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# Content

# Patient Compliance and Treatment Adherence

'Patient Compliance' was first introduced as a MeSH term in PubMed in 1975 and defined as 'voluntary cooperation of the patient in following a prescribed regimen'. In 2018, the term 'Treatment Adherence and Compliance' was introduced and refers to 'extent to which the patient follows prescribed treatment such as keeping appointment and schedules and medication adherence for desired therapeutic outcome, and implies active responsibility shared by patient and health care providers'.

These two terms serve as the foundation for rehabilitation practice and research as patients should be actively involved in treatment and therapy to achieve optimal goal of independent living. Therefore, it is important for rehabilitation physicians (physiatrists) and other rehabilitation professionals to ensure patients and their family members understand the process and benefit of rehabilitation, and the importance of their active participation for successful rehabilitation outcomes. Patient education session prior to initiation of treatment/therapy is essential to teach or train patients concerning their own needs and healthcare provider expectations. Once both parties understand each other needs and expectations and reach a mutual agreement on goals of rehabilitation, patients are likely to adhere to the prescribed treatment regimen and therapy.

This issue features research articles on usage of ankle-foot orthoses, exercises using a resistance band, and a home exercise program of muscle strengthening which points out the importance of patient compliance and/or treatment adherence.

For more information of MeSH terms, visit the website: https://www.ncbi.nlm.nih.gov/mesh/

Apichana Kovindha, MD, FRCPhysiatrT
Editor-in-chief

# Comparison of the Efficacy of Dextrose Prolotherapy in Lateral Elbow Tendinopathy: A Systematic Review and Meta-Analysis of Randomized Controlled trials

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## ABSTRACT

*Objectives:* To compare the efficacy of dextrose prolotherapy (DPT) and alternative treatments for lateral elbow tendinopathy (LET) patients.

*Study design:* A systematic review and meta-analysis.

*Setting:* Not applicable.

*Subjects:* Patients in all stages of LET.

*Methods:* The authors searched databases of studies that compared the efficacy of DPT to alternative treatments for LET published in PubMed and Scopus from 1 January 2001 to 20 April 2021. The primary outcomes were the visual analog scale for pain (VAS) at rest and during movement. Secondary outcomes included pain-free grip strength, Quick Disabilities of the Arm, Shoulder and Hands (QuickDASH) scores, and Patient-Rated Tennis Elbow Evaluation (PRTEE) scores. The data, provided as means and standard deviations, were converted to standardized mean differences (SMD) with 95% confidence intervals (CI). The Review Manager 5.3 Software, Risk of Bias 2, and Grading of Recommendations, Assessment, Development and Evaluations (GRADE) were used for data analysis, risk of bias assessment, and quality assessment.

*Results:* Six randomized controlled trials (RCTs) which met the eligibility criteria were included. In each of those trials, the DPT group had significantly reduced VAS pain scores at rest and during movement at 12 weeks post-treatment compared to the other treatment groups. In terms of function improvement, the DPT group also had significantly greater improvement in QuickDASH scores than the other treatment groups at 12 weeks. However, these positive findings were based on methodologies which had a moderate to high risk of bias and were underpowered.

*Conclusions:* DPT requires additional high-quality RCTs to determine the benefits to patients with LET. The main reason for the inconclusive results in this study was that most of the reviewed RCTs demonstrated a moderate to high risk of bias.

**Keywords***:* dextrose prolotherapy, lateral epicondylitis, regenerative medicine, tennis elbow, treatment

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## Introduction

Lateral elbow tendinopathy (LET) or tennis elbow is considered a common musculoskeletal pain disrupting normal daily functions and work activities. There are various alternative treatments for LET, including non-invasive and invasive management. The non-invasive treatments are usually the initial approaches and include "wait and see," elbow splint, physical modalities, exercise of wrist extensor muscles, and pain-relieving medications.[1] Some patients for whom non-invasive treatment failed are still suffering due to their pain. Practitioners caring for those patients should provide other options to help alleviate pain. Intervention procedures, including injection of corticosteroid, botulinum toxin, autologous blood products, hyaluronic acids, and prolotherapy, should also be considered.[2-4]

Recent discoveries about the pathophysiology of LET have revealed it to be a degenerative, rather than an inflammatory, process.[5,6] This has been confirmed by a meta-analysis showing that corticosteroids do not provide benefits in pain relief or improved function in patients with enthesopathy of the extensor carpi radialis brevis in the short-, intermediate-, or long-term when compared to a placebo.[7] Studies in regenerative medicine have provided a growing body of data regarding treatment of tendinopathy. In the area of pain reduction, several meta-analyses have reported that the long-term effects of Platelet-Rich Plasma (PRP) and autologous blood injection are superior to corticosteroid injections;[2,3,8] however, this finding has been questioned in a recently published meta-analysis comparing PRP with a placebo injection.[9] Another treatment, extracorporeal shockwave therapy (ESWT), which involves the application of regenerative mechanisms, has been reported to show efficacy in both pain and disability reduction;[10,11] however, the treatment is expensive and may be beyond the financial resources of some developing countries.

Prolotherapy, which uses a regenerative mechanism without biologic agents, is gaining interest for treatment of

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chronic tendinopathy. Hypertonic dextrose (10-20% dextrose) is one of the substances commonly injected in prolotherapy. Dextrose prolotherapy (DPT) produces an inflammatory response and stimulates fibroblast proliferation which accelerates the healing process.[12] In recent years, meta-analyses have described the efficacy of DPT in common chronic musculoskeletal problems such as knee osteoarthritis and tendinopathy.[13-15] DPT is a low-cost, easily accessible, and non-toxic treatment, accessible even to patients in low- and middle-income countries.

The efficacy of DPT for LET has been studied in a randomized controlled trial (RCT) comparing a variety of arms categorized into two groups: a non-active control group ("wait and see" treatment or placebo saline injection) and an active control group (physiotherapy, corticosteroid injection, hyaluronic acid injection, and radial ESWT).[16-21] The present study aimed to compare the efficacy of DPT with other treatments for patients with LET.

## Methods

The present study was conducted following PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analysis) guidelines.

### Inclusion and exclusion criteria

Inclusion criteria for this study were set based on the Population, Intervention, Control, Outcomes (PICO) framework as follows: (1) population: all stages of LET patients (2) intervention: dextrose prolotherapy, (3) control: any other comparators e.g., other treatments, placebo, "wait and see", (4) outcomes: pain scores and functional outcomes, (5) study design: RCTs. The exclusion criteria were: (1) articles not written in the English language, (2) articles which did not report major outcomes or which lacked data, (3) studies which included participants who had arthritis or connective tissue disease, e.g., rheumatoid arthritis.

### Data sources

The search for randomized controlled trials was conducted using the PubMed and Scopus electronic databases for the period 1 January 2001 to 20 April 2021. The present study was registered with the International Prospective Register of Systematic Reviews (PROSPERO). The registration (CRD42021258117) is available from https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021258117.

### Search strategy

Keywords used during searches included the following: (((tennis elbow) OR (lateral epicondylitis) OR (lateral elbow pain) OR (lateral humeral epicondylitis) OR (lateral epicondylalgia)) AND ((dextrose) OR (prolotherapy) OR (injection))) AND ((randomized controlled trial [Publication Type] OR (randomized [Title/Abstract] AND controlled [Title/Abstract] AND trial [Title/Abstract]))).

### Selection process

Covidence systematic review software[22] was used in screening for titles and abstracts compatible with the study criteria. Two reviewers independently reviewed the articles identified in the literature search. Duplicate articles were identified and excluded. Eligible articles were selected based on adherence to the inclusion and exclusion criteria. Disagreements regarding enrollment eligibility of articles were discussed and resolved by the two reviewers.

### Data collection process

The two reviewers independently extracted data from each of the articles. Discrepancies in the extracted data were evaluated and rechecked. Extracted items included background information, e.g., study design, number of participants, baseline characteristics of the participants, as well as details of the intervention and comparators, outcomes assessment, and follow-up timing. The primary outcome of interest was the pain scores, e.g., Visual Analogue Scale (VAS) pain score ratings at rest and during movement. Secondary outcomes included functional outcomes, e.g., pain-free grip strength (PFG) (newton-force values were converted to kilogram-force), Quick disabilities of the arm, shoulder and hands (QuickDASH) scores and Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire scores.

In assessing the effects of treatment, in this study short-term effects were defined as data recorded at between 4 and 12 weeks after the interventions. Intermediate effects were defined as effects recorded at more than 12 weeks but less than 24 weeks. Outcome data reported as median and range in the original article were converted to mean and standard deviation for data synthesis and analysis.[23,24] Missing standard deviations of changes from baseline were imputed using imputed correlation coefficient values.[25] PFG data in some articles were represented as a ratio; in those cases, the authors contacted the authors of those articles who were available to clarify the data.

### Risk of bias and quality assessment

The authors used the Risk of Bias 2 (RoB 2) tool[26] for the risk of bias assessment which included the following domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of outcomes, and bias in the selection of reported results. Both reviewers independently rated the bias concerns, giving a score of "Low concern", "Some concern," or "High concern" for each item. Risk of traffic light plot and summary plot bias were generated using Risk-Of-Bias VISualization (robvis).[27]

In rating the quality of the evidence, the authors worked independently using Grading of Recommendations Assessment, Development and Evaluation (GRADE).[28] A final consensus was reached through discussion.

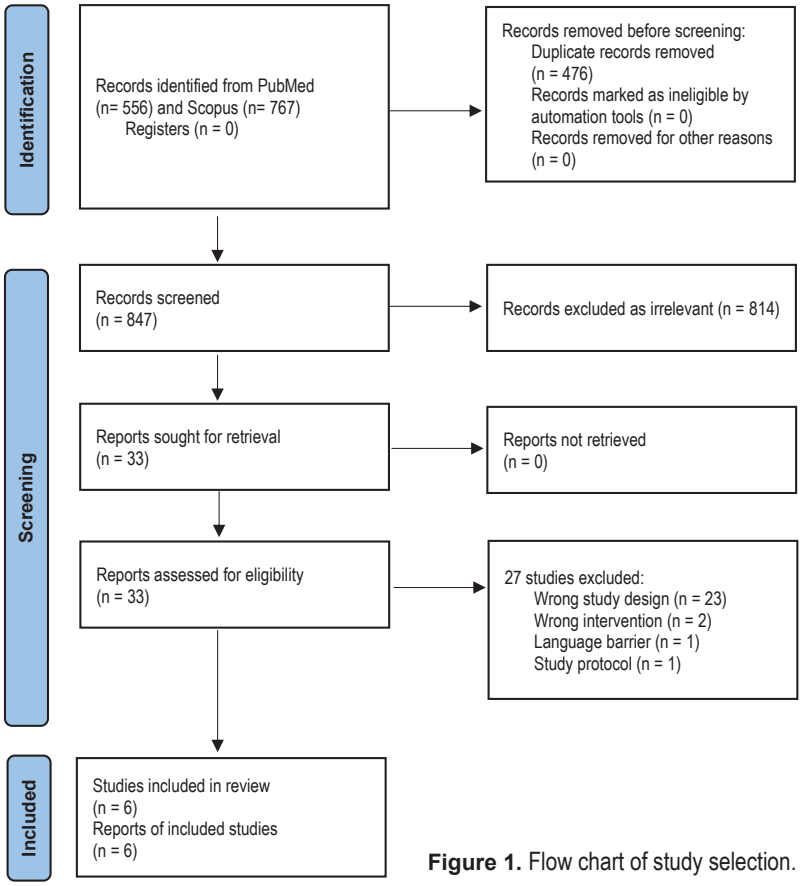


**Figure 1.** Flow chart of study selection.

**Table 1.** Characteristics of included studies

| Study | Year | Design | Number of subjects | | Age (years)[1] | | Female (%) | | Onset (months)[1] | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | DPT | Control | | Control | DPT | Control | DPT | Control |
| Rabogo et al. | 2013 | RCT | 10 | 12 | 50.4 (6.8) | 51.7 (6.8) | 14.0 | 40.0 | 61.7 (48.2) | 55.5 (73.4) |
| Yelland et al. | 2019 | RCT | 40 | 40 | 49.2 (7.2) | 51 (9) | 45.0 | 40.0 | 5.8 (4.07) | 5.25 (6.37) |
| Bayat et al. | 2019 | RCT | 14 | 14 | 46.2 (6.4) | 50.7 (7.5) | 43.0 | 79.0 | 5.7 (2.5) | 10.3 (8) |
| Ahadi et al. | 2019 | RCT | 17 | 16 | 46.7 | 47.3 | 64.7 | 75.0 | 6.82 (5.73) | 4.13 (1.48) |
| Akcay et al. | 2020 | RCT | 27 | 23 | 48.1 (8.9) | 46.7 (8.3) | 78.3 | 70.4 | 21 (32.81) | 12 (4.76) |
| Apaydin et al. | 2020 | RCT | 16 | 16 | 43.3 (7.4) | 45.6 (4.7) | 81.3 | 81.3 | > 6 | > 6 |

[1]Mean (SD); SD, standard deviation; DPT, dextrose prolotherapy; RCT, randomized control trial

### Statistical methods

The authors used Review Manager (RevMan) 5.3 software for data analysis. Continuous data that were originally presented as means and standard deviations were converted to standardized mean differences (SMD) and 95% confidence intervals. Statistical significance was set at $p$-value < 0.05. The $I^2$ statistic was used to analyze the heterogeneity of the data which was categorized as follows: low heterogeneity (25-50%), moderate heterogeneity (50-75%), high heterogeneity (greater than 75%). For outcomes with high heterogeneity, a random-effects model was used.

