms. 3) Comparative study (Median vs. Ulnar) peak latency different < 0.5 ms. All electrodiagnosis studies using supramaximal level and skin temperature not lower than 33 Celsius.[28]

For the NRS numbness, NRS pain, BQSSS, and BQFSS, the participants completed the test by themselves. If they were unable to read, the researcher read aloud to them.

The patients completed the first electrodiagnosis before the researcher invited them to participate in the research. The second electrodiagnosis study was conducted by an independent physiatrist blinded from the intervention group.

Statistical methods

The variables were described using descriptive statistics, including percentage, frequency, mean, and standard deviation (SD). Shapiro-Wilk tests were used to determine if the variable had a normal distribution. The comparison between two groups at baseline: 1) gender, affected side, chief complaint, and severity of CTS using Chisquare 2) Age, symptom duration, working hour per day, BMI, NRS numbness, NRS pain, BQSSS, BQFSS and all electrophysiologic parameters using an independent T-test (Mann-Whitney U test if the data are not of normal distribution). The comparison between pre-post treatment in the same group using pair T-test (Wilcoxon-signed rank test if the data are not of normal distribution). In comparing the control and treatment groups using two-way repeated measures in an ANOVA, the within-subjects variables are defined as two periods, and the between-subject factor is the treatment group (control and HILT). A *p*-value of less than 0.05 was considered to be significant. All analyses were carried out using SPSS.

Results

Between May 1, 2022, and Oct 31, 2022, a total of 76 hands were enrolled in this study, 12 hands met an exclusion criterion, and the remaining 64 hands were divided into two groups

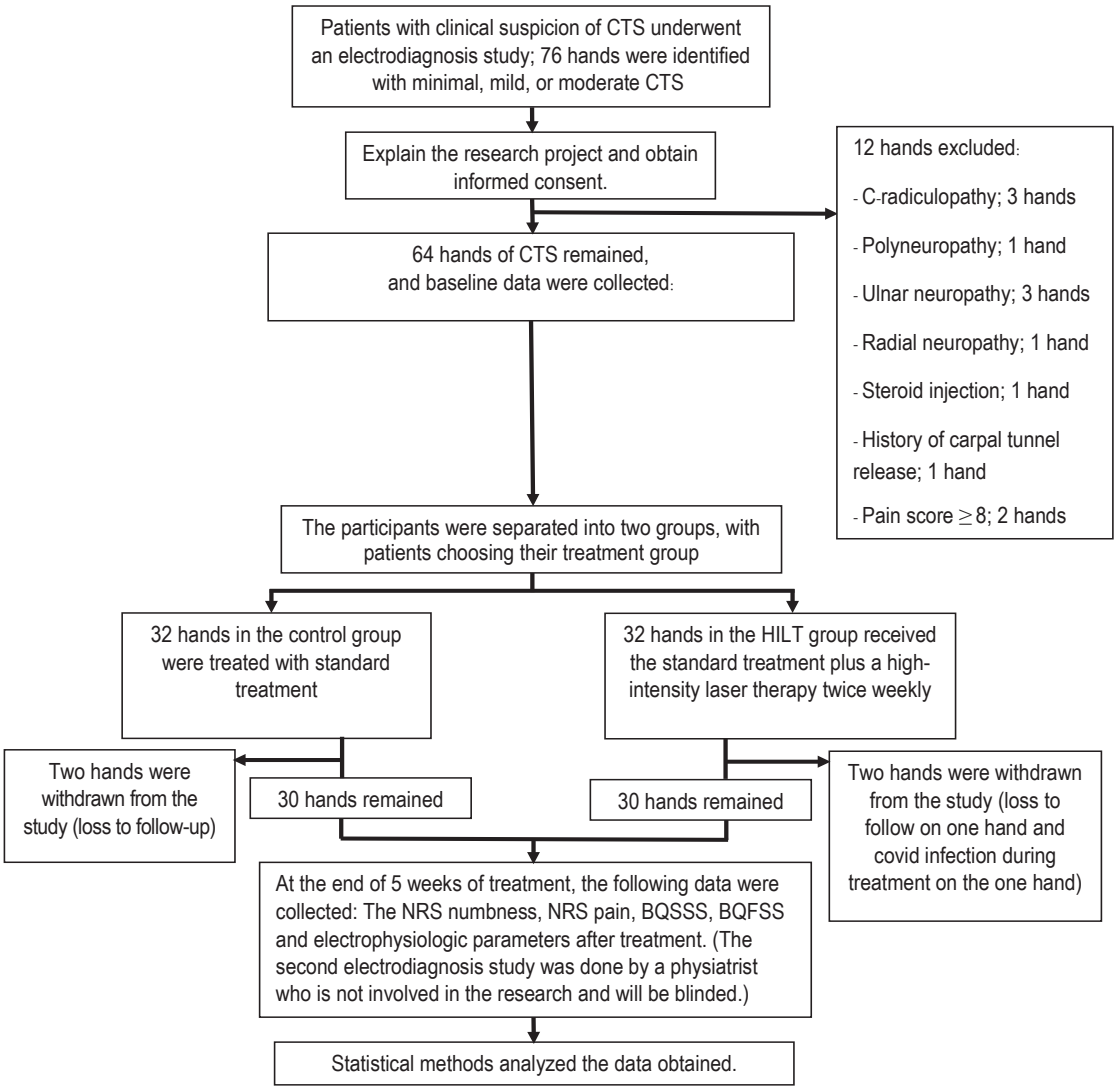

Figure 2. Flow Chart of the study

regarding patients' preferences. There were 32 hands in the control group and 32 in the HILT group. As depicted in Figure 2, 4 hands were removed from the study.

The baseline demographic and clinical characteristics were comparable between the two groups, except for the chief complaint, as shown in Table 1. The patients in the HILT group presented with more pain than those in the control group. No disparities in baseline electrophysiologic parameters were observed between the groups, except for the amplitude of SNAP, which was found to be higher in the HILT group.

A paired T-test was performed within each group to determine the effect of the treatment. The test results revealed that the HILT group demonstrated statistically significant improvement in all four symptom measures and five out of seven electrophysiological parameters, with *p*-values less than 0.05. The two electrophysiological parameters that did not show statistically significant improvement were the CMAP amplitude and CMAP area. On the other hand, the control group showed statistically significant improvement in one symptom measure (NRS numbness) and one electrophysio-logical parameter (SNAP amplitude). See table 2.

Table 3 provides a summary of the repeated-measures analysis of variance results. Group-by-time interaction was found to be significant for NRS numbness, NRS pain, BQSSS, BQFSS, SNAP PL, SNCV, Median vs. Ulnar, and CMAP OL, with *p*-values less than 0.05. These results demon-strate that the effects of the two treatment groups on these variables were differentiated. The results of a repeated measures analysis of variance indicate that NRS numbness improved before and after treatment in both groups. However, the HILT group displayed more outstanding outcomes. The improvement in SNAP amplitude before and after treatment did not differ between the two groups. Before and after therapy, neither the CMAP amp nor the CMAP area was different in either group.

Discussion

Overall, both groups had similar baseline characteristics, except for the chief complaint, where the HILT group presented with more pain than the control group. This finding may be because individuals with pain may experience tremendous suffering and, therefore, may need "more than usual" treatment.

Table 1. Baseline demographic and clinical characteristics by treatment group

Characteristic	Group		*p*-value
	Control	HILT	
Age[1]	52.17 (9.74)	47.63 (8.79)	0.063[a]
BMI[1]	26.31 (3.85)	27.31 (4.72)	0.371[a]
Symptom duration (week)[1]	30.67 (39.15)	47.20 (42.28)	0.084[b]
Hands used per day (hour)[1]	7.77 (1.63)	8.73 (3.93)	0.515[b]
Gender[2]			
- Female	27 (90.0)	24 (80.0)	0.278[c]
Affected side[2]			
- Right	15 (50.0)	18 (60.0)	0.436[c]
Chief complaint[2]			
- Numbness	29 (96.6)	24 (80.0)	0.044[c*]
- Pain	1 (3.4)	6 (20.0)	
Grade CTS[2]			
- Minimal	1 (3.3)	2 (6.6)	0.408[c]
- Mild	13 (43.3)	17 (56.6)	
- Moderate	16 (53.3)	11 (36.6)	
Severity of symptoms			
- NRS numbness[1]	6.23 (2.161)	5.60 (1.976)	0.241[a]
- NRS pain[1]	2.20 (2.68)	3.43 (2.60)	0.086[b]
- BQSSS[1]	23.53 (6.39)	25.77 (7.47)	0.205[b]
- BQFSS[1]	13.07 (4.97)	14.63 (6.14)	0.436[b]
Electrophysiologic parameters			
- SNAP PL[1]	5.08 (1.33)	4.58 (1.34)	0.069[b]
- SNCV[1]	27.11 (6.42)	30.15 (6.50)	0.064[b]
- SNAP amp[1]	16.74 (12.54)	26.26 (13.52)	0.009[b*]
- Median VS ulnar[1]	2.02 (1.14)	2.01 (1.58)	0.608[b]
- CMAP OL[1]	5.33 (1.82)	4.86 (1.56)	0.252[b]
- CMAP amp[1]	5.92 (1.81)	6.56 (2.33)	0.506[b]
- CMAP area[1]	19.74 (6.55)	21.57 (7.78)	0.473[b]

[1]mean (standard deviation), [2]number (%), [a]; Independent T-test, [b]; Mann-Whitney U test, [c]; Chi-square, [*]significant
CTS; carpal tunnel syndrome, HILT; high-intensity laser therapy
NRS numbness, numeric rating scale of numbness; NRS pain, numeric rating scale of pain; BQSSS, Boston questionnaire symptom severity score; BQFSS, Boston questionnaire functional severity score; SNAP PL, sensory nerve action potential peak latency; SNCV, sensory nerve conduction velocity; SNAP amp, sensory nerve action potential amplitude; Median VS ulnar, median–ulnar sensory latency difference to the ring finger; CMAP OL, compound muscle action potential onset latency; CMAP amp, compound muscle action potential amplitude; CMAP area, compound muscle action potential area under the curve