## Results

### Study selection

Searches of the literature databases identified 1,323 potential studies from which a total of 476 duplications were removed. After screening the remaining titles and abstracts following the PICO model (population, intervention, control, and outcomes),33 studies were selected for inclusion in a comprehensive review. Two studies which had used a combination of sclerotic agents in addition to dextrose, e.g., sodium morrhuate, phenol, and glycerine were excluded.[29-30] Finally, six articles[16-21] which met the study eligibility criteria were included in the meta-analysis. Figure 1 shows the flow of study selection.

### Study characteristics

All six of the included articles, all published between 2013 and 2020, were RCTs. In those studies, a combined total of 124 patients were enrolled in the DPT group with an additional 121 patients in the comparator group. The demographics of the participants and general information about the included studies are shown in Table 1 and Table 2, respectively.

**Table 2.** Summary of interventions, comparators, outcome assessment details and GRADE assessment of the included RCTs

| Study | DPT (percentage of concentration of dextrose): cocktail solutions [total volume per dose] | Comparators | Total DPT injection sessions (timing of injections) | Injection technique | Outcomes | Follow-ups (weeks) | Quality of the evidence (GRADE) |
|---|---|---|---|---|---|---|---|
| Rabogo et al. 2013 | DPT 20%: 4 mL 50% dextrose + 4 mL 0.9% saline + 2 mL1% lidocaine [10 mL] | Wait and see | 1 | US guided injection with a peppering technique | PFG, PRTEE, MRI-based severity scores | 4,8,16,32 | Low |
| Yelland et al. 2019 | DPT 20%: 20 % glucose and 0.4% lignocaine [0.5-1 mL per tender point, total does not exceed 5 mL] | Physiotherapy (education, manual therapy and therapeutic exercise was used in conjunction with a home exercise program) | 4 (0,4,8,12 week) | Blinded injection with a peppering technique | NRS at rest, PFG, PRTEE, GIC, EuroQoL EQ-5D-3L scored | 6,12,26,52 | High |
| Bayat et al. 2019 | DPT 16%: 2.5 mL dextrose20% and 1 mL lidocaine 2% [3 ml] | Steroid: 1 mL methylprednisolone 40 mg/mL and 2 ml of 1% lidocaine (total volume 3 mL) | 1 | Blinded injection with a peppering technique | VAS at rest, QuickDASH | 4, 12 | Low |
| Ahadi et al. 2019 | DPT 20%: 3 mL of 20% dextrose [3 mL] | Radial ESWT (2000 shots, intensity 1.5 bars, 10 Hz; 3 sessions with a weekly interval) | 1 | Blinded injection | VAS at rest, PFG, Pain pressure threshold, QuickDASH | 4,8 | Moderate |
| Akcay et al. 2020 | DPT 15%: 15% dextrose [1.5 mL] | 1.5 mL of saline (0.9% NaCl) | 1 | Blinded injection | VAS at rest, VAS during action, PFG, PRTEE, DASH | 4,8,12 | Low |
| Apaydin et al. 2020 | DPT 15%: 1 ml of 2% lidocaine, 5 ml of 30% hypertonic dextrose, and 4 mL of 0.9% isotonic [5 mL] | Hyaluronic acid: a single dose of 30 mg/2 mL 1500 kDa high-molecular-weigh | 3 (0,3,6 week) | Blinded injection with a peppering technique | VAS at rest, VAS during action, PFG, QuickDASH | 6,12 | Moderate |

DPT, dextrose prolotherapy; GRADE, Grading of Recommendations Assessment, Development and Evaluation; US, ultrasound; PFG, pain-free grip strength; PRTEE, Patient-Rated Tennis Elbow Evaluation; MRI, magnetic resonance imaging; NRS, numeric rating scale; GIC, Global Impression of Change; EQ-5D-3L, EQ-5D three-level version; VAS, Visual Analogue Scale; ESWT, Extracorporeal Shockwave Therapy; QuickDASH, Quick disabilities of arm, shoulder and hands

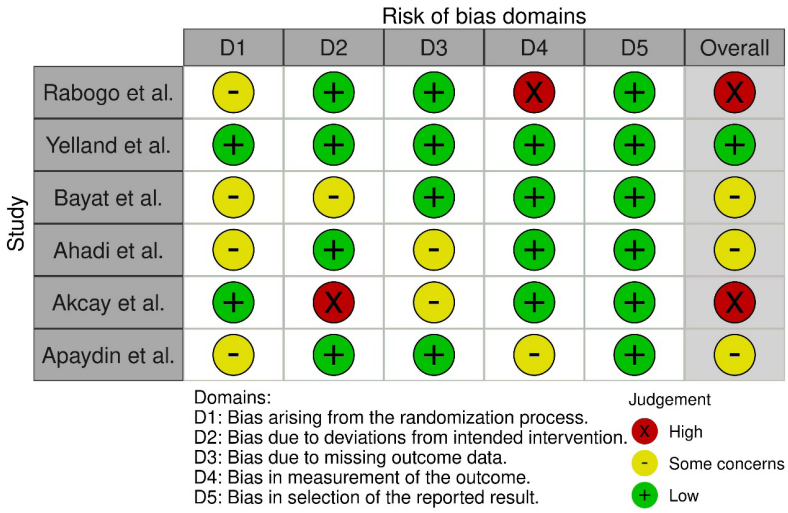


**Figure 2.** Summary of risk of bias assessment of the included study

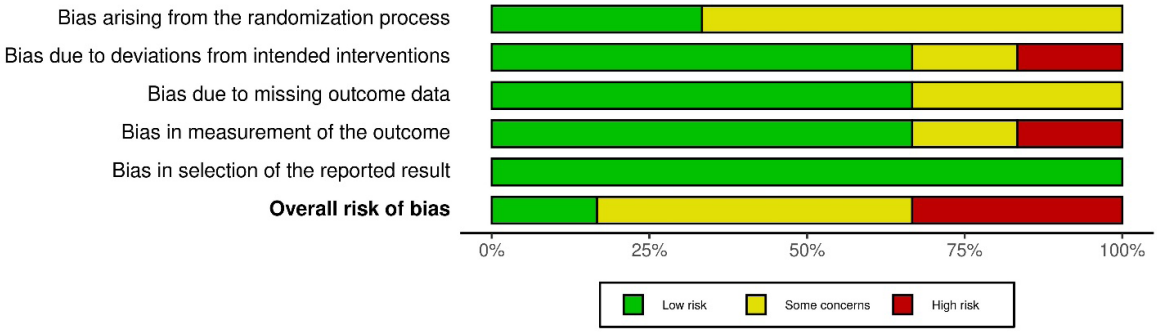


**Figure 3.** Risk of bias summary

## Risk of bias and quality assessment

Only two articles described the allocation concealment process used.[17,20] One study had a high risk of bias in the domain of deviations from intended intervention detected using per-protocol analysis despite a larger than five percent drop-out rate among the prolotherapy group.[20] Two studies raised some concerns regarding bias in missing outcome data.[18,20] One study did not blind the assessor which could potentially have influenced participant-reported outcomes resulting in a high risk of bias in the domain of measurement of the outcome.[16] There was a low risk of bias in the selective report of the outcome of all included articles. (Figures 2 and 3). In summary, the study of Yelland et al.[17] demonstrated a low risk of bias whereas the others evidenced a moderate to high risk of bias. Quality assessment with GRADE revealed that Yelland et al.[17] had a high quality of evidence compared to the low-to-moderate quality in the other studies which was primary due to their higher risk of bias and their small sample size which can lead to imprecision.

## Clinical outcomes

*Pain VAS at rest*

Four studies[18-21] reported the short-term effects (ranging from 4 to 6 weeks) (Figure 4A) and three studies[19-21] mentioned the intermediate-term effects (at 12 weeks) of the pain VAS at rest for DPT versus other comparators (Figure 4B). The results showed that DPT significantly reduced pain scores in the intermediate term (SMD, -0.62; 95% CI [–1.00 to –0.23], P = 0.002, $I^2$ = 0%) (Figure 4B). However, there was no statistically significant difference in the short-term effects (SMD, 0.18; 95% CI [-0.54 to 0.90]; P = 0.62; $I^2$ = 77%) (Figure 4A).

*Pain VAS during movement*

Two studies reported pain VAS during motion in the short term (4 to 6 weeks) (Figure 5A) and the intermediate term (at 12 weeks)(Figure 5B).[20,21] The results showed that DPT significantly reduced pain scores in the intermediate term (SMD, -0.80; 95% CI [–1.30 to –0.29]; P = 0.002; $I^2$ = 17%; Figure 5B). However, there was no significant difference in the short-term effects. (SMD, -0.37;95% CI [–0.81 to 0.07]; P = 0.10; $I^2$ = 0%; Figure 5A).

*Pain-free grip strength*

Four studies[16-18,21] reported PFG effects in the short term (4 to 8 weeks) and three studies[16,17,21] reported intermediate-term effects (12 to 16 weeks). Two studies[17,20] reported PFG as an affected/unaffected ratio, but only one study provided the raw PFG data for the affected side alone.[17] There was no statistically significant difference between DPT and other comparators in the short-term and intermediate-term effects on PFG. ((SMD, -0.13; 95% CI [-0.73 to 0.48]; P = 0.68; $I^2$ = 71%; Figure 6A), (SMD, 0.27;95% CI [-0.95 to 1.48]; P = 0.67; $I^2$ = 90%; Figure 6B)).

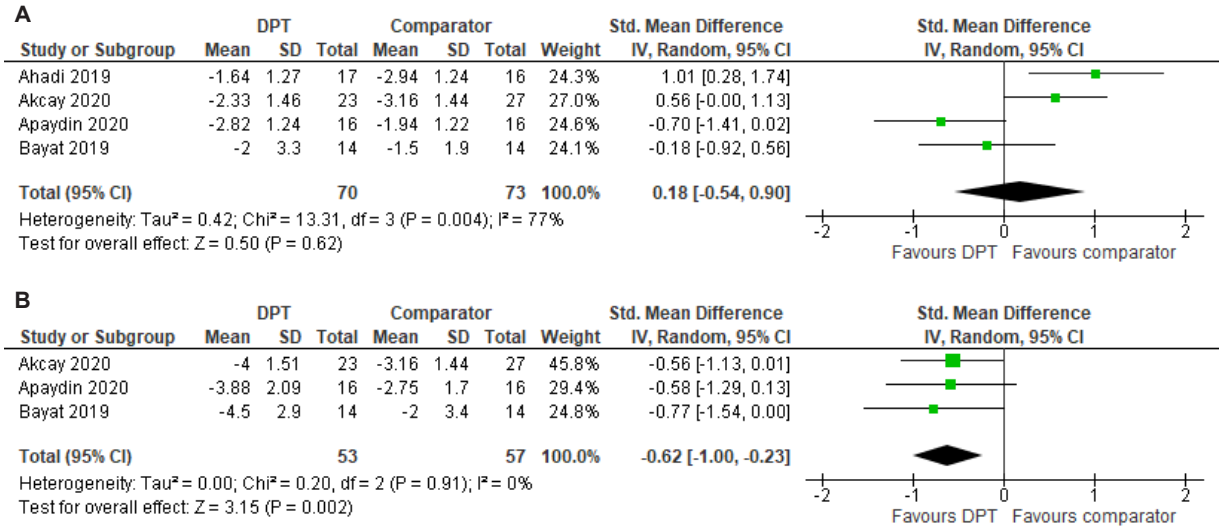


**Figure 4.** Forest plot of pain VAS at rest in the short (A) and intermediate term (B)

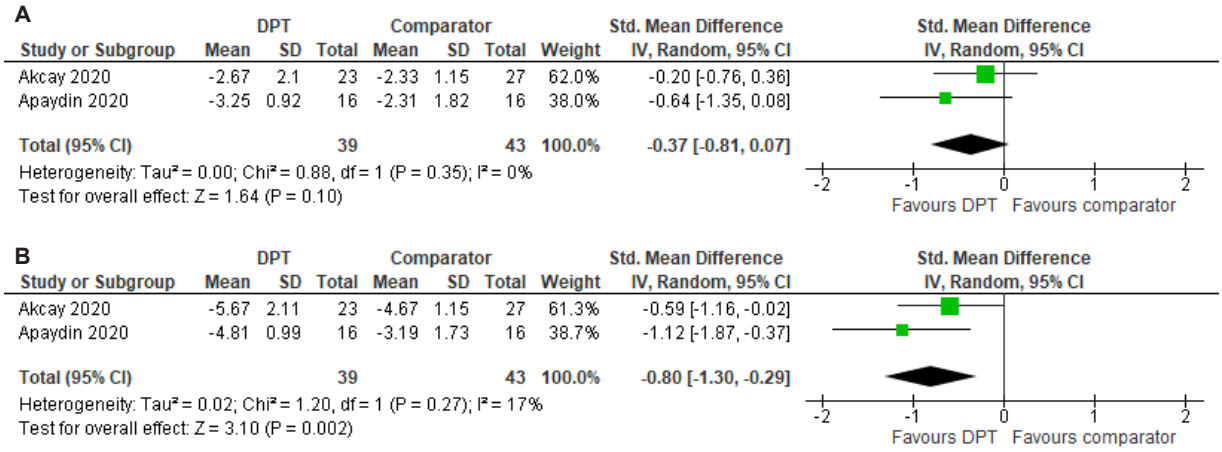


**Figure 5.** Forest plot of pain VAS during movement in the short (A) and intermediate term (B).

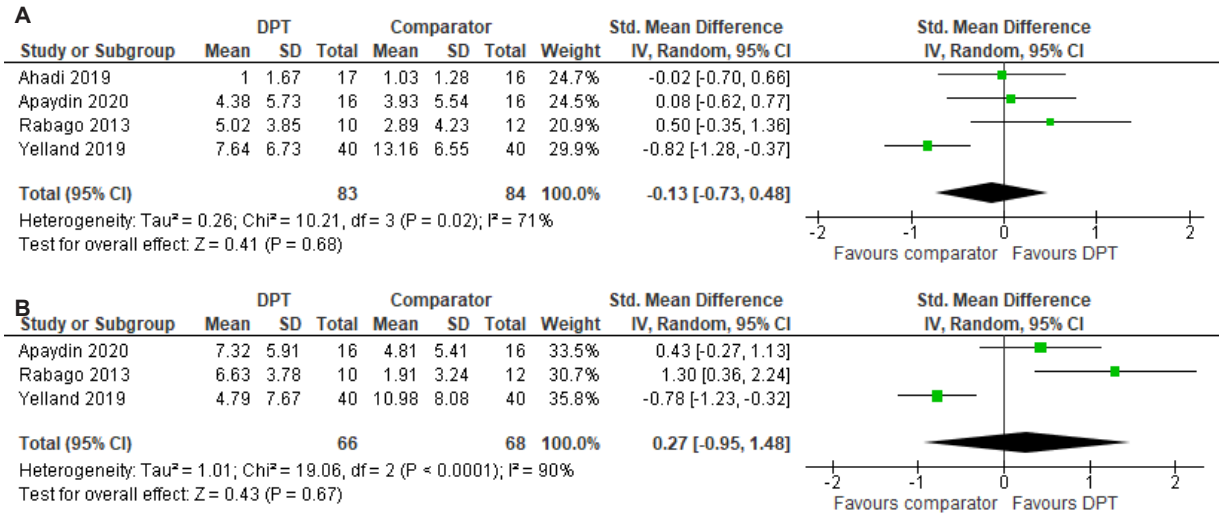


**Figure 6.** Forest plot of pain-free grip strength in the short (A) and intermediate term (B)

**Quick disabilities of arm, shoulder, and hands (QuickDASH)**

Three studies[18,19,21] reported QuickDASH outcomes in the short term (4-6 weeks) (Figure 7A) and two studies[19,21] reported outcomes in the intermediate term (at 12 weeks) (Figure 7B). One RCT used DASH instead of QuickDASH, so that outcome was excluded from our study.[20] The results revealed that DPT could improve QuickDASH scores better than the other treatments (steroid and hyaluronic injections) in the intermediate term. (SMD, -1.30; 95% CI [-1.86 to -0.73]; P < 0.001; I² = 0%; Figure 7B) However, the short-term effects as measured by QuickDASH scores demonstrated no

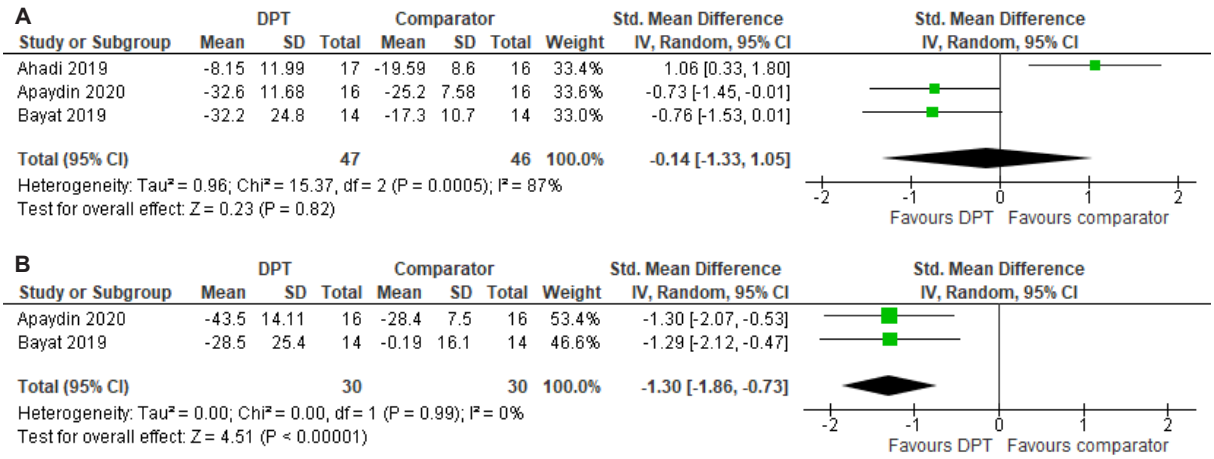


**Figure 7.** Forest plot of QuickDASH in the short (A) and intermediate term (B)

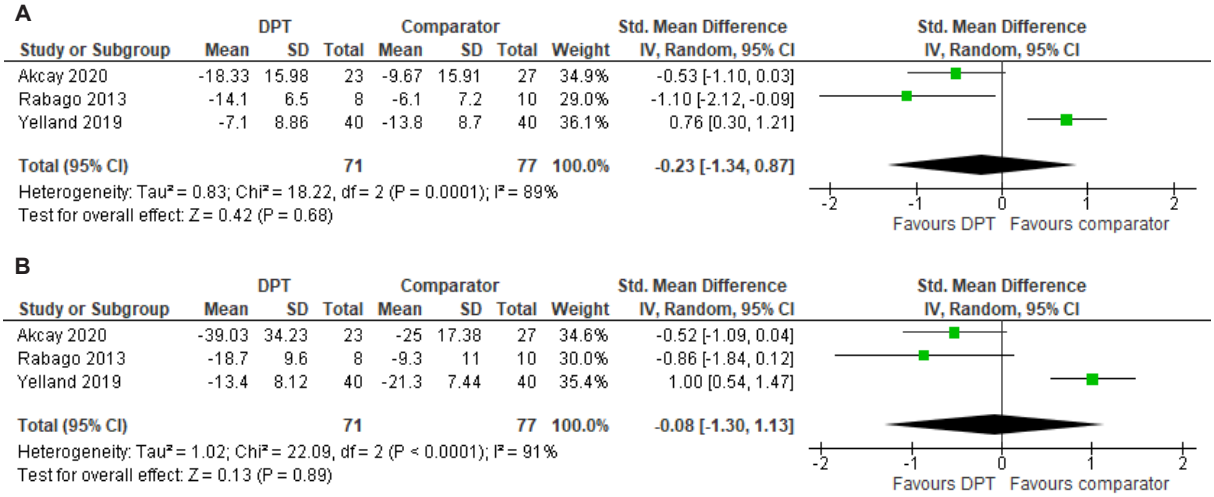


**Figure 8.** Forest plot of PRTEE in the short (A) and intermediate term (B)

statistically significant difference. (SMD, -0.14; 95% CI [-1.33 to 1.05]; P 0.82; $I^2$ = 87%; Figure 7A)

### Patient-Rated Tennis Elbow Evaluation (PRTEE)

Three studies[16,17,20] evaluated the effects of PRTEE in the short term (4 to 6 weeks) and in the intermediate term (12 to 16 weeks). The results revealed no statistically significant difference between DPT and other comparators in PRTEE outcome at any of the assessment points. ((SMD, -0.23; 95% CI [-1.34 to 0.87]; P = 0.68; $I^2$ = 89%; Figure 8A), (SMD, -0.08; 95% CI [-1.30 to 1.13]; P = 0.89; $I^2$ = 91%; Figure 8B)).

## Discussion

A comprehensive review of evidence related to the efficacy of DPT among LET patients found that the DPT group has significantly reduced pain both at rest and during motion in the intermediate term (12 weeks). In function improvement, the DPT group had significantly improved QuickDASH scores compared to other treatments at 12 weeks. Nevertheless, there were only insignificant short-term improvements in pain and function in the DPT group. These results appear to be explained by the fact that the mechanism of DPT requires several months for the regenerative process. Overall, we found that the positive findings were based on underpowered studies with a moderate to high risk of bias, and which thus should be interpreted with a high degree of caution.

We found moderate to high heterogeneity in some outcomes, a result which could be explained by several factors. First, participants included in the studies had subacute to chronic onset of pain, with the mean initial onset occurring between 5.7 and 61.7 months prior to the start of the study. Second, there was a high variation in the injection formula in the DPT group, with the injected volume ranging from 1.5 to 10 ml and the total number of injections varying from 1 to 4. The concentration of DPT, however, was quite consistent, ranging from 15 to 20% dextrose, the amount commonly used in the treatment of tendinopathy.[12] Finally, there were differences in the comparators to DPT, including active and non-active treatments which could have increased the heterogeneity of the results. Unfortunately, we were not able to perform further sensitivity analyses due to the small number of included studies.

Two RCTs of prolotherapy injected solutions that combined dextrose with other sclerosing substances.[29,30] The authors excluded these two studies to in order to determine

the effect of a pure dextrose-containing solution. Finally, only two studies included a comparison of DPT with non-active comparators.[16,20] Rabago et al.[16] compared the efficacy of DPT to "wait and see", the natural history of the disease. The findings of that study demonstrated that DPT could improve functional outcomes as assessed with PTREE better than "wait and see" in both the short and intermediate term. PFG of the DPT group was also greater than the "wait and see" group at 12 weeks. Another RCT[20] which compared DPT with saline injection showed greater pain reduction in the short and intermediate term in the DPT group. Nevertheless, only insignificant differences in improvement of the affected/unaffected PFG were found between the two groups. Although their findings showed that DPT seemed to be more effective than non-active comparators in reducing pain and providing functional improvement, the authors found these two studies[16,20] had a rather high risk of bias, making it difficult to draw conclusions.

One of the included RCTs had a low risk of bias and high quality of evidence comparing the efficacy of DPT with physiotherapy.[17] That study reported that physiotherapy demonstrated superior results to DPT in functional outcome as evaluated by PFG and PTREE. That form of treatment is easily accessible in low- and middle-income countries, although physiotherapy has the drawback of requiring multiple out-patient visits.

A previous meta-analysis reported greater results in pain and functional outcomes with PRP injection compared to corticosteroid injection in LET patients.[2,3] Treatment which focuses on the regenerative process has recently been explored in chronic tendinopathy as well as DPT. The studies of Bayat et al.[19] comparing the efficacy of DPT to corticosteroid injection found significant pain reduction and reduced disability in QuickDASH scores with DPT, although the study had a moderate risk of bias and a high probability of imprecision. Additionally, corticosteroid injection was found to have a detrimental effect at 12 weeks, so the superior efficacy of the DPT compared to the corticosteroid injection should be interpreted cautiously.[7] However, in one study of overall chronic musculoskeletal pain, there was evidence that DPT had a therapeutic effect comparable to that of corticosteroid and PRP injection.[15] Another study reported that steroid injection leads to a higher rate of surgery, although injection could delay the time to surgery.[31] Hence, based on the pathophysiology of the disease and the adverse effects related to injection therapy in LET, DPT or the other regenerative therapy can be considered an alternative to corticosteroids.