Table 2. Summary of all pre-post treatment variable results from the paired T-test in each group

Characteristic	Control		*p*-value[a]	HILT		*p*-value[a]
	Pre	Post		Pre	Post	
NRS numbness[1]	6.23 (2.161)	4.70 (2.29)	0.001[*]	5.60 (1.976)	2.37 (1.67)	< 0.001[*]
NRS pain[1]	2.20 (2.68)	2.17 (2.81)	0.905	3.43 (2.60)	0.97 (1.40)	< 0.001[*]
BQSSS[1]	23.53 (6.39)	22.13 (7.49)	0.288	25.77 (7.47)	15.43 (3.21)	< 0.001[*]
BQFSS[1]	13.07 (4.97)	13.38 (5.23)	0.984	14.63 (6.14)	9.93 (2.11)	< 0.001[*]
SNAP PL[1]	5.08 (1.33)	5.12 (1.30)	0.545	4.58 (1.34)	4.27 (1.24)	< 0.001[*]
SNCV[1]	27.11 (6.42)	26.92 (6.49)	0.567	30.15 (6.50)	32.33 (7.15)	< 0.001[*]
SNAP amp[1]	16.74 (12.54)	19.49 (15.20)	0.005[*]	26.26 (13.52)	30.29 (17.91)	0.015[*]
Median VS ul-nar[1]	2.02 (1.14)	2.09 (1.24)	0.524	2.01 (1.58)	1.43 (1.30)	< 0.001[*]
CMAP OL[1]	5.33 (1.82)	5.19 (1.66)	0.171	4.86 (1.56)	4.42 (1.39)	< 0.001[*]
CMAP amp[1]	5.92 (1.81)	6.26 (2.33)	0.478	6.56 (2.33)	6.75 (1.91)	0.436
CMAP area[1]	19.74 (6.55)	21.29 (8.38)	0.434	21.57 (7.78)	21.55 (7.07)	0.829

[1]mean (standard deviation), [a]Wilcoxon Signed Rank Test, [*]significant
NRS numbness, numeric rating scale of numbness; NRS pain, numeric rating scale of pain; BQSSS, Boston questionnaire symptom severity score; BQFSS, Boston questionnaire functional severity score; SNAP PL, sensory nerve action potential peak latency; SNCV, sensory nerve conduction velocity; SNAP amp, sensory nerve action potential amplitude; Median VS ulnar, median–ulnar sensory latency difference to the ring finger; CMAP OL, compound muscle action potential onset latency; CMAP amp, compound muscle action potential amplitude; CMAP area, compound muscle action potential area under the curve

Table 3. Summary of all variables results from repeated measure analysis of variance

Variable	Group		Time		Group-by-time interaction	
	F statistic	*p*-value	F statistic	*p*-value	F statistic	*p*-value
NRS numbness	13.927	< 0.001	78.356	< 0.001	8.149	0.006*
NRS pain	0.280	0.599	18.996	< 0.001	17.962	< 0.001*
BQSSS	1.675	0.201	44.506	< 0.001	24.762	< 0.001*
BQFSS	0.375	0.543	14.156	< 0.001	17.973	< 0.001*
SNAP PL	2.919	0.093	5.258	0.026	8.399	0.005*
SNCV	4.456	0.039	15.713	< 0.001	21.747	< 0.001*
SNAP amp	6.652	0.013	12.901	0.001	0.845	0.362
Median vs ulnar	0.819	0.369	7.776	0.007	11.979	0.001*
CMAP OL	1.787	0.187	27.161	< 0.001	6.594	0.013*
CMAP amp	2.459	0.123	0.410	0.524	0.002	0.963
CMAP area	1.063	0.307	0.146	0.704	0.395	0.532

*significant

NRS numbness, numeric rating scale of numbness; NRS pain, numeric rating scale of pain; BQSSS, Boston questionnaire symptom severity score; BQFSS, Boston questionnaire functional severity score; SNAP PL, sensory nerve action potential peak latency; SNCV, sensory nerve conduction velocity; SNAP amp, sensory nerve action potential amplitude; Median VS ulnar, median–ulnar sensory latency difference to the ring finger; CMAP OL, compound muscle action potential onset latency; CMAP amp, compound muscle action potential amplitude; CMAP

However, there was no significant difference in NRS pain scores between the two groups at baseline, so this should not alter the statistical analyses.

In this trial, the average decrease in NRS numbness for the HILT group was 3.23 point. Based on the findings of Ogura et al.,[29] if the NRS numbness dropped by 2 point, there was a mean clinically significant difference (MCID), showing that the numbness was significantly improved following HILT. Salaffi et al.[30] discovered an MCID if NRS pain was reduced by 1 point or more than 15% compared to the prior. This study found a mean reduction of 2.46 point (71%) in the HILT group. According to the study of De Kleermaeker et al.,[31] there will be MCID for BQSSS and BQFSS if the score is reduced by 46% and 28% compared to the previous score, respectively. This study for the HILT group indicated a decrease of 40.1% in BQSSS and 32.1% in BQFSS. Therefore, HILT should be effective in lowering clinical symptoms in CTS patients.

In this study, the clinical outcome and almost all electrophysiologic parameters improved for the HILT group, consistent with the study by Casale et al.[16] They found that treatment with HILT using a wavelength of 830 and 1,064 nm, intensity dosage 250 J/cm^2, and power 25 W, given in 15 sessions over three weeks (5 days a week), improved non-painful sensory alterations (VAS npsa), pain (VAS pain), SNCV, and CMAP OL in a group of 10 hands. This result is in line with the study by Sudiyono et al.,[17] which found that HILT with a wavelength of 1,064 nm, intensity dosage 10 J/cm^2 in analgesic mode and 120 J/cm^2 in biostimulation mode, and power 12 W, given in 10 sessions over two weeks (5 days a week), improved electrophysiological parameters including the combined sensory index (CSI), SNCV, and CMAP OL in a group of 8 hands.

Hojjati et al.[25] compared the effects of HILT (wavelength 1,064 nm, intensity dosage 20 J/cm^2, power 5 W) with LILT and wrist support on treating CTS patients. They found that VAS pain, BQSSS, and BQFSS improved significantly in all groups. However, electrophysiological parameters (SNAP PL, SNAP amp, CMAP OL, and CMAP amp) did not significantly change and were not different among the groups. The study included 15 hands in each group. The researchers pointed out that this effect may be due to the low energy used in the treatment, which requires more research to confirm the results.

Besides the findings mentioned earlier, this study had some limitations that should be discussed. This study is a non-randomized design, and some baseline characteristics were unbalanced (even though they were not statistically significant), which may affect the study's internal validity. The patients in the HILT group may have been more likely to take a break from work because they had more appointments (10 sessions). In addition, patients in the HILT group who are getting treatment frequently inquire about the disease and lifestyle modification in addition to the initial treatment, needing the physiatrist to answer these inquiries; hence, the HILT group may have had better treatment outcomes. Research may be needed to solve this issue. Even though there was no statistically significant difference in the duration of hands used per day (for work and home chores) between the two groups, this investigation could not guarantee that each occupation in each group had the same interfering effect on the therapy. This factor may affect the treatment outcomes of the study. Due to the lack of a sham device, this was a single-blind study with no blind patients. Therefore, the treatment outcome may have a placebo effect, influencing the patients' self-reported NRS numbness, NRS pain, BQSSS, and BQFSS scores. In this study, the participants were Thai people who needed to use the Thai version of the Boston questionnaire. However, it was only tested for internal consistency with Cronbach's alpha, which may affect the reliability of the result.

It is worth noting that the parameters of HILT used in earlier investigations varied greatly, including the number of

laser sessions. This research uses HILT with a wavelength of 810-1,064nm, intensity dosage 20 J/cm^2, power 5 W for each wavelength (810 5W, 980 5W, and 1,064 5W), and ten sessions (2 days per week). Patients may be more convenient to receive treatment because this disease is common in working age.[32,33] Five days per week of treatment can negatively impact work performance. The outcomes of this study were quite favorable, and no adverse effects of HILT were found. In the future, this may serve as a guide for prescribing HILT. However, the long-term outcomes still need further study.

Conclusions

This study showed that adding a HILT to conventional conservative treatment is an effective and noninvasive method. In addition, it provided a better result for minimal, mild, and moderate carpal tunnel syndrome in terms of clinical outcomes for numbness, pain, and electrophysiologic parameters.

Disclosure

The author declares no conflict of interest relating to the materials and equipment used in this study.

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Original Article

The Effect of Pediatric Telerehabilitation on Parental Stress, Caregiver Burden, and Satisfaction of Children with Disabilities during the COVID-19 Outbreak in Thailand

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ABSTRACT

Objectives: To assess the effect of pediatric telerehabilitation on parental stress, caregiver burden, and satisfaction of children with disabilities during the corona virus disease 2019 (COVID-19) outbreak in Thailand.

Study design: A retrospective cohort study.

Setting: Department of Rehabilitation Medicine, Siriraj Hospital, Thailand.

Subjects: A total of 40 caregivers of patients with disabilities who were followed up at the outpatient unit of the Pediatric Rehabilitation Service between February 1, 2021 and November 30, 2021 were divided into a participating telerehabilitation group (n = 20) and a non-participating telerehabilitation or non-intervention group (n = 20). Only caregivers who answered the questionnaires completely were included in the study.

Methods: The researchers collected information from caregivers using both pre-intervention questionnaires (before commencing telerehabilitation) and post-intervention questionnaires (after two months of telerehabilitation) including general data, the Depression Anxiety and Stress Scales (DASS-21), the Zarit Burden Interview (ZBI), and The Client Satisfaction Questionnaire (CSQ-8). The primary outcome of interest was pre-intervention to post-intervention change in DASS-21. The secondary outcomes were pre-intervention to post-intervention changes in ZBI in the telerehabilitation and non-intervention groups and telerehabilitation satisfaction (CSQ-8) in the telerehabilitation group

Results: Changes reduction in ZBI scores was statistically significantly greater in the telerehabilitation group than in the non-intervention group. Caregivers in the telerehabilitation group indicated high satisfaction and reported good compliance with the online intervention. However, there was no statistically significant difference in DASS-21 change between the telerehabilitation and non-intervention groups. No clinical complaints were reported in either group.