Hyaluronic acid (HA) has a proven efficacy in pain reduction and functional improvement in osteoarthritis as well as tendinopathy.[32-33] The main mechanism of HA for osteoarthritis is chondroprotection. In tendinopathy, promoting collagen synthesis in the extracellular matrix is the key mechanism.[33] Results from Apaydin et al.[21] reported greater efficacy of DPT than HA in LET, suggesting consideration should be given to the use of DPT injection in patients living in low- and middle-incomes countries.

When compared to radial ESWT, DPT demonstrated significantly lower efficacy in terms of pain reduction and functional improvement in the short term.[18] However, intermediate to long-term effects were not assessed in that study. In practice, a limitation of ESWT in developing countries is the expense of machine maintenance.

Two important points were identified in this present meta-analysis. First, DPT seems to reduce the severity of pain and disability by 12 weeks. Second, DPT is a good option among the injection therapies even though it has demonstrated lower efficacy than physiotherapy and radial ESWT because it can be performed without ultrasound guidance, using palpation to determine the precise anatomical location, and because it maintains a constant dextrose concentration of 15-20%.

There were some limitations in the present study. (1) The authors selected RCTs that used only pure dextrose, leading to a smaller number of studies included for analysis. The authors did not perform subgroup analysis; thus, the cause of the heterogeneity could not be clearly explained. (2) The comparator groups were varied and there were few studies which included a non-active control. (3) The total injected volume and number of injections varied among the included studies. (4) Only one study[17] evaluated long-term outcomes, so the long-term effect of DPT for treating LET patients could not be evaluated. Further high-quality RCTs which compare DPT to a non-active control is required to obtain more explicit results.

## Conclusions

More high-quality RCTs of dextrose prolotherapy are needed to determine its benefit for patients with LET. The main reason for the inconclusive results of most of the RCTs reviewed was a moderate to high risk of bias. The only study with a reasonable number of participants and a low risk of bias reported that DPT was significantly inferior to the physiotherapy.

## Disclosure

The authors declare that there are no conflicts of interest.


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**Original Article**

# Positive Effects of Group Exercises Using a Resistance Band on Trunk Balance of Elderly Thais in Rural Communities

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## ABSTRACT

*Objectives:* To determine the effects of a group exercise program using a resistance band on the trunk balance of elderly Thais in rural communities.

*Study design:* A quasi-experimental study.

*Setting:* Ten villages in two districts of Phayao Province, Thailand.

*Subjects:* A total of 196 elderly people aged over 60.

*Methods:* The ten villages were randomly divided into two groups of five, the exercise (EX) villages group and the non-exercise (NE) villages group. Participants in both groups, village residents age > 60 were given instruction on the risks and prevention of falls, but only the EX group received training and then participated in group exercises using a low resistance band (a yellow Thera-Band®) for 30 minutes 3 times a week for 8 weeks. They were evaluated using the Berg Balance Scale (BBS) and the Timed Up and Go (TUG) test before and at the end of the study. Comparisons were made both within groups and between groups using the dependent t-test and the independent t-test. The occurrence of falls in the 6 months prior to the study and falls during the study were also recorded.

*Results:* At the conclusion of the study, the EX group (n = 99) had a significant higher BBS score and a shorter TUG time ($p < 0.001$) than before the exercise program, while the NE group (n = 97) had a significantly lower BBS score and a longer TUG time ($p < 0.001$) than at the start of the study. The BBS scores of the EX group were significantly higher than those of the NE group (independent t-test, $p < 0.001$) and their TUG times were also significantly lower (Gaussian process regression, mean difference -1.22 (95%CI = -1.68, -0.75, $p < 0.001$). Of the EX group participants, 28.2% reported a fall in the six months prior to the study as did 25.5% in the NE group. No falls were reported by either group during the 8 weeks of the study.

*Conclusions:* A 30-minute session of group exercises using a low resistance band 3 times a week for 8 weeks can have positive effects on the trunk balance and mobility of elderly individuals living in rural communities.

**Keywords**: elderly, exercise, resistance band, trunk balance, fall

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## Introduction

According to a report from the National Health Security Office, Thailand will become an ageing society, i.e., a society whose median age rises due to rising life expectancy and/or declining birthrates, as the elderly population is expected to be 20.5 million in 2040.[1] A 2015 health survey by the Ministry of Public Health of 6.4 million elderly adults reported 21% of that group could not help themselves and were counted as people with disability, i.e., individuals who require health care as well as social support.[1] During the period 2015 to 2020, there was an increase in the average life expectancy of both the female and male populations in Thailand to 80.10 and 73.28 years, respectively.[2] That suggests an increase in elderly dependency from 14.30% of the population in 2000 to 36% in 2027.[2]

According to an international report on falls, hip fractures, traumatic brain injuries and upper limb injuries are the major underlying causes for fall-related hospital admission.[3] In addition to any significant physical injuries, the psychological impact of a fall or near fall often results in a fear of falling as well as an increase in self-restriction of activities.[4]

In Thailand, two studies have been done of hip fractures in people over 50 years old, one in Chiang Mai for the period 2006-2007[5] and one in Nan for the period 2014-2017.[6] Both studies reported that a simple fall was the most common cause of the hip fractures and that most occurred in individuals over 70.[5,6] More than 80% needed surgery, internal fixation and/or prosthesis replacement at an average cost of treatment of approximately 50,000 baht, 3.1 times more than for treatment of non-surgical cases.[6]

Factors increasing the risk of falls include lack of regular exercise, a low body mass index, and having musculoskeletal, mental, and/or neurological problems.[7-9] It is recommended that the elderly should do exercises such as muscle stretching, exercises to strengthen the ankle muscles, and physical activities during the day to delay the onset of dysfunction of trunk balance and to reduce the risk of falls.[9-13]

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There have been several studies of exercises for the elderly in Thailand. Ballroom dancing,[14] exercises with a long stick[15] and Tai Chi Chuan[16] have been reported to improve trunk balance and to reduce the risk of falls. Exercises with resistance bands have become more popular among all age groups, including elderly, because they are convenient to do anywhere.[17] There have been studies in Thailand of exercises with elastic or resistance bands. Some studies of exercises using resistance bands, e.g., Thera-Band®, have reported significant improvement in muscle strength of the upper and lower extremities[18] as well as balance in the elderly.[19] One small experiment which involved 12 weeks of exercise with an elastic band reported improvement in strength and endurance of the arm muscles and endurance of the leg muscles in older adults.[20] A comparison study of a home-based exercise program comparing stationery cycle elastic bands and resistance bands reported that leg muscle strength increased in both groups. However, in that study the dropout rate was high, and the level of resistance of the band was not specified.[21] A study of elderly villagers reported that individuals exercising with an elastic band improved their physical fitness, muscle strength, flexibility and cardiovascular fitness compared to others who did not exercise.[22]

In Thailand, village-level groups of elderly people have been formed and have received support from health-promoting hospitals, encouraging the elderly to exercise as a part of a health promotion program. In Mae Jai sub-district of Phayao Province in the north of the country, a community survey of exercises done by elderly people found that 63.7% had done exercises in the previous month, and that cycling was the preferred mode of exercise (32.2%) followed by brisk walking (26.7%).[23] The researcher, a physiatrist at the provincial hospital which is responsible not only for rehabilitation but also for disease prevention and health promotion, thought that exercises with resistance bands would be safer than cycling and might benefit a wider range of elderly people. In another study, community-based group exercise programs have been shown to have long-term adherence rates of almost 70%.[24] However, the above-mentioned studies have some limitations, e.g., a small number of participants,[20,22] high dropout rates,[21] not specifying the level of resistance of the bands used.[21-22] Additionally, some of the studies included institutionalized elderly people.[19] The present study avoided those limitations by using a group exercise program that involved a specific single low resistance band, a yellow Thera-Band®, to evaluate the effects of exercise on trunk balance among the elderly living in rural areas.

## Methods

This quasi-experimental research study was approved by the Phayao Hospital Research Ethics Committee, (HE-60-02-0010).

### Participants

The districts of Phukamyao and Muang in Phayao Province were purposively selected as the study area because of their high number of elderly people compared to others districts. Using a simple randomization, five villages from each district were selected: five were assigned to be the exercise (EX) group villages and five to be the non-exercise (NE) group villages. Residents of these villages who were at least 60 years old were invited to participate in the study. After receiving informed consent, the health records of the participants were obtained from the public health database and their physical fitness and health problems were assessed. Inclusion criteria were the ability to independently perform daily self-care activities and to be able to walk without a gait aid. Individuals who had a medical history of ischemic heart disease or heart failure, dizziness caused by low blood pressure (hypotension), uncontrolled high blood pressure, or acute arthritis/arthralgia in the upper or the lower extremities, were excluded from the study.

### Intervention

After screening based on the inclusion and exclusion criteria, the participants in both groups were asked about the occurrence of falls in the previous 6 months. Each group then separately attended a 2-hour health education program on risk factors for and how to prevent falls which was conducted by an internist. Participants in the NE group were advised to perform their daily physical activities as usual, whereas the participants in the EX group received a low resistance band (a yellow Thera-Band®) 1.5 m long and with a resistance of 1.3 kg with 100% elongation and 2.0 kg with 200% elongation, and were taught how to perform exercises using the resistance band.

Exercises for participants in the EX group included 5 different calisthenics for warm-up followed by 8 exercises using the resistance band (see Appendix). The exercise program was modified from a study conducted by the Department of Health, Ministry of Public Health[20] and was conducted by trained health personnel from health promoting hospitals, village headmen and/or leaders of village elderly groups. The duration of the exercises was 30 minutes per session, and participants were instructed to practice 3 times a week for 8 weeks, a total of 24 sessions. This regimen was based on a study that found 8 weeks of exercising with a Thera-Band® resistance band yielded gains in the Berg Balance Scale score and in the Timed Up and Go (TUG) test.[21] Participants who were absent for more than 3 consecutive sessions and those who were not re-assessed at the end of the study were counted as dropouts and were not included in the analysis. Participation in the EX group was monitored and individuals were reminded to join the group exercise sessions. If they were unable to join a group exercise session, they were told they should practice the exercises at home. If a resistance band became torn, a new one was provided gratis. Participants

in the EX group were asked to record the number and duration of exercises in a logbook provided by the study. Nurses at health promoting hospitals helped collect the logbooks for the researcher.

### Outcome measures

The primary outcome measure was the Berg balance scale (BBS), which has demonstrated adequate internal consistency reliability, inter-rater reliability, and construct validity for measuring balance in community-dwelling older adults.[25] The secondary outcome measure was the Timed Up and Go test (TUG).[22] A systematic review of TUG found it to be a valid and reliable mobility test. It is recommended in fall prevention guidelines, TUG is moderately associated with BBS, and can be used in most settings.[26] In this study, trained research assistants (physical therapists and occupational therapists) were responsible for the assessments. They assessed participants before and at the end of the 8-week group exercise program. In addition, the participants were asked whether any falls had occurred during the 8 weeks of the study.

### Statistical analysis

Descriptive statistics, including frequency, percentage, mean and standardization, were used to describe the demographic data. Chi-square and the independent t-test were used for comparing baseline data between the EX and the NE groups. The dependent t-test was used to evaluate differences between means of BBS scores and TUG times before and after intervention within groups, and the independent t-test was used to evaluate differences between the groups.

## Results

Of a total of 300 elderly individuals from the 10 study villages, 280 met the inclusion criteria and 20 were excluded due to various reasons (Figure 1). At the start of the study, there were 220 participants (110 in each group) all of whom voluntarily participated in a 2-hour educational program on the risks for and means of prevention of falls. During the study, 11 participants (10%) in the EX group failed to complete the program, 8 moved out of the study village, 3 were hospitalized for treatment of illness not related to falls, and in

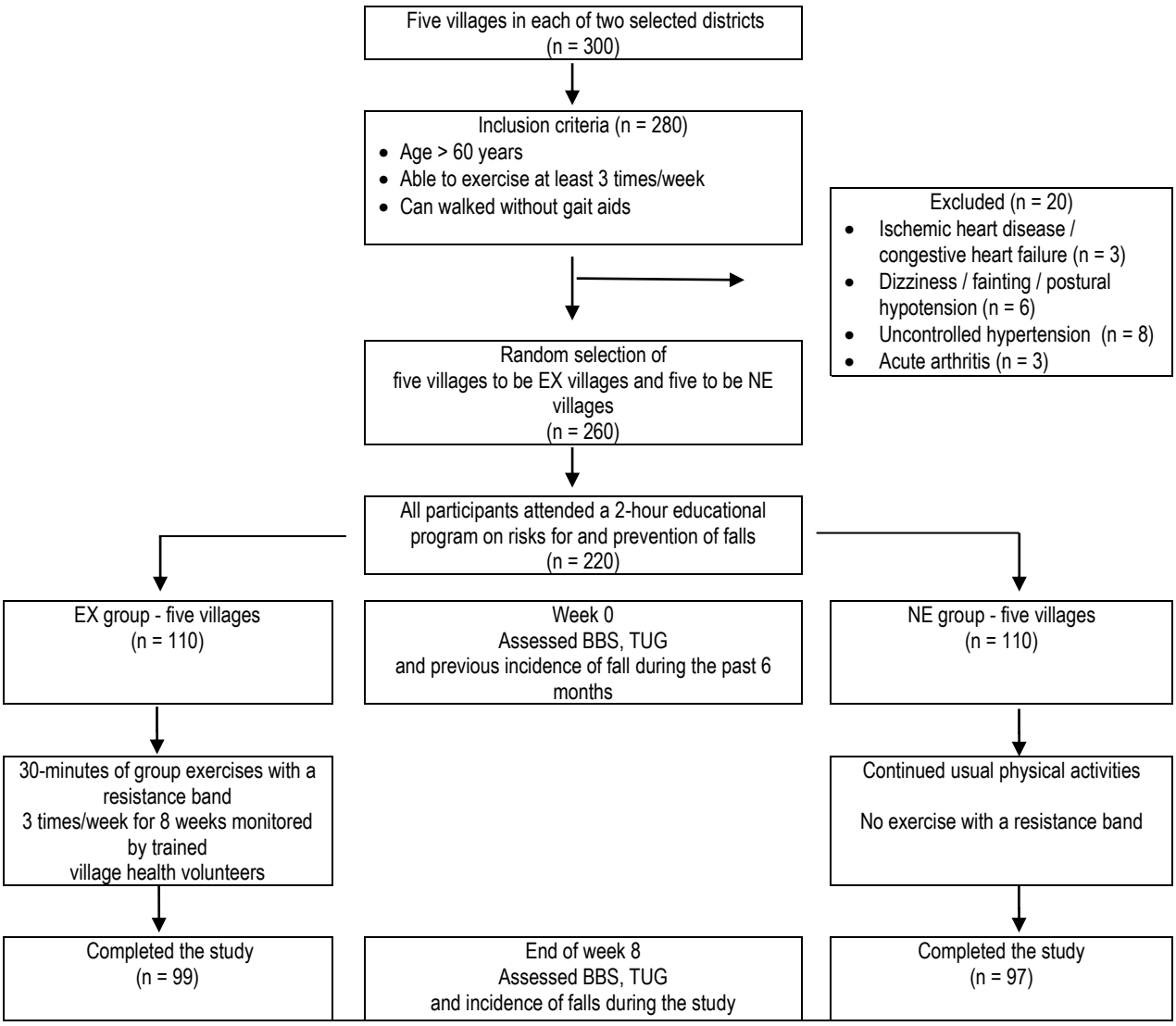


**Figure 1.** Flowchart of the study

**Table 1.** Socio-demographic data of participants who completed the study

| | Exercise group (n = 99) | Non-exercise group (n = 97) | *p*-value |
|---|---|---|---|
| Age[1] | 66.95 (5.32) | 67.75 (5.85) | 0.244[a] |
| Gender (male)[2] | 36 (18.37) | 44 (22.45) | 0.20[b] |
| Body mass index (BMI)[1] | 22.05 (3.25) | 21.98 (3.61) | 0.86[b] |
| Marriage status (married)[2] | 93 (47.45) | 91 (46.43) | 0.942[b] |
| Education level (primary or below)[2] | 93 (47.45) | 91 (46.43) | 0.942[b] |
| Income below 3,000 baht/month[2] | 80 (40.82) | 78 (39.79) | 0.889[b] |
| Alone more than 16 hours/day[2] | 3 (1.53) | 4 (2.04) | 0.221[b] |

[1]Mean (SD), [2]number (%)

[a]Independent t-test; [b]chi-square test; * $p < 0.05$

**Table 2.** Comparison of Berg Balance Scale (BBS) scores and Timed Up and Go (TUG) times of the EX and NE groups both between and within groups pre- and post-study

| | Exercise group (n=99) | | Non-exercise group (n=97) | | t | *p*-value |
|---|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | | |
| BBS score | | | | | | |
| Pre-study | 54.48 | 1.89 | 54.84 | 1.57 | 1.406 | 0.161[a] |
| Post-study | 55.30 | 1.25 | 53.28 | 1.87 | 9.013 | < 0.001[a*] |
| | t 4.663, $p < 0.001$[b*] | | t 9.047, $p < 0.001$[b*] | | | |
| TUG time (seconds) | | | | | | |
| Pre-study | 9.44 | 2.16 | 8.34 | 2.01 | 3.700 | < 0.001[a*] |
| Post-study | 8.42 | 2.22 | 8.83 | 2.14 | 1.331 | 0.185[a] |
| | t 5.113, $p < 0.001$[b*] | | t 3.808, $p < 0.001$[b*] | | | |

[a]Independent t-test; [b]dependent t-test; *$p < 0.05$

**Table 3.** Mean difference in TUG time post study between the exercise and non-exercise groups

| | Mean difference | Standard Error | t | 95%CI | *p*-value |
|---|---|---|---|---|---|
| Group | -1.22 | 0.23 | -5.20 | -1.68, -0.75 | < 0.001* |

Gaussian process regression; *$p < 0.05$

**Table 4.** Incidence of falls in the 6 months prior to the study and during the study

| | Exercise group (n = 110) | Non-exercise group (n = 110) |
|---|---|---|
| During the 6 months prior to the study | 31 (28.2) | 28 (25.5) |
| During the 8 weeks of the study | 0 (0) | 0 (0) |

Number (%)

the NE group 13 (11.8%) did not complete the program due to absence from the post-study re-assessment. At the end of the study, there were 87 participants in the EX group (87.9%) who had attended all 24 sessions and 12 participants (12.1%) who had missed only one session. The baseline socio-demographics of the two groups are shown in Table 1.

The pre-study BBS scores were not significantly different between the two groups, but the post-study score of the EX group was significantly higher than that group's pre-study score ($p < 0.001$) and significantly higher than the NE group ($p < 0.001$) (Table 2). Regarding the TUG time, there was no statistically significant difference between the two groups post study; however, the NE group had a significantly shorter pre-study average time than the EX group ($p < 0.001$) (Table 2). Gaussian process regression was applied to adjust for the difference in TUG times at the beginning point before testing the effect of intervention on TUG time. The TUG time of the EX group was significantly shorter than NE group at post study with a mean deference of -1.22 (95%CI = -1.68, -0.75, $p < 0.001$) (Table 3).

The overall incidence of falls during the 6 months period immediately prior to the study was 26.8%: 28.2% in the EX group and 25.5% in the NE group. Neither group reported falls during the study (Table 4). Sixteen participants received a replacement resistance band when their original band became torn due to practicing the exercises on a rough surface.

## Discussion

The study found that after the healthy elderly had practiced the group exercises using a low resistance exercise

band for approximately 30 minutes 3 times per weeks for 8 weeks, trunk balance improved as shown by the EX group's significantly higher BBS scores and shorter TUG times at the end of the study compared to the negative results in the NE group (lower BBS scores and longer TUG times at the end of the study). The findings of the EX group are in line with previous studies that reported exercises with a resistance band improved the balance of elderly adults.[20,21]

In this study, the initial mean BBS scores of both groups were close to the maximum score of 56. The average BBS scores in the NE group declined about 1.5 points, from 54.84 to 53.28 at the end of the study, but the EX group increased about 1 point, from 54.48 to 55.30. The value of recommending such exercises for 8 weeks for a gain of only 1 point may not be immediately obvious. However, according to a study by Shumway-Cook et al.,[27] a 1-point increase in BBS score was found to lead to a reduction in the probability of falling, i.e., in the BBS score range of 54 to 46, a 1-point decline is associated with a 6% to 8% increase in fall risk, while in the range of 56 to 54, the same 1-point reduction is associated with a 3% to 4% increase in fall risk.[27]

In addition to BBS, this study also assessed TUG time. The average pre-study TUG times of both groups were less than 10 which is normal for healthy older adults based on the manual of evaluation and screening older adults published by the Department of Medical Service, Ministry of Public Health.[28] At the end of this study, the average TUG time was shorter in the EX group but longer in the NE group, with a mean difference of 1.22 seconds which was statistically significant (Table 3).

How does a program of exercises with a low resistance exercise band improve trunk balance? As shown in the appendix, all the exercises focus on isometric and isotonic contraction of muscles of the upper extremities. While distal muscles act as agonists and antagonists, the proximal muscles, such as trapezius and latissimus dorsi which are superficial muscles of the back, act as stabilizers. In addition, when exercising the upper extremities, especially bilateral shoulder extension and unilateral horizontal shoulder extension in a standing position, core trunk muscles are indirectly activated.[29]

Previous studies of exercises with resistance/elastic bands have demonstrated increased strength of upper and lower extremities.[19-20] This study, however, did not measure participants' muscle strength, so it cannot be concluded that the observed improvements in trunk balance were due to an increase in muscle strength. A low resistance band such as the one used in this study is suitable for elderly individuals. The exercise program in this study was not designed to increase loads over the duration of the study. For strengthening exercises, bands with higher resistance are recommended.

Exercise programs using resistance bands can help the elderly to improve their balance over a period of from 5 to 12 weeks.[19-21] This study's results are comparable to a previous study of an 8-week exercise program with resistance bands,[21] including positive effects on trunk balance. In that study,[21] it was not mentioned whether a low, medium or high resistance band was used. In a comparison between a resistance band and a cycle with elastic resistance bands, both were found to result in significant improvement in both BBS and 8-foot TUG results.[21] In this study, the NE group had an increase in TUG time and a decline in BBS score, suggesting an increase in fall risk.[27] This result would indicate that elderly individuals should exercise regularly to maintain good balance.

Although this study found positive effects on the trunk, that only demonstrates that the exercises program was safe during the period of the study as no EX group participants reported falls. Data on the incidence of falls after the end of the exercise program, which could have permitted evaluation of the reduction in the incidence of falls over a longer period, was not recorded. The 26.8% of the participants in this study who reported falls during the 6 months prior to the study is similar to the 27% reported in a study of falls and balance in the elderly which included regular exercises conducted in Khon Kaen province, Thailand. The Khon Kaen study reported the causes of falls as follows: inappropriate environment (42.9%), inappropriate shoes (14.3%), alcohol drinking (14.3%) and fast movement (8.6%).[30]

Compared with other studies using different modes of exercise, e.g., walking on a treadmill with partial body weigh support,31 exercise programs using a resistance band are cost-effective. Resistance bands cost about 160 baht per piece, much less than a dumbbell or weight training equipment. A resistance band can be easily carried anywhere, and exercises with a band can be done even in a small area, unlike dancing exercises[14] and exercises with a long stick[15] which need a larger space (and perhaps more training). The resistance band does have one disadvantage: it is not durable when used on a rough surface, as reported by the participants in this study. It should, therefore, be used on a smooth surface or else a resistance band made of a different material must be selected. A Thai-style braided rubber rope is cheaper than most resistance bands, but the level of resistance of the rope is inconsistent, depending on the number of rubber bands used in each loop.[32]

In planning this study, the researcher reduced selection bias by using simple randomization when selecting villages and by increasing the sample size by purposively recruiting from two districts with a high percentage of elderly people. Design bias was reduced by having participants from the same village all be in the same group, either EX or NE. The participant drop-out rate was reduced by having the group exercises conducted and monitored by trained local health personnel and village leaders.

This study had some limitations: there was no sample size calculation, no data on participants' physical activities (other than the exercise program), no sub-group analysis of participants who reported falls during the 6 months prior to

the study, and no long-term follow-up study to determine if the incidence of falls declined. A well-planned prospective cohort study is needed to determine if an exercise program using a low resistance band can significantly reduce the incidence of falls in the elderly and whether using a higher resistance band or increasing the level of resistance over time would result in better muscle strength and trunk balance.