Conclusions: Pediatric telerehabilitation during the COVID-19 outbreak helped relieve caregiver burden with a high level of satisfaction and without clinical complaints.

Keywords: caregiver burden, COVID-19, pediatric, telerehabilitation, Thailand

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Introduction

Pediatric rehabilitation helps disabled children with neurological diseases, musculoskeletal diseases, and multiple congenital anomalies to maximize their functions. Not only physical problems that should be a concern, but also the mentality of parents and patients. Because a family that understands and accepts their child's disability with a positive attitude tends to develop an effective coping process and achieve a better therapeutic outcome.[1]

Nowadays, in Thailand, technologies have more essential roles in the medical field, such as videoconferences for exchanging medical information among healthcare providers or virtual appointments between doctors and patients. These technologies are defined as telehealth.[2,3] Due to these online communications, patients can easily access medical services wherever they want.

In 2020, there was an outbreak of COVID-19 worldwide, including in Thailand. This pandemic led to lockdown as people needed to stay home and could not move freely to reduce disease transmission. Consequently, the hospital had to postpone the medical appointments of patients without emergency conditions. As a result, an early and intensive pediatric rehabilitation program, which was crucial for vulnerable children, had to be temporarily discontinued. Therefore, The Pediatric Rehabilitation Service at Siriraj hospital started to use telerehabilitation during the COVID-19 outbreak. The treatment team provided telerehabilitation services to various pediatric patients, such as a child with a disability, cerebral palsy, global delay development, multiple congenital anomalies, Down's syndrome, torticollis, flatfeet, scoliosis, and congenital facial palsy.

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To date, there is a lot of established evidence showing the benefits of telerehabilitation in adults and children. Nevertheless, most studies concluded that there should be more research on telerehabilitation because of insufficient significant outcomes to provide more available data. Moreover, previous studies were conducted in developed countries, where people seemed familiar with advanced technology.[4-9] To the author's knowledge, no prior publication reported the use of telerehabilitation for children in Thailand. Therefore, the authors used this opportunity to lead this present study and evaluate telerehabilitation outcomes. Our study aimed to assess pediatric telerehabilitation's effect on parental stress, caregiver burden, and satisfaction during the Coronavirus disease 2019 (COVID-19) outbreak in Thailand.

Methods

The Siriraj Institutional Review Board approved this retrospective cohort study (SIRB), Faculty of Medicine Siriraj Hospital, Mahidol University (SIRB Protocol number 208/2564 (IRB2)). We collected questionnaires that had been interviewed during the COVID-19 outbreak between February 1, 2021, and November 30, 2021. Our telerehabilitation referred to videoconference for providing physical or occupational therapy through online video calls. Caregivers use their computers or smartphones at home to communicate with physicians or therapists at the hospital. Each session lasted approximately 30 minutes. We made an appointment with the caregivers to attend the 2-month program, one session a week. The caregivers of children, who did not receive online intervention, were defined as a non-intervention group. Physicians and therapists would telephone them once a month to follow the child's symptoms and ask whether there were any complications. Caregivers in the non-intervention group were asked to do the physical and occupational therapy by themselves, using the last hospital-based rehabilitation programs they received before the lock-down period in 2020-2021. (Figure 1)

Caregivers in both telerehabilitation and non-intervention groups were interviewed via telephone before commencing (Pre-intervention) and after two months of telerehabilitation (post-intervention). The questionnaires included the general data and caregiver-reported outcomes to evaluate the caregiver's stress reduction and satisfaction after participating in telerehabilitation. The sample size was 18 per group, calculated by referring to the Connell et al. study[10] by type I error was 0.05, and β was 0.20. The estimated missing data was 10%, so the number of subjects to be recruited was 20 per group. A total of 40 caregivers were interviewed between February 1, 2021, and November 30, 2021. The inclusion criteria were the presence of both pre-intervention and post-intervention questionnaires. Incomplete interviews and caregivers in a telerehabilitation group participating in an online intervention of fewer than two sessions in 2 months were excluded. Therefore, we included 40 caregivers according to the inclusion and exclusion criteria. The caregiver reported outcomes which were the depression anxiety and stress scales (DASS-21), the Zarit burden interview (ZBI), the Client Satisfaction Questionnaire-8 (CSQ-8), and the questionnaires collecting the baseline demographic and clinical characteristics of children and caregivers.

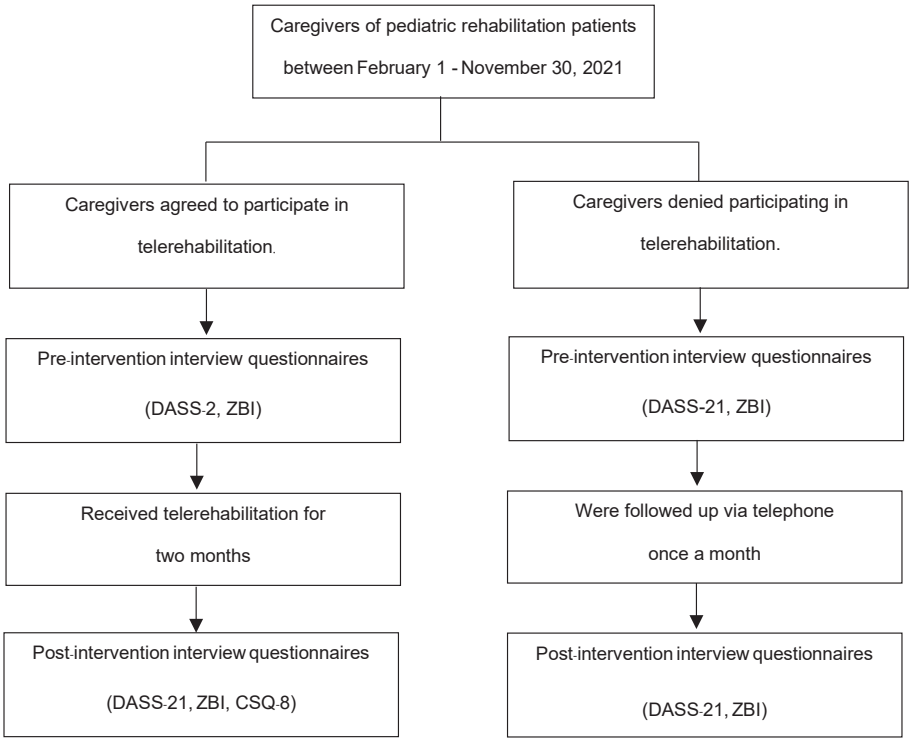

Figure 1.

DASS-21, Depression anxiety and stress scales; ZBI, Zarit burden interview; CSQ-8, The Client Satisfaction Questionnaire.

Outcome measurements

The primary outcome was the changes in caregivers' negative emotion reduction assessed by DASS-21. The DASS-21 was developed by Lovibond et al.[11,12] to screen depression, anxiety, and stress and translated into Thai by Sukanlaya Sawang from The National Centre in HIV Epidemiology and Clinical Research.[13] The questionnaires included 21 questions. The scores ranged from 0-42, with 0 representing no or rarely depression, anxiety, or stress. Cronbach's alpha coefficient was 0.91, 0.81, and 0.89 for depression, anxiety, and pressure, respectively.[11] The DASS-21 had been used as parents reported outcomes in pediatric telerehabilitation research.[5,10]

The secondary outcomes were caregiver burden reduction and satisfaction assessed by ZBI and CSQ-8, respectively. Pre-intervention to post-intervention change in ZBI was compared between telerehabilitation and the non-intervention group. The satisfaction was evaluated in caregivers receiving an online intervention. The Zarit burden interview (ZBI) was created by Zarit et al.[14] to assess caregiver burden and translated into Thai version by Toonsiri et al.[15] It involved 22 questions, scoring from 0-88, which 0 meant no or rarely had caregiver burden. Cronbach's alpha coefficient was high at 0.92.[16] The Client Satisfaction Questionnaire-8 (CSQ-8) was used to assess customer satisfaction. Larsen and Attkisson et al. developed it,[17] the authors used the Thai version of CSQ-8 from CSQScales®. It consisted of 8 questions. Each question was rated on a scale of 1-4, with 1 showing the least satisfaction. Total scores ranged from 8-32. Items include questions enquiring about caregivers' opinion of the telerehabilitation services they have received, which is a four-point scale (response options: 1 = "Quite dissatisfied," 2 = "Indifferent or mildly dissatisfied," 3 = "Mostly satisfied," 4 = "Very satisfied"). This instrument was once used to assess parent satisfaction in pediatric telerehabilitation.[18] The questionnaires also had high reliability, with Cronbach's alpha coefficient up to 0.94.[7,19] The CSQ-8 was assessed post-intervention for the telerehabilitation group only.

Statistical methods

This study used SPSS version 18.0 for analysis. Qualitative data were represented by mean (SD) for normal distribution and median with IQRs for non-normal distribution following the Kolmogorov-Smirnov and Shapiro-Wilk tests. The quantitative data was shown by numbers and percentages. In comparisons between the telerehabilitation and non-intervention groups, we used independent sample t-tests or Mann-Whitney U-test for continuous variables and the Chi-squared test or Fisher exact test for categorical variables. Within-group comparisons of DASS-21 and ZBI scores between pre and post-intervention, we used a dependent sample t-test or Wilcoxon test.