## Conclusions

A group exercise program consisting of 5 calisthenics for warm-up and 8 exercises using a low resistance band such as a yellow TheraBand® for 3 sessions per week for 8 weeks can increase BBS scores and shorten TUG times, thus indicating improvement in trunk balance and mobility of functionally independent elderly persons in rural communities. It is noteworthy that having the group exercises facilitated and monitored by trained health village volunteers and health personnel from a health promoting hospital in this study helped achieve a high level of adherence to the program. In the group of individuals who did not participate in the 8-week exercise program, there was a decline in trunk balance although factors related to that decline were not immediately apparent. A group exercise program using a low resistance band is a safe option to help elderly individuals in rural communities maintain or improve their trunk balance and potentially reduce their risk of falls.

## Disclosure

The researcher received no compensation from the Thera-Band® Company.

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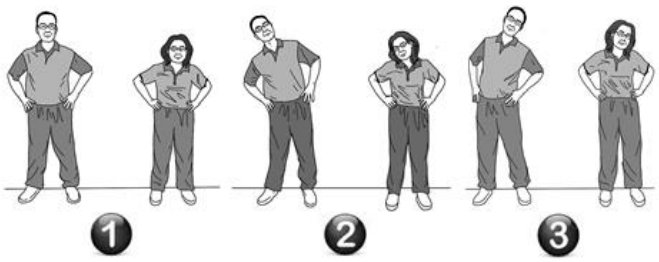
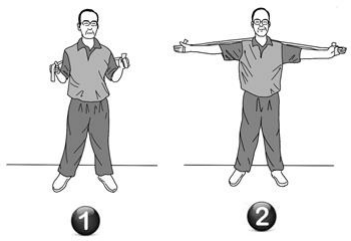
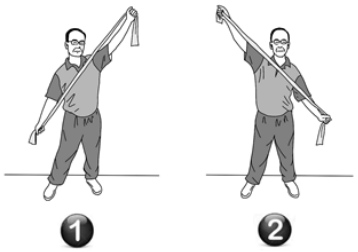
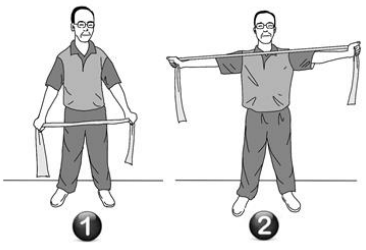
## Appendix: Exercise program for improving trunk balance and prevention of falls

**Instruction:**

The starting position is standing upright with feet apart as wide as the shoulders and looking straight ahead.
Start from Part A, 5 simple calisthenics exercises to warm up your body.
Then, do Part B, 8 exercises with a resistance band.
Repeat regularly, at least 3 days per week.

<table>
<tr><th colspan="2">Part A. Simple calisthenics for warm-up</th></tr>
<tr><td colspan="2">  </td></tr>
<tr><td colspan="2">Exercise 1: Neck and side bending<br>Bend to the right, hold for few seconds, and then to the left.<br>Repeat 10 times for each side.</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Exercise 2: Trunk twisting<br>Turn your body to the right, and then to the left.<br>Repeat 10 times for each turn.</td><td>Exercise 3: Raising hands up and down<br>Raise the right hand up and lean the body to the left, and then repeat on the opposite side.<br>Repeat 10 times for each side.</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Exercise 4: Shaking hands<br>Shake both hands 10 times.</td><td>Exercise 5: Ankle rotation<br>Rotate the right ankle 10 times.<br>Repeat 10 times, then switch to the opposite side and repeat.</td></tr>
</table>

| Part B. Exercises with a resistance band | |
|---|---|
|  |  |
| **Exercise 1:** Stretching the band out laterally<br>Start with the elbows bent at the chest level; then stretch the band by straightening the arms at shoulder level. Hold and count to 5;<br>Then return to the starting position.<br>Repeat 10 times. | **Exercise 2:** Stretching one end of the band in front<br>Start with the elbow bent at chest level, then stretch the band by extending the left elbow and moving the left foot forward. Hold and count to 5;<br>Then return to the starting position.<br>Repeat 10 times, then switch to the opposite side and repeat. |
|  |  |
| **Exercise 3:** Stretching the band forward in a diagonal direction<br>Pull the band upward in front of the body with one hand and downward with the opposite hand.<br>Hold and count to 5.<br>Repeat 10 times, then switch to the opposite side and repeat. | **Exercise 4:** Stretching the band backward in a diagonal direction<br>Pull the band upward with one hand and downward and backward with the opposite hand.<br>Hold and count to 5.<br>Repeat 10 times, then switch to the opposite side and repeat. |
|  |  |
| **Exercise 5:** Stretching the band while raising it upward<br>Place the band in front of the body at hip level. Slowly stretch it while lifting it to shoulder level with both arms straight.<br>Hold and count to 5. Then return to the starting position.<br>Repeat 10 times. | **Exercise 6:** Stretching the band up<br>Step on the band with both feet.<br>Pull the elastic band up until the elbows are bent at the waist level. Then pull it up further to chest level.<br>Hold and count to 5. Then return to the starting position.<br>Repeat 10 times. |

| | |
|---|---|
|  |  |
| **Exercise 7:** Stretching the band with one hand<br>Step on the band with the left foot.<br>Pull it up with the left hand until the elbows are bent at the waist level. Lean the body to the right side.<br>Hold and count to 5.<br>Then return to the starting position.<br>Repeat 10 times, then switch to the opposite side and repeat. | **Exercise 8:** Stretching the band with one foot<br>Step on the band with the right foot.<br>Pull the band up while lifting the right foot.<br>Hold and count to 5.<br>Then return to the starting position.<br>Repeat 10 times, then switch to the opposite side and repeat. |

**Original Article**

# Effects of Three Different Programs of Static and Dynamic Balance Training on Agility, Stability, and Balance in Healthy Male University Students: A Quasi-Experimental Study

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## ABSTRACT

*Objectives:* To determine the effects of three different programs of static and dynamic balance training on agility, stability, and balance in healthy male university students.

*Study design:* A quasi-experimental design.

*Setting:* Walailak University, Nakhon Si Thammarat, Thailand.

*Subjects:* Thirty-six healthy male university students aged 18-25 years with functional ankle disability index score equal to 100 and body mass index between 18.5-22.9 kg/m$^2$.

*Methods:* The participants were allocated by block randomization into three groups. Group A (n = 9) received static balance training for 6 sessions followed by dynamic balance training for 6 sessions. Group B (n = 11) received dynamic balance training for 6 sessions followed by static balance training for 6 sessions. Group C (n = 12) alternated between static and dynamic balance training for 12 sessions. The participants underwent one position for one session every other day. The total time of the training program was 15 minutes for each session. Agility, ankle stability, and balance before training and after completion of the 12$^{th}$ session were analyzed between the three groups by using one-way ANOVA and within the groups by paired simple t-test and with a *p*-value < 0.05.

*Results:* There was no significant difference in agility, ankle stability, and balance between the three groups ($p > 0.05$). When analyzing before training and after completion of the 12$^{th}$ session, a significant difference was found in agility, ankle stability, and balance within Group A, B, and C ($p < 0.05$).

*Conclusions:* The results of the three training programs were not different. Nevertheless, the three different programs of static and dynamic balance training showed an improvement in all variables after completion of the 12$^{th}$ training session. Therefore, a healthy person can use any of the three different training programs for improving agility, ankle stability, and balance.

**Keywords:** agility, balance, exercise program, lower extremities, stability

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## Introduction

Daily movement takes place in the lower limbs, which relies on hip, knee, and foot coordination. Healthy university students aged 18-26 years have experienced 54% of musculoskeletal problems, and the top three problems are with the lower extremities: hip and thigh at 24.9%, ankle and foot at 19.3%, and knee at 17.1%.[1] The causes of the problems in daily life activity have resulted from trauma (26.7%), playing sports (18.8%), running (18.0%), and idiopathic factors (9%).[2] Each stable step in walking indicates effective lower extremity function depending on kinetic and kinematic factors.[3,4] The kinetic factors consist of power of the lower extremities, alignment of the joint forces, and momentum. The kinematic factors consist of stepping speed, lower limb angle, and lower limb velocity.[5] The kinetic and kinematic factors are related to physical function (e.g., muscular strength, lower limb stability, flexibility, cardiovascular endurance, balance, coordination, and neuromuscular control). Effective lower extremity movement will result in increased ability to engage in physical activity.[6,7]

Lower limb exercises are not only crucial for people with health problems but also for athletes with injuries.[8] Athletes with lower extremity problems require a rehabilitation program to effectively return to sports activity. Young athletes need to train their lower extremities to perform sport-specific skills at a high level.[9] In addition, a study in staying healthy found insufficient training to address physical activity problems, especially in adolescents who were unable to reach their goals of moderate to vigorous physical activity.[10] Exercise programs are essential to increasing physical activity and increasing the effectiveness of locomotion in routine activities.[11] A previous study has found that increased exercise prescription through physical activity is related to a better quality of life in healthy people and university students.[11] Some research found that university athletes who undergo

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physical training can prevent lower limb musculoskeletal problems.[9]

Previous studies have found that musculoskeletal problems are associated with physical fitness, such as power, speed, flexibility, balance, and agility.[12,13] In addition, the studies have found that balance, agility, and stability are associated.[14,15] Balance training can improve agility and stability.[16]

Static balance training promotes the body's ability to maintain its center of gravity on a support base.[17] Static balance training increases awareness of the joints or joint proprioceptive sense, balance, and muscle onset latency.[17,18] In contrast, dynamic balance training promotes the body's ability to maintain its center of gravity on a support base with a constantly changing center of gravity and base.[17] Dynamic balance training increases the awareness of joints, strength of tendon muscle and ligaments, kinesthesia joints motion, balance, and coordination.[17,19] Both types of training increase agility while playing sports and engaging in various activities that depend on balance.[20] Furthermore, both types of training consist of static and dynamic balance combined with body movements that help work with the neuromuscular, musculoskeletal, and proprioceptive systems; and both trainings reduce the incidence of injuries in the ankle and lower extremities.[17,21] Literature reviews have shown that there has not been a study to compare the effects of static and dynamic balance training on agility, stability, and balance. Our pilot study found that static, dynamic, and alternating balance trainings seem to improve agility, stability, and balance. However, the effects of training still need to be investigated further.

The primary purpose of this study was to compare the effects of three different programs (static followed by dynamic balance training, dynamic followed by static balance training, and alternating between static and dynamic balance training) after 12 training sessions to determine their suitability for increasing agility, stability, and balance in a short period. The secondary purpose of this study was to compare the effects before and after the completion of the 12$^{th}$ training session within the groups that showed an improvement in the results in our pilot study. The study was conducted among healthy male university student volunteers without a history of musculoskeletal injury.

## Methods

### Study design

This research was approved for ethical consideration by the Ethics Committee of Human Research, Walailak University. It was performed under the Declaration of Helsinki (Ethic of WUEC No. 14/095). This study was a quasi-experimental design among male students from Walailak University.

### Participants

The number of participants in this study was calculated by G-Power Version 3.1.9.4 after the pilot study in a sample of 10 people and by performing testing according to the research procedures. The values of the balance test were used in the calculations because they covered the number of participants of all variables in this study. The mean and standard deviation value of the balance test was 31.25 and 25.10, respectively. The participants were divided into three groups, with 12 persons per group (36 male volunteers).

For the inclusion criteria, the participants had to meet the following requirements: (1) right leg dominance, (2) age between 18-25 years old, (3) body mass index between 18.5-22.9 kg/m$^2$, and (4) functional ankle disability index (FADI) score equal to 100. The exclusion criteria included the following conditions affecting balance: (1) history of accidents or disorders of the musculoskeletal system, (2) disorders of the nervous system, (3) disorders of the cardiovascular system, (4) disorders of the respiratory system, (5) drinking alcoholic beverages within 24 hours before the test, and (6) taking drugs (e.g., muscle relaxant, antidepressants, and anti-seizure drugs) within 24 hours before the test. The enrollment method is shown in Figure 1.

### Research equipment

The research tools included the following: (1) functional ankle disability index (FADI) test, (2) an ankle disk (Physio-Room® Air Stability Wobble Balance, Model AB305107, Physioroom Company, Burnley, UK), (3) a mini trampoline (Contrix® Trampoline, Model 68559, CONTRIX INC., New York, USA), (4) a metal measuring tape, (5) a metronome, (6) six cones, (7) a football, (8) three tripod canes, (9) marking tape, and (10) a stopwatch.

### Research procedure

After passing the inclusion-exclusion screening criteria, the volunteers signed an informed consent form and were allocated by block randomization into three groups. Before and after training, stretching was performed to prevent soft tissue injury.

The static balance training program with an ankle disk was divided into six positions and the dynamic balance training program with a mini trampoline was divided into six positions that were arranged from easy to hard. The participants underwent one position for one session every other day. The participants performed 3 repetitions/set within 2 minutes/repetition, 2 sets/session with 30 seconds of rest between repetitions, and 1 minute of rest between sets. The total time of the training program was 15 minutes for each session.

Group A received static balance training for 6 sessions followed by dynamic balance training for 6 sessions. The training program was arranged as follows: Session 1 practiced Static 1, Session 2 practiced Static 2, Session 3 practiced Static 3, Session 4 practiced Static 4, Session 5 practiced Static 5, Session 6 practiced Static 6, Session 7 practiced Dynamic 1, Session 8 practiced Dynamic 2, Session 9 practiced Dynamic 3, Session 10 practiced Dynamic 4, Session 11 practiced Dynamic 5, and Session 12 practiced Dynamic 6 (Figure 2).

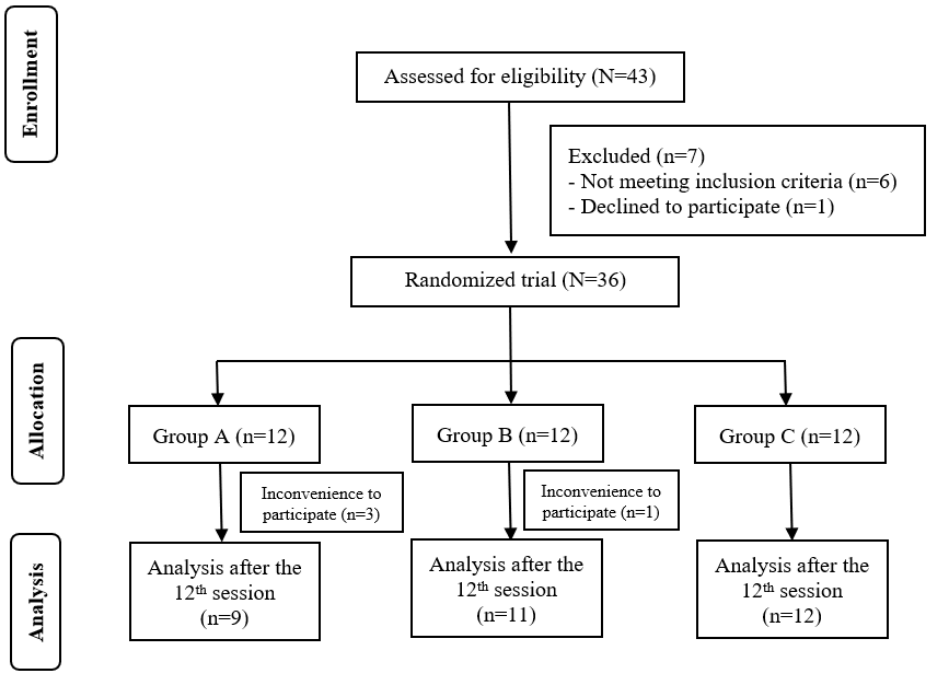


**Figure 1.** Flow diagram

| Number | Position | Exercise descriptions |
|---|---|---|
| Static 1 |  | Standing with both knees bending and eyes opened |
| Static 2 |  | Standing with one knee bending and eyes opened |
| Static 3 |  | Standing with both knees bending and eyes closed |
| Static 4 |  | Standing with one knee bending and eyes closed |
| Static 5 |  | Standing with one knee bending with eyes opened and arm raised to touch the target within the base of the support according to a metronome (55 beats/minute) |
| Static 6 |  | Standing with one knee bending with eyes opened and taking a ball within the base of the support according to a metronome (55 beats/minute) |

| Number | Position | Exercise descriptions |
|---|---|---|
| Dynamic 1 |  | Standing and reaching out to touch the target outside the base of the support with eyes opened according to a metronome (55 beats/minute) |
| Dynamic 2 |  | Jumping and alternating legs to the front and back with eyes opened according to a metronome (55 beats/minute) |
| Dynamic 3 |  | Jumping by both legs with eyes opened according to a metronome (55 beats/minute) |
| Dynamic 4 |  | Jumping and alternating legs to the front and back with eyes closed according to a metronome (55 beats/minute) |
| Dynamic 5 |  | Jumping with both legs in a stationary position for five repetitions with eyes opened and taking a ball outside the base of the support |
| Dynamic 6 |  | Jumping with both legs in a stationary position with eyes opened and kicking a ball after completing five repetitions |

**Group A** received static balance training for 6 sessions followed by dynamic balance training for 6 sessions.
**Group B** received dynamic balance training for 6 sessions followed by static balance training for 6 sessions.
**Group C** alternated between static and dynamic balance training for 12 sessions.

**Protocol:** Training program was practiced every other day with one position for one session.
A total training period was 15 minutes/session, 2 minutes/repetition, 3 repetitions/set,
2 sets/day with 30 seconds of rest between repetitions and 1 minute rest between sets.

**Figure 2.** Training program

Group B received dynamic balance training for 6 sessions followed by static balance training for 6 sessions. The training program was arranged as follows: Session 1 practiced Dynamic 1, Session 2 practiced Dynamic 2, Session 3 practiced Dynamic 3, Session 4 practiced Dynamic 4, Session 5 practiced Dynamic 5, Session 6 practiced Dynamic 6, Session 7 practiced Static 1, Session 8 practiced Static 2, Session 9 practiced Static 3, Session 10 practiced Static 4, Session 11 practiced Static 5, and Session 12 practiced Static 6 (Figure 2).

Group C alternated between static and dynamic balance training for 12 sessions. The training program was arranged as follows: Session 1 practiced Static 1, Session 2 practiced Dynamic 1, Session 3 practiced Static 2, Session 4 practiced Dynamic 2, Session 5 practiced Static 3, Session 6 practiced Dynamic 3, Session 7 practiced Static 4, Session 8 practiced Dynamic 4, Session 9 practiced Static 5, Session 10 practiced Dynamic 5, Session 11 practiced Static 6, and Session 12 practiced Dynamic 6 (Figure 2).

### Outcome measures

All participants received the Side Hop Test for measuring stability, the Illinois Agility Test for measuring agility, and the Balance Test for measuring balance before the first day of training and after completion of the 12$^{th}$ session (on the 24$^{th}$ day after participants underwent the program).

Illinois Agility Test:[22] This test was performed to assess agility performance. The reliability (ICC) was between 0.85-0.98.[22] There was a total of 8 cones, 4 of which was used to form a rectangle that was 5 meters wide and 10 meters long, and the other 4 cones were placed down the center of the rectangle at 3.3 meters apart.[23] When testing, the participants must run as quickly as possible through a specified path (Figure 3). A total of three cycles were conducted, and the shortest time representing the best agility performance was chosen and recorded in seconds.

Side Hop Test:[24] This test was performed to assess ankle stability. The reliability (ICC) was between 0.84-0.98.[24,25] The test method involved the participants jumping to the right and left as quickly as possible, consisting of 10 hops over a 30-centimeter line. The test was performed three times with one minute of rest between each time, and the shortest time representing the best stability performance was chosen and recorded in seconds.

Balance Test (on an ankle disk):[26] This test was performed to assess balance performance, which is affected by the perception of joints in different ways including controlling the posture of the body and modifying the contraction of the muscles around the ankle. The reliability (ICC) was between 0.79-0.95.[27] The test method involved the participants standing with one leg on the ankle disk and arms crossed. If the raised foot touched the floor at any time, the time was immediately stopped and recorded in seconds. The longest time represented the best balance performance. The test was performed on both sides for each leg.

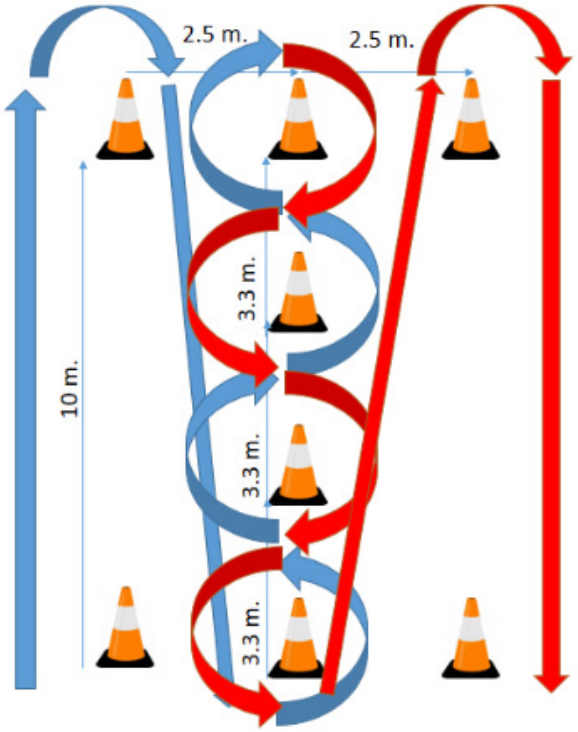


**Figure 3.** Illinois Agility Test Pathway

### Statistical analysis

Statistical analysis was calculated before training and after completion of the 12$^{th}$ session. The statistical significance was set at $p$-value < 0.05. The selected statistics were analyzed as follows: (1) the Kolmogorov–Smirnov goodness of fit test was used to analyze the normal distribution; (2) the one-way ANOVA and Bonferroni tests were used to test differences in the mean values for agility, ankle stability, and balance of the three training programs; and (3) the paired sample t-test was used before training and after completion of the 12$^{th}$ session within the groups. Statistical calculations were performed using IBM SPSS, Version 26 for Windows.

## Results

All participants were allocated into three groups, which consisted of 12 people per group. A total of four participants (three in Group A and one in Group B) requested to withdraw due to inconvenience in continuing with the training. The number of participants in each group was consequently equal to 9, 11, and 12 in Group A, B, and C, respectively. There were no significant differences in the general characteristics between the three groups ($p$ > 0.05) (Table 1). There were no significant differences in the Illinois Agility Test, Side Hop Test for both legs, and Balance Test for both legs at baseline between the three groups.

### Illinois Agility test

The mean differences in agility by the Illinois Agility Test among the three groups showed no significant differences

**Table 1.** General characteristics of participants

| Demographic | Mean (SD) | | | *p*-value |
|---|---|---|---|---|
| | Group A (n = 9) | Group B (n = 11) | Group C (n = 12) | |
| Age (years) | 20.0 (1.66) | 20.27 (1.49) | 19.50 (0.80) | 0.897 |
| Weight (kg) | 62.52 (9.85) | 60.45 (4.66) | 60.75 (6.76) | 0.650 |
| Height (cm) | 173.80 (3.59) | 170.75 (5.07) | 171.82 (5.12) | 0.175 |
| BMI (kg/m$^2$) | 22.07 (2.87) | 21.07 (1.58) | 20.84 (2.67) | 0.393 |

*Significant level; *p*-value < 0.05

**Table 2.** Comparison of the difference in stability, balance, and agility between the three groups

| Outcome | Mean difference (sec) | | | *p*-value |
|---|---|---|---|---|
| | Group A (n = 9) | Group B (n = 11) | Group C (n = 12) | |
| Agility | | | | |
| Both legs | 0.80 | 0.50 | 0.96 | 0.079 |
| Stability | | | | |
| Right leg | 0.80 | 0.90 | 0.87 | 0.870 |
| Left leg | 0.88 | 0.88 | 0.85 | 0.992 |
| Balance | | | | |
| Right leg | -68.19 | -63.55 | -65.70 | 0.995 |
| Left leg | -62.73 | -65.46 | -83.83 | 0.389 |

*Significant level; *p*-value < 0.05

Note: Negative value for balance shows an improvement in balance.

when comparing between Group A, B, and C ($p = 0.079$). The results are presented in Table 2.

However, a comparison of the agility values before training and after completion of the 12th session showed a statistically significant difference within Group A ($p = 0.006$), B ($p < 0.001$), and C ($p < 0.001$). The results are presented in Table 3.

### Side Hop Test

The mean differences in ankle stability by the Side Hop Test among the three groups showed no significant differences when comparing between Group A, B, and C of the right leg ($p = 0.870$) and the left leg ($p = 0.992$). The results are presented in Table 2.

However, a comparison of the Side Hop Test representing ankle stability before training and after completion of the 12th session of the right leg showed a statistically significant difference within Group A ($p = 0.001$), B ($p < 0.001$), and C ($p < 0.001$). In addition, the Side Hop Test of the left leg showed a statistically significant difference within Group A ($p = 0.023$), B ($p < 0.001$), and C ($p = 0.001$). The results are presented in Table 3.