Results

A total of 40 eligible caregivers were divided into a telerehabilitation group (n = 20) and a non-intervention group (n = 20). Table 1 represents the baseline demographic and clinical characteristics of children and caregivers. The caregiver's characteristics showed statistical differences in the estimated travel time to the hospital (hours). The median estimated travel time to the hospital was 6 hours in the telerehabilitation group and 5 hours in the non-intervention group. There was no statistical difference found in a child-caregiver relationship, caregiver's helper, health care coverage, financial income, the estimated travel cost to the hospital, and other caregiver's characteristics, including gender, age, marital status, education, occupation, health problem, the presence of anxiety or depression, presence of helpers and family incomes. Most caregivers (> 85%) of the two groups were familiar with the voice and video calls via the LINE application, the mobile messenger application used for telerehabilitation in this study.

Table 2 compares pre- and post-intervention scores in DASS-21 total score in each telerehabilitation and non-intervention group. There was no statistical difference in the DASS-21 total score comparing the pre-score and post-intervention between telerehabilitation and non-intervention groups.

This table also shows the comparison between the pre-intervention and post-intervention scores of ZBI in each telerehabilitation and non-intervention group. There was a statistical difference in ZBI comparing the pre-intervention score between the two groups. The median pre-intervention ZBI score of the telerehabilitation group was 10.50, while the median pre-intervention ZBI score of the non-intervention group was 3. This data shows that the caregivers of the telerehabilitation group started with a higher caregiver burden score at baseline compared to the non-intervention group. However, after receiving the intervention, the caregiver burden score of the telerehabilitation group was significantly lower in telerehabilitation group. The median post-intervention ZBI score was 2, while the median post-intervention ZBI score of the non-intervention group was 5.

Furthermore, the two groups had a statistical difference ($p < 0.05$) in the post-intervention score. Figure 2 illustrates the scatter plot with a 45-degree line of ZBI score compared between the two groups. The ZBI scores of the telerehabilitation group were below the 45-degree line, referring to the pre-intervention ZBI score being higher than the post-intervention ZBI score. On the contrary, the ZBI scores of the non-intervention group were mostly above and on the 45-degree line. It means that the post-intervention ZBI scores of the non-intervention group were mainly higher or equal to the pre-intervention ZBI score.

Table 1. Baseline demographic and clinical characteristics of caregivers and children

Characteristics	Telerehabilitation group (N = 20)	Non-intervention group (N = 20)	*p*-value
Median of the children's age (Q1, Q3) in months	37 (21,50.2)	43 (8.5,76.5)	.989[b]
Homeland (rural), n (%)	10 (50)	7 (35)	.337[c]
Gender (male), n (%)	11 (55)	10 (50)	.752[c]
Parents' marriage status, n (% marriage)	19 (95)	16 (80)	.342[d]
Severity, n (%)			
- Severe disability*	20 (100)	16 (80)	.106[d]
- Mild problem/disease**	0 (0)	4 (20)	
Children's relationship, n (%)			
- Parents	20 (100)	18 (90)	.487[d]
- Relatives & others	0 (0)	2 (10)	
Mean (SD) of the caregiver's age and [range]	34.8 (7.09) [23-53]	37.85 (9.89) [23-62]	.269[a]
Female caregiver, n (%)	19 (95)	18 (90)	1.000[d]
Caregiver's education, n (% uneducated/primary school)	1 (5)	2 (10)	1.000[d]
Presence of caregiver's health problem, n (%)	3 (15)	4 (20)	1.000[d]
Presence of caregiver's anxiety or depression, n (%)	1 (5)	1 (5)	1.000[d]
Caregiver's employment status, n (% employed)	9 (45)	11 (55)	.527[c]
Presence of caregiver's helper, n (%)	18 (90)	16 (80)	.661[d]
Healthcare coverage, n (% universal health coverage)	20 (100)	17 (85)	.231[d]
Sufficient financial income, n (%)	17 (85)	18 (90)	1.000[d]
Median of the estimated travel cost to the hospital (Q1, Q3) in baht	450 (150,1800)	500 (225,900)	.902[b]
Median of the estimated travel time to the hospital (Q1, Q3) in hours	6 (6,24)	5 (4,6)	.014[b]
Familiar with Line call, n (%)	17 (85)	17 (85)	1.000[d]
Familiar with Line VDO call, n (%)	17 (85)	18 (90)	1.000[d]

[a]T-test for Equality of Means, [b]Mann-Whitney U test, [c]Pearson Chi-Square, [d]Fisher's exact test, [e]Linear-by-Linear Association

*Cerebral palsy, Global delay development, Multiple congenital anomalies, Down's syndrome

**Torticollis, Flatfeet, Scoliosis, Congenital facial palsy

Table 2. Pre-intervention and the post-intervention score of DASS-21 and ZBI comparison

	Telerehabilitation group (N = 20)	Control group (N = 20)	*p*-value	Telerehabilitation group (N= 20)	Control group (N= 20)	*p*-value
	DASS- 21	DASS- 21		(N = 20)	ZBI	
Pre-intervention	0 (0,2)[1]	0 (0,1)[1]	0.721[a]	10.5 (4.25,20.75)[1]	3 (2,11.75)[1]	0.013[b]
Post-intervention	0 (0,0.75)[1]	0 (0,0.75)[1]	0.929[a]	2 (0,7.75)[1]	5 (2,13.5)[1]	0.046[b]

[1]Median (Q1, Q3); [a]Mann-Whitney U test; [b]Wilcoxon signed ranks test

Table 3. DASS-21, anxiety, depression, and stress score, ZBI change comparison

		Telerehabilitation group (N = 20)	Non-intervention group (N = 20)	*p*-value
Pre-test – post-test	DASS-21	0.00 (.00,1.00)[1]	0.00 (.00,0.00)[1]	0.867[a]
Pre-test – post-test	anxiety score	0.00 (.00,0.00)[1]	0.00 (.00,0.00)[1]	0.739[a]
Pre-test – post-test	depression score	0.00 (.00,0.00)[1]	0.00 (.00,0.00)[1]	0.180[a]
Pre-test – post-test	stress score	0.00 (.00,0.75)[1]	0.00 (.00,0.00)[1]	0.416[a]
Pre-test – post-test	ZBI	4.5 (2.25,9.75)[1]	0 (-2.00, 0)[1]	< 0.001[a]

[1]Median (Q1, Q3); [a]Mann-Whitney U test

Table 3 shows the primary outcome comparison (DASS-21) total score, anxiety, depression, and stress score of the two groups. According to the data, there was no statistical difference in DASS-21, anxiety, depression, and stress score change between these two groups. However, the median pre-intervention and post-intervention DASS-21, anxiety, depression, and stress scores for the telerehabilitation and non-intervention groups were normal (score = 0). It means that many respondents score at or near the lowest possible value on a DASS-21 questionnaire, making it impossible to compare the average scores between each group to determine if the intervention made any difference. In addition, comparing the change in score between the pre-intervention and post-intervention scores also makes it challenging to measure dispersion accurately.

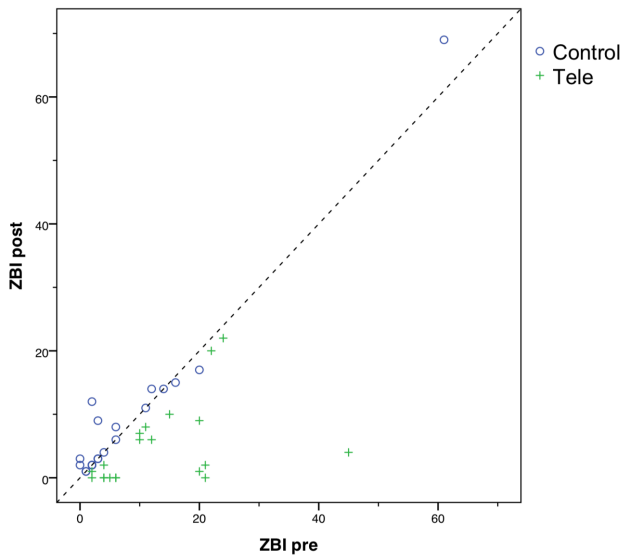

Figure 2. The scatter plot with a 45-degree line of ZBI score

This table also shows a statistical difference ($p < 0.05$) in ZBI change score compared between these two groups. Caregivers reported a significant reduction in caregiver burden after receiving telerehabilitation intervention. There was no significant difference in caregiver burden scores in the non-intervention groups. The CSQ-8 score was illustrated in table 4, in which all the items got a median score above three. The CSQ-8 score ranges from 8 to 32, with higher values indicating higher satisfaction. The mean overall satisfaction score was 29.60 (SD = 3.315), close to the maximum score range.

Most patients (95%) received telerehabilitation service with good compliance, which was more than 80% of appointments. The mean telerehabilitation treatment duration was 23 minutes (SD = 7.847), ranging from 15 to 45 minutes. Most caregivers (90%) reported that telerehabilitation helped relieve anxiety during COVID-19 without any complications or disadvantages. It was convenient and saved cost and time when compared with on-site treatment. Furthermore, most patients (95%) cooperated well, similar to or better than on-site treatment. However, one-fourth of caregivers reported internet connection problems during the treatment.

Discussion

This present study found that caregivers in the telerehabilitation group report a longer estimated travel time to a hospital than non-intervention groups. We expected these results, as people who required longer commuting to the hospital usually tended to accept the telerehabilitation programs.

Both groups started with standard DASS-21 scores at baseline and did not show a significant score of depression, anxiety, and stress in our subjects. Therefore, we could not find the statistical difference between the two groups' pre-intervention and post-intervention DASS-21 total scores. There was no significant difference between DASS-21, anxiety, depression, and stress score change between these two

Table 4. Telerehabilitation satisfaction

CSQ-8	Mean	SD	Range
Total score	29.60	3.315	24-32
1. Quality of service	3.75	0.550	2-4
2. Kind of service	3.70	0.470	2-3
3. Met need	3.50	0.761	2-4
4. Recommend to a friend	3.55	0.759	1-4
5. Amount of help	3.75	0.444	3-4
6. Deal with problems	3.75	0.444	3-4
7. Overall satisfaction	3.85	0.366	3-4
8. Come back	3.75	0.444	3-4

groups. On the contrary, Dhima et al. study found a high prevalence of Indian caregivers' depression (62.5%), anxiety (20.5%), and stress (36.4%) symptoms, which were also assessed by DASS-21 during the COVID-19 outbreak. They reported main associated risk factors with poor psychological health was caregivers who were not using telerehabilitation and had a negative perception of home-based therapy.[20] Alenezi et al. found high anxiety levels in Saudi caregivers during the pandemic.[21] Furthermore, the study from Italy by Grumi et al. also reported the caregivers' depression, anxiety, and stress of neurodevelopmental disabilities children during a COVID-19 situation due to concerns about the lack of rehabilitation programs. They suggested that telerehabilitation programs for families with disabled children should be promoted and continued.[22] Our study did not find a caregiver with significant depression, anxiety, and stress scores at baseline. This finding might be from the difference in culture and healthcare resources. Furthermore, most of our subjects had received hospital-based rehabilitation or home programs before the lockdown period.

We found that the ZBI score in the telerehabilitation group showed a significant reduction after receiving this online intervention for two months. Furthermore, there was a statistical difference in the change of ZBI score between the two groups, which could be implied that using telerehabilitation in the COVID-19 situation can relieve the burden of the caregiver, who is the crucial person taking care of the patients.

However, the caregivers of the telerehabilitation group started with a higher caregiver burden score at baseline. This reason might explain why the caregivers of this group chose to use telerehabilitation. In contrast, the non-intervention group (lower ZBI score at baseline) has no problems or concerns to require treatment intervention.

The study revealed a high level of caregiver satisfaction and adherence to telerehabilitation services, which helped alleviate caregiver anxiety during the COVID-19 pandemic. Our telerehabilitation programs could handle caregivers' needs and problems, and they preferred to use telerehabilitation again. The caregivers also reported that this online intervention is convenient and saves costs and travel time to the hospitals without any clinical complaints. These findings are consistent

with Kruse et al.[2] who conducted a systemic review study, which found that telehealth was a preferred modality because it can improve outcomes and communication. In addition, it is easy to use, has low cost, and decreases travel time.

Telerehabilitation helps the patients maintain the treatment, especially those unable to access the on-site service. Not only for the COVID-19 situation, but we should apply to patients who live far from the hospital in a normal situation too. Edirippulige et al.[23] suggest that traditional face-to-face service for pediatric cerebral palsy patients does not meet the patient's needs compared to the telehealth service since most patients in this study (96%, n = 307) were from remote or rural areas.

Telerehabilitation is one of the effective interventions for pediatric disability groups. Our study found that the children can engage and cooperate reasonably during telerehabilitation. Since they have undertaken treatment with their parents in a familiar environment or their living places, this finding might help the child with anxiety or fear with the therapist's on-site treatment. Many studies also found that telehealth is a feasible and satisfactory method with pediatric patients.[3,4,23] Camden et al. conducted a systematic review of the characteristics and effectiveness of pediatric telerehabilitation interventions and found that telerehabilitation showed improvement of 56.1% of evaluating outcomes.[4] Furthermore, the therapist can effectively coach the parents with a video call, a simple and easy-access technology in this era. The physicians and therapists can monitor the progression of the patient's conditions and parental skills via telerehabilitation. After training, the parents and patients can continue the daily home-based treatment program, which Beckers et al. reported was feasible, acceptable, and practical for implementation with moderate to high compliance.[24]

Limitations and suggestions

This present study only identified the advantages of using pediatric telerehabilitation in the COVID-19 situation in the aspect of burden reduction and satisfaction of caregivers. It could not be generalized to other conditions use. Moreover, our primary outcome or DASS-21 change was not found any significant improvement because the baseline caregivers' mental health was in a normal range. Future telerehabilitation research should focus on the effectiveness of telerehabilitation compared with face-to-face interventions and explore the cost-effectiveness. Furthermore, from our experiences, telerehabilitation has some limitations, especially for a new family who needs a hands-on demonstration of the therapy program. Telerehabilitation might be better for monitoring the progression and training at the follow-up visits for the parents and caregivers who had received the hospital-based rehabilitation programs.

Conclusions

Using pediatric telerehabilitation in the COVID-19 situation helps relieve the caregiver burden without any clinical complaints. This approach should be considered for disabled children who require a maintenance therapy program. We suggested an ongoing comprehensive treatment plan for families with children with disabilities after the pandemic, especially for patients living in remote and rural areas. The benefits of telerehabilitation should be studied in a randomized controlled trial focusing on the effectiveness of telerehabilitation compared with face-to-face interventions.

Disclosure

The author(s) declared no potential conflicts of interest concerning this article's research, authorship, or publication.

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Health Statuses and Post-COVID-19 Conditions in Patients with Spinal Cord Injury: A Case Series

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ABSTRACT

Objectives: To describe the health status and post-COVID-19 condition experienced by patients with spinal cord injury (SCI).
Study design: Case series.
Setting: Sirindhorn National Medical Rehabilitation Institute.
Subjects: Patients with spinal cord injury infected with COVID-19.
Methods: Participants were recruited from SCI patients infected with COVID-19 who had been admitted to the Sirindhorn Science Home Field Hospital for Persons with Disabilities or the Home Isolation Unit of the Sirindhorn National Medical Rehabilitation Institute (SNMRI) and who had been followed up in the SCI clinic at SNMRI. All participants were interviewed by telephone regarding their COVID-19 infection signs, symptoms, treatment received, post-COVID-19 condition, their functional capacity as measured by the Spinal Cord Independence Measure (SCIM)-III Thai version, and their overall quality of life rated on a 0-100 scale.
Results: There were seven SCI patients in this series: four had mild COVID-19 symptoms, while the other three required oxygen therapy. During the six months after the initial infection, all experienced post-COVID-19 symptoms. The most common symptoms were fatigue, dyspnea, anxiety, insomnia, cough, and muscle pain. Among these symptoms, fatigue was reported as being the most severe with a numerical rating of 8 on a scale of 1 to 10. Two of the seven had sought medical advice for their post-COVID-19 condition. Only one patient had a lower
Spinal Cord Independence Measure (SCIM) score after being infected with COVID-19 due to a reduced ability to use a toilet. Two patients reported lower overall quality of life during the post-COVID-19 period due to symptoms of fatigue affecting their daily living activities.
Conclusions: In this series, all patients with spinal cord injuries experienced varying degrees of post-COVID-19 symptoms. Some also reported reduced functional capacity and quality of life resulting from their condition post-COVID-19.

Keywords: spinal cord injury, COVID-19, post-COVID-19 condition
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Introduction

COVID-19 is an emerging disease causing a pandemic. Until now (Jul 14, 2022), more than 500 million people have been infected, with more than six million deaths worldwide.[1] Apart from the direct respiratory symptoms, it can also create long-term effects on other organ systems. Post-COVID-19 condition is widely recognized as having long-term consequences in many body systems after the infection of SARS-CoV-2, which could be persistent symptoms from the initial illness or the new onset after recovery of an acute episode.[2]

The symptoms of the post-COVID-19 condition range from almost every organ system, e.g., respiratory, cardiovascular, neurocognitive, and gastrointestinal systems.[3] The most common symptoms were reported differently by many studies; however, the common and usually most severe symptoms included fatigue, dyspnea, and insomnia.[4-6] Although most studies described the period of post-COVID-19 condition between 3-6 months after the initial disease, there was a report in France with a significant number of patients experiencing persistent taste and smell disorders at seven months.[7] Some studies also reported the effect on physical activities and quality of life.[8,9] A study in the Netherlands re-assessed the physical activities from the walking time and reported a significantly lower capacity at six months after comparing to the pre-COVID-19 level.[8] In Spain, Taboada studied the quality of life of COVID-19 survivors six months after requiring intensive care unit treatment and discovered a significantly lower quality of life in all aspects of mobility, self-care, and usual activities.[9]

The pathophysiology of these multi-system manifestations of the post-COVID-19 condition remains unclear. However, there are postulations of the involvement of the immune system, the systemic inflammatory response, and gut dysbiosis.[3,10,11] As the mechanism is uncertain, the current management guideline in Thailand is tailored to the symptoms of post-COVID-19 conditions that patients experience, including physiotherapy, exercise, nutrition management, psychotherapy, and medication as needed.[12]

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Patients with spinal cord injury (SCI) are among the most vulnerable, with difficulty accessing healthcare services.[13] The pandemic rendered them at a far more marginalized edge of healthcare provision.[14,15] Moreover, many comorbidities accompanying SCI, e.g., the weakness of respiratory muscles, reduced lung capacity, and the inability to cough[16] could intensify the symptoms of COVID-19. Barman et al. reviewed the clinical condition of patients with spinal cord injury who were infected with COVID-19.[17] Among 11 studies reviewed; the largest report was from the United States, which found the mortality rate in SCI as high as 19% while it was only 7.7% in non-SCI.[18] It was also noticed that mild COVID-19 patients might not receive the COVID-19 screening in the United States. Therefore, SCI patients might presume that the mild viral infection symptoms were from other co-morbidities, e.g., urinary tract infections. Consequently, SCI patients might receive COVID-19 treatment at a late stage with more severe symptoms, resulting in the poorer result.[18]

There is still no clinical report regarding the post-COVID-19 condition in persons with SCI. Therefore, this study aims to explore the post-COVID-19 condition in this group of patients. Furthermore, as the health status of persons with disabilities does not lie only in body structure but also in activity and participation,[19] this study would explore these dimensions of SCI patients before and after the infection. Additionally, as COVID-19 also created stigmatization and discrimination problems among survivors,[20,21] the participation and quality of life concerning this issue will also be studied.

Methods

After the SNMRI ethic committee approved the research proposal, the participants were recruited, including SCI patients who were admitted to Sirindhorn Science Home Field Hospital for Persons with Disabilities or SNMRI home isolation unit or those who followed up in the SNMRI SCI clinic. Inclusion criteria were a history of COVID-19 infection during the past 12 months and able to communicate in Thai. Those with comorbidities that affected cognitive function or intellectual and communication skills were excluded. The participants were contacted via telephone in January 2022, and verbal consent was obtained before the telephone interview. The interview was performed solely by the author (DS) using a structured interview case record form. Data collection included demographic information, COVID-19 severity and treatment, post-COVID-19 condition, and severity on a scale of 0-10 according to the Department of Medical Services, Ministry of Public Health checklist. The post-COVID-19 condition was determined from the symptoms that occurred more than three times/day and occurred after or continuously after the discharge from hospital, or home isolation within six months. Information on patients' functional capacity was obtained using the SCIM-III Thai version.[22] The quality of life before and after COVID-19 infection was determined using a numerical rating scale of 0-100. Some additional participation aspects of health according to the International Classification of Functioning, Disability, and Health (ICF) were also interviewed comparing before and after being infected with COVID-19, e.g., the need for a personal assistant, the employment status, the leisure activities, the need to seek medical advice for post-COVID-19 condition. The patient's medical records were reviewed to verify the demographic information on the neurological level and completeness. All information was summarized and analyzed descriptively, using mean and standard deviation where appropriate.

Results

From the database of 650 patients admitted to Sirindhorn Science Home Field Hospital for Persons with Disabilities, there were four patients with SCI. Of 469 patients who received COVID-19 treatment from the SNMRI home isolation unit,

Table 1. Demographic data, history of COVID-19 infection and treatment

	Demographic					COVID-19 information				
	Diagnosis	sex	age	Duration of SCI (months)	Co-morbidity	Duration since COVID-19 discharge (days)	Treatment facility	Duration of admission (days)	COVID-19 severity	Treatment received
1	T10B	M	44	288	CTS	162	Field hospital	9	Mild	Favi
2	T11	F	45	246	-	173	Field hospital	14	Mild	-
3	C4D	M	29	90	-	147	Home isolation	14	Mild	Favi
4	T11	F	61	252	DM, HT, DLP	195	Field hospital	21	Moderate (Abnormal CXR)	Favi, steroid oxygen
5	T4	M	27	108		105	Field hospital	13	Mild	Favi
6	C6A	M	38	102	- -	188	General hospital	15	Moderate (Abnormal CXR)	Favi, oxygen
7	T12B	F	55	301	-	144	General hospital	18	Moderate (Abnormal CXR)	Favi, steroid, oxygen

CTS, carpal tunnel syndrome; DM, diabetes mellitus; HT, hypertension; DLP, dyslipidemia; CXR, chest x-ray; Favi, favipiravir

there was one tetraplegic patient. Another two patients in the SCI clinic got infected and were treated in hospitals elsewhere. Altogether, seven patients were contacted and recruited for this series. There were four males, five out of seven were paraplegic, and the average duration of SCI was 198.1 ± 93.9 months. The average age of all participants was 42.7 ± 12.6. At the time of the study, the patients were discharged from the COVID-19 treatment at an average of 159.1 ± 30.6 days. Most of them had mild symptoms; less than half needed oxygen therapy (Table 1).

All seven patients reported post-COVID-19 symptoms during six months after discharge. The most common symptom was fatigue, found in 5 patients. The second most common was dyspnea, anxiety, and insomnia, reported by four patients. Three patients recognized cough and muscle pain. Some other symptoms were also reported, as shown in Table 2.

The most severe reported symptoms of the post-COVID-19 condition were fatigue and dyspnea, rated by one patient on a scale of 8 out of 10. One patient reported spasticity at the level of 7 out of 10. Some other symptoms with severity from 4 to 6 were cough, tachycardia, dizziness, anxiety, insomnia,

Table 2. Post-COVID-19 conditions and health statuses of each patient

	Demographic			Post-COVID-19 condition			SCIM		QOL	
	Diagnosis	Sex	Age	Symptoms	Severity (0-10)	Treatment	Pre	Post	Pre	Post
1	T10B	M	44	Fatigue	3	Self-exercise (taught from the field hospital)	69	69	80	80
				Anxiety	6					
				Depress	6					
				Insomnia	5					
2	T11	F	45	Fatigue	1	Tele-consultation with physician (received advice to do home exercise)	67	66	90	80
				Dyspnea	1					
				Cough	1					
				Palpitation	1					
				Tachycardia	1					
				Chest pain	1					
				Insomnia	1					
				Hair loss	4					
				Muscle pain	1					
				Joint pain	1					
3	C4D	M	29	Spasticity	7	-	34	34	30	30
				Anosmia	1					
4	T11	F	61	Dizziness	1	-	38	38	80	80
				Hair loss	5					
				Muscle pain	1					
5	T4	M	27	Fatigue	5	Self-exercise	58	58	90	90
				Dyspnea	4					
				Cough	4					
				Brain fatigue	3					
				Memory	3					
				Anxiety	5					
				Fever, chill	1					
6	C6A	M	38	Fatigue	8	Followed up by physician at general hospital (had CXR), bought medicine from the pharmacy, self-exercise	29	29	65	65
				Dyspnea	8					
				Cough	6					
				Anxiety	4					
				Insomnia	5					
7	T12B	F	55	Fatigue	7	Physical therapy, self-exercise	52	52	95	85
				Dyspnea	6					
				Tachycardia	6					
				Dizziness	5					
				Anxiety	5					
				Insomnia	3					
				Dysphagia	2					
				Muscle pain	4					
				Joint pain	4					
				Fever, chill	1					
				Ageusia	1					

SCIM, spinal cord independence measure; QOL, quality of life

hair loss, muscle pain, and joint pain (Table 2). Two patients consulted with the physician about their post-COVID-19 condition, while three self-exercised at home. Only one patient with the highest severity of fatigue and dyspnea had bought some medicines from the pharmacy.

Regarding the SCIM-III assessment, six patients had the same functional score level comparing before and after the COVID-19 infection. Only one patient had a lower score after discharge from the field hospital due to the increasing difficulty in using a toilet. She had changed from totally independent status to using assisted rail in transferring due to the fatigue experienced after the COVID-19 infection.

In terms of quality of life, five out of seven patients reported the same level before and after the infection. Two patients had lower scores after the infection because of fatigue during performing activities of daily living. However, all seven patients stated there was no difference in the need for personal assistance, leisure activities participation, and employment status before and after the COVID-19 infection.

Discussion

Regarding the post-COVID-19 condition, all seven patients reported some symptoms six months after the infection. The most frequent symptoms were fatigue, dyspnea, anxiety, and insomnia. This finding does not differ from post-COVID-19 conditions reported in non-SCI individuals.[6]

Although the mechanism underlying post-COVID-19 condition is still unclear, the most common postulations are the disturbance of the immune system and the body's systemic inflammatory response.[3,10,11] It is proposed that SAR-CoV-2 might affect the permeability of the blood-brain barrier and facilitate neurological inflammation through the penetration of peripheral cytokines into the central nervous system.[3] There is also autopsy evidence of SARS-CoV-2 genes and pathologic immune activations in the brainstem of COVID-19 patients.[11] A study in Italy revealed the correlation between the systemic immune-inflammation index and neurocognitive symptoms at three months post-infection.[23] In this series, one participant reported a severe level of spasticity after the infection. Therefore, the systemic inflammatory response might play a role in motor neuron excitability. However, further investigation and long-term follow-up are still needed to ascertain the proposed mechanism.

The post-COVID-19 symptoms severity does not correlate with the severity of COVID-19 infection. The majority of patients in this series, 4 out of 7 (57.2%), had mild COVID-19 infection. This result aligns with the systematic review in 2020, which revealed that although 63% of patients had abnormal chest x-rays, 75% presented with mild symptoms.[24] However, those with mild COVID-19 symptoms had post-COVID spasticity at 7/10 and depression at 6/10. Huang et al. followed 1,733 COVID-19 patients for six months and found that the disease severity was not a significantly correlated factor to post-COVID-19 condition.[5] Regarding the severity of the post-COVID-19 symptoms, SCI patients do not differ from the general population.

Two patients rated a poorer quality of life after COVID-19 infection. These two patients reported the highest number of symptoms of the post-COVID-19 condition in the series, one of them also rated a relatively high degree of post-COVID-19 symptoms severity. The poorer quality of life could be due to the worsened health status. There was one patient with a lower SCIM-III score. This result was also possible from the lower physical activity during 14 days of admission in the field hospital. The post-COVID-19 condition also kept the patient at a lower activity level compared to the pre-infection state. In 2020, a survey in the Netherlands revealed that post-COVID-19 conditions could bring about lower physical activity even in non-disabled individuals.[8] A systematic review in 2022 also confirmed that lifestyle changes during COVID-19 could harm the level of physical activity and worsen the symptoms of people with neurological diseases.[25]

This case series has certain limitations. First, the number of participants might need to be more extensive for population inference. Second, the usage of SCIM-III in this study was not the self-report version of the SCIM, as the self-report version has yet to be translated and validated in Thai. This limitation could pose inaccuracy in the measurement of the patient's function. Third, there was an unavoidable bias regarding the recall nature of the interview. Moreover, because it was the follow-up of the infected patients in the middle of 2021, most of the COVID-19 strain in Thailand was delta. Therefore, the post-COVID-19 condition may differ from the strain widely spread afterward. However, the series could inform medical providers that post-COVID-19 condition is also common in patients with SCI and could affect the functional capacity and quality of life. Therefore, rehabilitation personnel taking care of SCI patients should be cautious and anticipate the conditions.

Conclusions

Every SCI patient in this series experienced post-COVID-19 conditions within six months after the infection. Some patients reported lower functional capacity and quality of life due to the condition. Therefore, medical professionals responsible for SCI patients should be aware of and prepared to care for this condition.

Disclosure

The author declares no conflict of interest.

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Outcome of a Telerehabilitation Program for a Home-Bound Geriatric Patient with Post Covid-19 Syndrome in Indonesia: A Case Report and Literature Review

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ABSTRACT

Objectives: This study aimed to share a local experience in implementing a telerehabilitation program for a geriatric patient with post-COVID-19 syndrome following the third-wave pandemic and to describe the clinical outcomes.

Study design: A case report and literature review.

Setting: Hermina Kemayoran General Hospital, Jakarta, Indonesia.

Subjects: An unvaccinated 80-year-old male patient diagnosed with post-COVID-19 syndrome from the Delta strain presented with desaturation.

Methods: The patient underwent an individualized telerehabilitation program for 4 weeks via video call.

Results: His pulmonary symptoms, functional capacity, functional independence, and quality of life improved following the telerehabilitation program. The investigators found the challenges to initiating telerehabilitation in Indonesia include inequality of access to the internet, portable medical and health-monitoring home devices, reliable telecommunication devices, home exercise equipment, and competent caregivers. Fortunately, the patient and his family presented in this case report were able to overcome these challenges.

Conclusions: Telerehabilitation is an option for patients who have difficulty visiting a hospital to access rehabilitation services. It is necessary to improve various aspects of health among patients infected with COVID-19.

Keywords: functional status, geriatrics, telerehabilitation, COVID-19, quality of life

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Introduction

Telerehabilitation is the provision of rehabilitation services through any form of information and communication technology, including Internet-based platforms, allowing patients to interact with rehabilitation providers remotely for evaluation and intervention.[1] It consists of teleconsultation and teletherapy sessions. Telerehabilitation (TR) programs have been proven effective in many conditions including for patients after COVID-19, geriatric patients, and many more.[2] Since the COVID-19 pandemic in 2020, telemedicine services have begun to develop in Indonesia. One sort of telemedicine is telerehabilitation which focuses on rehabilitation services.[3] However, telerehabilitation has not been commonly employed or studied in Indonesia despite its usefulness abroad.

Post-COVID-19 syndrome is characterized by persistent symptoms and/or delayed or long-term complications of COVID-19 disease beyond 4 weeks from the onset of symptoms.[4] The study conducted by Huang et al. that followed 1,733 patients for 6 months showed that the majority of post-COVID-19 symptoms include fatigue or muscular weakness (63%), insomnia (26%), and anxiety or depression (23%) among others. Most of the patients reported the presence of at least one symptom (76%).[4,5] These symptoms can cause disability and reduce the quality of life among COVID-19 survivors. Another study by Carfi and colleagues found that among the persistent symptoms 2 months after disease onset, persistent fatigue was seen in more than 50% of patients, dyspnea in 43%, and joint pain in 27%. The rates of these symptoms were higher among older people. Older people who were relatively healthy before the infection experienced

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more severe functional decline and deterioration in activities of daily living, along with other phenotypic characteristics of frailty following COVID-19.[6,7]

In-person rehabilitation programs can help prevent or minimize these consequences. However, many patients have difficulty in going physically to the hospital because of various reasons, such as older adults/geriatric patients, O2-dependent, absence of facilities.[3] Geriatric patients are particularly vulnerable to COVID-19 contagion when they come in for center-based rehabilitation frequently.[3] Telerehabilitation can be a feasible solution to address these constraints. A study by Vieira et al. showed that telerehabilitation may improve functional capacity, dyspnea, and quality of life without a substantial increase in adverse events.[8] This case report shares a local experience in Jakarta, Indonesia regarding the challenges and outcomes in employing telerehabilitation for a geriatric COVID-19 patient to hopefully contribute to the very meager evidence of telerehabilitation in the country and provide insight on its feasibility and safety amid limited resources.[1,2]

Case presentation, intervention, and outcomes

An 80-year-old male patient was referred for rehabilitation with the chief complaint of shortness of breath even at rest. He has been dependent on high-flow oxygen support, and all functional activities were done lying in bed because his oxygen saturation dropped by > 5% every time he tried to sit-dangle on the bed. Cough was also triggered every time he tried to move his body. The patient lives more than 30 kilometers away from the nearest rehabilitation facility in their area. Since he could not get out of bed for in-person consultation and renting an ambulance at that time was difficult because of the high demand for emergency services during the pandemic, his internist referred him to the online rehabilitation facility in our hospital. At that time, our hospital was among the very few hospitals in Indonesia providing telerehabilitation services. The telerehabilitation consultation through video call was done with a physiatrist.

He had a COVID-19 infection approximately two months prior to the teleconsultation and was hospitalized for 33 days. He was never intubated nor admitted to the intensive care unit. He was given a high-flow nasal cannula for 14 days in an isolation room and oxygen supplementation at 5 Liters per minute for another 14 days in the regular room. He was discharged after a negative COVID-19 result on the Polymerase Chain Reaction (PCR) test. He was still dyspneic and dependent on oxygen supplementation at 5 liters per minute upon discharge. The COVID medicines were unknown because the patient was hospitalized in another center.

He has been home for 3 weeks, but the patient and family were concerned about the patient's persistent dyspnea that severely limited his functional capacity and independence. The patient was previously ambulatory and independent in activities of daily living with no co-morbid condition. On virtual physical examination, the patient was found to have dyspnea and tachypnea on activity, wherein the oxygen saturation dropped from 95% to 85% and respiratory rate increased up to 28 cycles per minute after attempting to sit-dangle from a supine position with suprasternal, intercostal and epigastrium retractions. The patient also had frequent coughing when moving. The Barthel Index was 55/100 (i.e., limitations in toileting, bathing, mobilization, transfer, and stair climbing). The sit-to-stand test was not done due to desaturation. Based on the EQ-5D-5L (EuroQOL with 5 dimensions and 5 levels), the patient had severe problems with mobility and daily activities. The pertinent physical examination is summarized in Table 1. The patient was not referred for inpatient rehabilitation because there was no rehabilitation facility in the previous hospital. Based on the examination, the patient was diagnosed with the post-COVID-19 syndrome. The main symptoms were dyspnea and functional decline that persisted for about 2 months after discharge.

Eventually, telerehabilitation was offered to the patient. The patient's consent was recorded through video prior to the teleconsultation. The goals of the telerehabilitation program included the following: (1) reduce the symptoms of resting and exertional dyspnea, (2) improve functional capacity and independence, and (3) wean from oxygen supplementation. The program consisted of the following: breathing retraining (diaphragmatic and segmental breathing that focused on developing breathing control); chest mobility exercises (such as chest expansion exercises with and without holding a towel in line with controlled breathing technique); and respiratory muscle relaxation techniques through gentle passive stretching of the upper trapezius, pectoralis major, and paracervical muscles. The prescription of the exercise was 2-3 sets as tolerated with 10 repetitions and a 2-3-second hold per set as tolerated. All the exercises were done in supine and sitting positions according to the patient's response. The exercise program was terminated if the oxygen saturation fell ≤ 80% or the patient requested to stop. The patient completed the initial two-week program of physical therapy conducted via synchronous, online video-based telerehabilitation for 45 minutes three times a week (a total of 6 sessions).

During the teletherapy, a dedicated physiotherapist contacted the patient using video call via a hospital-based telemedicine platform to virtually facilitate the exercise program prescribed by the physiatrist. There are no technical issues such as the internet connection, the voice, the sound, and the videos during teletherapy. The physiotherapist provided execise instructions, supervision, and monitoring during each session, and properly paced the exercises depending on the patient's tolerance. The vital signs (i.e., blood pressure, heart rate, and oxygen saturation) were measured in person by the caregiver using a sphygmomanometer and oximeter available at home and were recorded by the remote physiotherapist on the medical record for each session. The patient had his daughter as his caregiver, who set up their tablet for each video call, directly supervised

the exercise at home, and measured the vital signs during each exercise. The daughter was taught about vital signs monitoring and safety precautions by the physiotherapist during the first session. Initially, the patient could not tolerate 45 minutes of exercise even when done supine and intermittently (i.e., a cycle of exercise for 10 minutes and rest of 5 minutes for a total duration of 45 minutes). He eventually tolerated the sessions with lesser rest periods (e.g., only 5 minutes in the middle of the therapy session).

After two weeks, the patient was evaluated by the physiatrist through teleconsultation. He showed some improvements in pulmonary symptoms (e.g., need for oxygen supplementation; cough; secretions), Barthel Index score, 5 times sit-to-stand test, and EQ-5D-5L (Table 1). He was found to be needing oxygen support only after performing basic activities of daily living (ADL), such as toilet habits, bathing, and changing clothes. He could walk around the house on his own with a walker. No adverse event was noted.

The patient then continued with another set of 6 telerehabilitation sessions for 2 weeks. The following were added to the program: aerobic exercise using a portable mini pedal for upper and lower extremities for 15-20 minutes; muscle strengthening using a 600-mL mineral water bottle for exercising the upper limbs and ankle weight (1 kilogram) for the quadriceps (i.e., 3 sets with 5-10 repetitions, 3-5-second hold per set); and balance exercises (such as sit-to-stand for 10 repetitions and ambulation using walker for 50 meters). All the exercises were either done in sitting or standing. The total duration of teletherapy was 45 minutes, with the patient resting for 5 minutes after each type of exercise. The indications of exercise termination were the same as the previous exercise program. He was asked to continue the breathing retraining and relaxation exercises on his own even on days between telerehabilitation sessions. All the exercise equipment (portable mini pedal and ankle weight) were bought online by the patient's family.

After a total of 12 telerehabilitation sessions, he was evaluated through teleconsultation with noted improvements in oxygen dependence, cough, functional status, and functional independence (Table 1). His activities were no longer interfered by cough and dyspnea. He could walk around the house independently without a walking aid. The patient was given a home program to continue all the exercises even without supervision from a remote physical therapist.

Discussion

We report the case of an elderly infected by COVID-19 (delta strain), which was highly contagious, presenting with breathlessness that persisted up to the recovery phase. The patient never had COVID-19 immunization prior to the infection. His symptoms of post-COVID-19 syndrome included dyspnea at rest and exertional dyspnea, supplemental oxygen dependence, and functional decline. Post-COVID-19 syndrome in the aged population is affected by several factors, including residual organ damage, the persistence of systemic inflammation, the effects of hospitalization, and associated comorbidities.[9] Immunosenescence and age-related immune remodeling may also be the reason for this susceptibility.[10] In Post-COVID-19 Syndrome, symptoms persist from the time of the acute clinical illness to the recovery phase. Several studies have shown that hospitalized older adults were mostly males who presented with fever (74.6%), cough (35.8%), breathlessness (24%), fatigue (21.8%), and myalgia (19.7%). The most prevalent comorbidities were hypertension (58.4%),

Table 1. Functional status and functional independence before and after telerehabilitation

	Outcome Criteria	Teleconsultation I (Initial assessment)	Teleconsultation II (mid-evaluation after first set of six sessions of therapy)	Teleconsultation III (Final evaluation after second set of six sessions of therapy)
Pulmonary symptoms	Oxygen supplementation at rest in sitting position	1-2 Lpm to reach 97-98% oxygen saturation	1-2 Lpm to reach 97-98% oxygen saturation	Room air
	Oxygen supplementation after performing an ADL	5-6 Lpm to reach 93-94% oxygen saturation	5-6 Lpm to reach 97-98% oxygen saturation	Room air
	Cough	Exercise-induced cough (cough is strong and dry)	Exercise-induced cough (cough is strong and dry)	Exercise-induced cough less frequent
	Secretion	Liquid, whitish	Liquid, whitish	No secretion
Barthel Index		55/100	95/100	95/100
5 Times Sit-to-Stand Test		Not tolerated	30 seconds (with EID)	30 seconds (no EID)
EQ-5D-5L	Mobility	4	3	2
	Self-Care	4	3	2
	Usual Activities	4	3	2
	Pain/Discomfort	1	1	1
	Anxiety/Depression	1	1	1

Lpm, liters per minute; EID, exercise-induced dyspnea; EQ-5D-5L (EuroQOL with 5 dimensions and 5 levels), A standardized measure of health status describing different dimensions of health (Mobility, Self-Care, Usual Activities, Pain/Discomfort, and Anxiety/Depression), rated in a 5-point Likert scale: no problems (1), slight problems (2), moderate problems (3), severe problems (4), and unable to/extreme problems (5)

diabetes mellitus (52.8%), and coronary artery disease (20.8%).[11]

Post-COVID-19 Syndrome is the presence of at least two clinical symptoms over 12 weeks after recovery, its overall prevalence was approximately 9.3% among older adults. Especially in elderly patients, functional status after recovery from acute COVID-19 infection can be compromised due to persistent clinical symptoms and age-related factors.[12-14]

A study by Sathyamurthy et al. showed that the most common symptom of older adults reported 90 days after recovery was fatigue, which was followed by cough and breathlessness.[15] Their population was comprised of hypertensive individuals in 58.4% of cases and those with prior chronic obstructive pulmonary disease in 4%. The study also showed that older adults nearly regained their baseline functional status within 90 days of the acute illness.[15] In our report, the patient regained his near-baseline functional status within 30 days after undergoing a telerehabilitation program.

In lower middle-income countries, such as Indonesia, telemedicine, more so telerehabilitation, was neither widely known nor implemented before the COVID-19 pandemic.[16] The suspension or limited capacity of center-based rehabilitation services in many hospitals, along with the concern about COVID-19 contagion during the pandemic, accelerated the unprecedented adoption of telerehabilitation.[16,17] Catalyzed by the pandemic, telemedicine in Indonesia is now regulated by the Ministry of Health Regulation No. 20 of 2019, but the guideline does not mention about telerehabilitation. Telemedicine in Indonesia is usually implemented for teleconsultation (through video call using a national platform called TEMENIN or Telemedicine Indonesia), teleradiology, tele-ultrasonography, and tele-electrocardiography (through the uploading of documents or results for a remote specialist consultation). Starting in 2017, the platform has been in use by approximately 200 primary healthcare services and hospitals in selected areas. It was originally developed to help deliver health services to more isolated and rural areas, especially those that do not have physical facilities. It was intended to allow people with limited access to healthcare to be diagnosed and treated as soon as possible. The concept of telemedicine is very suitable for Indonesia given its vast, archipelagic, and populous landscape. Unfortunately, TEMENIN is not yet ready to be implemented on a national scale and has not been thoroughly used by the public, especially outside the metropolis area, primarily due to internet connectivity issues and limited digital infrastructure that does not cover remote areas.[18,19]

Many national guidelines from other countries recommend telemedicine as an option for remote screening and, if possible, for providing remote treatment to patients to curtail the high transmission rates of COVID-19 during the pandemic. Telemedicine may be considered electronic personal protective equipment (PPE) by reducing the risk of COVID-19 exposure and spread among patients and clinicians.[20]

With the existence of telerehabilitation, the provision of rehabilitation services can be easier and wider in scope, so it is beneficial for people who cannot come to the rehabilitation center because of various barriers, such as impaired mobility, difficulties in travel and logistics, time constraints, and costs among others.[21] The patient in this case report had limited access to rehabilitation services because there was no rehabilitation center nearby and arranging for transportation was cumbersome, similar to the experience reported in the Philippines.[22] Patients like them with constraints to in-person rehabilitation access can benefit from a telerehabilitation service program. Telerehabilitation services are divided into two categories: virtual assessment (to assess the functional abilities of patients) and virtual therapy (to facilitate therapeutic exercises and interventions from a distance).[22] Telerehabilitation may be performed using any form of Information and Communication Technologies (ICT), as outlined in Table 2.[23,24]

Telerehabilitation has been applied to patients with neurodegenerative disease, heart failure, cerebrovascular disease, chronic obstructive pulmonary disease, geriatrics, and musculoskeletal disorder. The application of telerehabilitation in health care has shown promising results, in terms of functional ability, disability improvement and others.[25-27]

The disadvantage of implementing telerehabilitation is the inability of the patient to accurately replicate the exact exercise regimen taught by the physiatrist and guided by a physical therapist. Other barriers that can be encountered when implementing telerehabilitation are communication barriers and different perceptions when facilitating mirroring techniques during teletherapy sessions. Barriers can also be found in patients with neurological disabilities in operating communication devices. In this current study, there were no adverse events noted, such as desaturation, falls, and muscle soreness.[25,28]

The most challenging experience we had during the telerehabilitation sessions was the difficulty of the patient following exercise instructions via video call. An adult competent caregiver was needed to help the patient follow the instruction step-by-step. The peculiar situation of telerehabilitation in Indonesia was every physiatrist has their own protocol in conducting telerehabilitation because there are no policies, guidelines, or laws that specifically regulate the liability and implementation of telerehabilitation in Indonesia. There are still many challenges to implementing telerehabilitation in Indonesia, such as the cost of each telerehabilitation session (i.e., approximately 13-20 US dollars for each session, while the average household income in Jakarta is 307 US dollars). This patient had a total of 2 teleconsultations and 12 teletherapy sessions in one month, which cost approximately 280 US dollars. This cost is still a challenge to telerehabilitation in Indonesia and there is no solution yet therefore lack of tele-rehabilitation enthusiasts because of the cost.

National health insurance does not cover telemedicine, including telerehabilitation. Other challenges were the internet access, lack of medical devices to monitor patient response, lack of ideal exercise equipment, and a competent caregiver

Table 2. Examples of telerehabilitation techniques and their inherent benefits and limitations

Telerehabilitation method	Examples	Benefits	Limitations
Synchronous	Video call/video conference using Zoom meeting, Google meet, or WhatsApp	Time-efficient Mutual support Individualized The patient can be monitored in real-time	Time-limited Need sophisticated communication tools (camera, speaker, internet network, and devices that support the platform)
Asynchronous	Text messaging or E-mail to send the exercise program instruction	Does not need sophisticated communication tools Cost-effective	The telerehabilitation program cannot be individualized Inability to measure participant's physical performance and compliance The patients cannot be intensively monitored (cannot be done in high-risk patient)
	Video upload	The patient can watch and follow the video whenever they want and as frequently as they want	The telerehabilitation program cannot be individualized Inability to measure participant's physical performance and compliance Cannot be done in high-risk patient (cannot be monitored)
	Certain mobile applications on smartphone for home exercise program	The application can meet a variety of user needs, and facilitate patient adherence by creating an interactive exercise environment that promotes self-efficacy and behavior change through enhanced communication, goal setting, and progress reporting means. Cost-effective	The patient should have a smartphone that supports the application This method is suitable for patients accustomed to using the technology

as supervisor. Based on the author's experience, one of the important eligibility criteria for telerehabilitation for geriatric patients in Indonesia is the availability of home equipment needed to consistently and reliably conduct quality telerehabilitation sessions.

There was only one published paper about the telerehabilitation program in Indonesia. The paper was a case report about the combination of telerehabilitation with conventional therapy in the treatment of bilateral carpal tunnel syndrome (CTS). This case report involved a 51-year-old patient. The telerehabilitation was given for 5 weeks consisting of telerehabilitation (using instant messages and video calls using WhatsApp Messenger every 4-5 days on average, with durations varying from 5-40 minutes to supervise and give feedback on the home education program) combined with conventional therapy (using low-level LASER therapy and Ultrasound Diathermy phonophoresis). The study showed that the combination program was feasible in improving the patient's symptoms and functional ability for a patient with bilateral CTS.[29]

To the authors' knowledge, this case report was the second paper about the implementation of telerehabilitation in Indonesia. The contribution of this paper to the severely scarce local literature is emphasizing the feasibility and safety of telerehabilitation among post-COVID geriatric patients in low-resource settings as long as proper support systems are in place, such as reliable internet connection, and available home medical devices, telecommunication devices, exercise equipment, and a competent adult caregiver. Telerehabilitation can be an innovation to resolve gaps in rehabilitation service delivery following hospital discharge for COVID-19 patients. Further large-scale and more robust studies are needed to establish its effectiveness.

Conclusions

A structured/ systematic telerehabilitation program can improve pulmonary symptoms, functional status, functional independence, and quality of life in 4 weeks. This study also showed that the telerehabilitation program is safe and feasible for geriatric patients with post-COVID-19 syndrome in low-resource settings as long as a proper support system can be provided. This program also can be a suitable solution for patients that cannot personally access rehabilitation services and can reduce exposure to coronavirus infection among healthcare workers and patients.

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