### Balance Test

The mean differences in the Balance Test among the three groups showed no significant difference when comparing between Group A, B, and C of the right leg ($p = 0.995$) and the left leg ($p = 0.389$). The results are presented in Table 2.

However, a comparison of the balance values before training and after completion of the 12th session of the right leg showed a statistically significant difference within Group A ($p < 0.001$), B ($p < 0.001$), and C ($p < 0.001$). In addition, the balance test of the left leg showed a statistically significant difference within Group A ($p = 0.001$), B ($p < 0.001$), and C ($p < 0.001$). The results are presented in Table 3.

## Discussion

This study aimed to compare 12 sessions of static and dynamic balance training from three different programs that are suitable for increasing agility, stability, and balance in a short period. Comparisons were made between the three groups and within the groups before and after the completion of the 12th training session among healthy male university student volunteers.

Ankle stability by the Side Hop Test showed no difference between the three groups (static followed by dynamic balance training, dynamic followed by static balance training, and alternating between static and dynamic balance training programs) after completion of the 12th session. The programs for all three groups may have resulted in muscle contraction. Muscle onset latency of the peroneus longus and tibialis anterior muscles after a balance training program thereby improves the mechanoreceptor function, where both muscles are related to the postural control and medial longitudinal arch of foot stability.[28] Therefore, the participants from all three groups demonstrated an increase in ankle stability after completing the training programs in this study.

However, after completion of the 12th session, ankle stability by the Side Hop Test within each group increased when comparing before and after training. Consistent with a

**Table 3.** Comparison of the difference in stability, balance, and agility before and after training within the three groups

| Outcome | Mean (SD) (sec) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Group A (n = 9) | | | Group B (n = 11) | | | Group C (n = 12) | | |
| | Before training | After training | *p*-value | Before training | After training | *p*-value | Before training | After training | *p*-value |
| Agility | | | | | | | | | |
| Both legs | 18.25 (1.24) | 17.45 (0.87) | 0.006* | 18.25 (0.89) | 17.75 (0.75) | < 0.001* | 18.58 (0.77) | 17.63 (0.73) | < 0.001* |
| Stability | | | | | | | | | |
| Right leg | 3.95 (0.58) | 3.16 (0.29) | 0.001* | 4.34 (0.71) | 3.43 (0.39) | < 0.001* | 4.10 (0.59) | 3.23 (0.30) | < 0.001* |
| Left leg | 4.13 (1.07) | 3.25 (0.30) | 0.023* | 4.40 (0.58) | 3.51 (0.50) | < 0.001* | 4.23 (0.62) | 3.38 (0.31) | 0.001* |
| Balance | | | | | | | | | |
| Right leg | 19.55 (15.39) | 87.75 (38.33) | < 0.001* | 6.11 (5.30) | 69.66 (36.76) | < 0.001* | 16.68 (17.70) | 82.38 (39.12) | < 0.001* |
| Left leg | 12.46 (10.30) | 75.19 (44.36) | 0.001* | 4.74 (2.99) | 70.19 (32.29) | < 0.001* | 8.71 (6.12) | 91.54 (42.08) | < 0.001* |

previous study, lower extremity training can improve muscle strength, balance, and proprioception, which are the components of ankle stability.[29,30] A previous study showed that balance training on a balance board for an appropriate amount of time of more than three weeks can effectively increase ankle stability and the medial-lateral center of pressure of the foot, thus improving foot stability.[31] Consistent with a period program, this study used over three weeks for balance training on an ankle disk and a mini trampoline, in which the results showed an improvement in stability in all training programs. Dynamic training by using a mini trampoline involved movements that occurred when the body's position changed from one location to another, which caused a disturbance in the balance of the body.[32] In contrast, static balance training by using an ankle disk involved a small pivot movement at a central point where the postural adjustment was controlled by a platform and the base of the unit.[17] The effects of static and dynamic balance training increased body movement and stability of the lower limbs, which can improve muscle strength and maintain balance resulting in muscles working harder to achieve a certain posture and improvement in ankle stability.[17,32] The minimal detectable change (MDC) of the Side Hop Test ranged from 1.4 to 1.9 seconds in male children and adolescents aged 10-16 years.[25] The average stability time values in this study were 0.8, 0.9, and 0.9 seconds in Group A, B, and C, respectively, in regard to improvement after completion of the 12$^{th}$ session on the dominant side of participants aged 18-22 years. The reason for the difference in improvement value might be due to the difference in age.

The agility values from the Illinois Agility Test showed no difference between the three groups in improvement due to the static and dynamic balance exercises, which were used to improve agility and functional movement in daily life consistent with a previous study.[33]

However, comparing the agility values before and after completion of the 12$^{th}$ training session showed an increase in agility performance within each group. The results of the Illinois Agility Test were consistent with a previous study, which determined that static and dynamic balance training should be practiced appropriately to increase agility.[34] Static balance training using an ankle disk resulted in an increase in proprioceptive senses, balance, and coordination. Dynamic balance training using a mini trampoline resulted in an increase in stability, balance, proprioceptive senses, muscle power, muscle strength, and coordination. The results of alternating between the static and dynamic balance training showed an increase in agility performance, the same as in the other groups. In addition, a previous study on football players determined that agility training combined with balance training could increase athletic performance.[35] Another study has also determined that agility and coordination were highly correlated with the ability to maintain balance.[36] The Illinois Agility Test's minimal detectable change (MDC) was equal to 0.52 seconds in male athletes of team sports.[22] This study showed improvement of agility time values, which were 0.8, 0.5, and 1.0 seconds in Group A, B, and C, respectively, after completion of the 12$^{th}$ session.

The balance test showed no difference between the three groups of training program. Several studies have suggested using static and dynamic exercise for improving balance.[32,37] The results of the static balance training on an unstable surface were related to the center of pressure excursion, surface pressure, and degree of sway, while the results of the dynamic balance training were related to leg movements and landing from a jump.[37] As a result, all three groups in this study exhibited good balance.

When comparing within each group for the Balance Test, an increase in balance was found after completion of the 12$^{th}$ training session. Consistent with a previous study, the improvement of balance was due to the function of the internal movement of the joints, sensory organization, musculoskeletal system, motor coordination, weight balance adjustment, and environment adaptation.[38] The training program in this study was comprised of static and dynamic balance training to improve joint awareness and balance related to closed and opened kinetic chains. A previous study among healthy adults who had no exercise habits found that both closed and opened kinetic chains increased balance. Moreover, closed kinetic chain training affected joint compression, proprioceptive feedback from the foot, muscle activity, and neuro-

muscular control during exercise with a posture similar in real life.[39] A previous study found that static balance training involved standing still on both feet and causing the body to sway from the base of the support. The measurement indicated the average of the center of pressure and the variance of the position by the function of the nervous system and muscles.[32] A static balance training program with an ankle disk can prevent ankle sprain by stimulating proprioception and helping to slow down the activation of the tibialis anterior and tibialis posterior muscles, which twist the ankle inward to prevent excessive ankle inversion.[40] During training on an ankle disk, the difficulty level can be increased by decreasing the base of the support. An ankle disk training program was used as a learning mechanism. Proprioceptive activity can help improve postural control and physical movements in ordinary people.[27] Some research on ankle disk training focused on the contraction of the muscles around the ankle in healthy individuals. The training program with an ankle disk helped prevent the occurrence of ankle sprain and prevent functional instability in terms of acute ankle sprains for people with first-time ankle sprains.[41] Dynamic training involved movement that occurred when the body's position changed from one location to another, which caused disturbance in the balance of the body.[32] This research used a mini trampoline because it can increase body movement outside the base of the support to improve muscle strength and maintain balance. A mini trampoline is a device that has an unstable surface, which makes the muscles work harder to achieve a certain posture and induces postural control after training.[42] The minimal detectable change (MDC) of the balance test on an ankle disk is needed for further study.

The benefits of this study included the development of effective training programs and the option to select a training pattern that is appropriate for specific problems. The strengths of this study included easy training and minimal equipment. The limitation of this study was in the limited time available to collect data. If the training period was longer, the results might be more evident due to the period of training. Further studies should identify training programs for each sport and study the long-term effects of training to determine how to improve ankle stability, balance, and agility.

## Conclusions

The effects of three different programs (static balance training for 6 sessions followed by dynamic balance training for 6 sessions, dynamic balance training for 6 sessions followed by static balance training for 6 sessions, and alternating between static and dynamic balance training for 12 sessions) on agility, stability, and balance in healthy male university students demonstrated improvement after completion of the 12$^{th}$ session in all training programs. However, no significant differences were found between the three groups because the three exercise programs induced body movement that led to maintaining position. Therefore, a healthy person who aims to improve agility, stability, and balance can use any of the three training programs within a short training period to increase physical performance.

## Disclosure

No potential conflict of interest relevant to this article was reported.

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**Original Article**

# Patient Compliance and Factors Related to Usage of Plastic Ankle-Foot Orthoses by Chronic Stroke Patients

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## ABSTRACT

*Objectives:* To investigate chronic stroke patient compliance with usage of plastic ankle-foot orthosis (AFO) and to identify factors significantly associated with compliance with AFO use.

*Study design:* Cross-sectional study.

*Setting:* Department of Rehabilitation Medicine, Siriraj Hospital and Sirindhorn National Rehabilitation Center.

*Subjects:* Chronic stroke patients who had received a plastic AFO at least one year ago, had no cognitive impairment, no aphasia, and who had visited a physiatrist for follow-up.

*Methods:* Patients' demographic and clinical data were collected. Modified Barthel Index (mBI) and Functional Ambulation Category (FAC) were used for assessment. Patients were asked to complete a specially designed AFO use questionnaire. Patient compliance was defined as AFO use for ambulation for more than 3 hours per day at least 5 days per week over a period of not less than a year. Patients who did not meet those provisions were classified as non-compliant. Patient compliance/non-compliance with AFO usage was analyzed using descriptive statistics. Factors associated with compliance were analyzed using forward stepwise logistic regression.

*Results:* A total of 93 patients, 63 men and 30 women, with a mean age of 60 years were included in the study. Of those patients, 38.7% had discontinued the use of AFO, 61.3% reported continuous use of AFO, but only 23.7% were categorized as compliant with AFO usage. FAC level 4 or 5, independent ambulator on level surfaces only and independent ambulator, respectively, was the only factor statistically significantly related to patient compliance (odds ratio: 15.2, 95% confidence interval: 1.9-120.6).

*Conclusions:* Almost two-thirds of chronic stroke patients reported continuous usage of AFOs for at least a year, but only one-fourth could be categorized as compliant with AFO usage. Independent ambulation, including ambulation on level surfaces only, was the only factor independently associated with compliance with AFO use.

**Keywords:** foot orthosis, patient compliance, stroke rehabilitation, ambulation

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## Introduction

Ankle-foot orthoses (AFOs) are often prescribed to correct gait pattern after a stroke. An AFO can provide mediolateral stability at the ankle in the stance phase, facilitate toe clearance in the swing phase, and promote heel strike.[1] User-reported benefits of AFOs include increased confidence, fewer difficulties walking, and faster walking speed.[2-4] In addition, in subacute hemiparetic stroke patients wearing an AFO may improve aerobic capacity, energy efficiency, and gait endurance.[5] However, those benefits are realized only when the AFO is worn on a regular basis.

In Thailand, plastic AFOs are much more commonly prescribed than metal AFOs for stroke patients. The two types of plastic AFOs used are the posterior leaf spring type, which is commercially available, and the solid ankle type, which is custom-made for individual patients. The solid ankle type is more suitable for stroke patients because it provides more stability. Both types of AFOs must be worn with shoes. Traditionally, Thai people do not wear shoes inside the house, which suggests that patient compliance with AFO usage may be compromised in this population. Additionally, various types of sandals are routinely preferred to other types of footwear for outdoor activities due to the hot and humid climate. After suffering a stroke, patients either try to acclimate to wearing new shoes with an AFO or refuse to use an AFO. In addition to the loss of independence due to difficulty walking, refusal to consistently wear an AFOs leads to wasted healthcare resources. No information is currently available regarding long-term patient compliance with AFO use among stroke patients in Thailand, where the lifestyle, climate, and traditions

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are quite different from those of Western countries. The objective of the present study was to investigate the use of a plastic AFO by chronic stroke patients who had received their AFO at least one year prior to study, and to identify factors significantly associated with patient compliance with AFO usage.

## Methods

This cross-sectional study was conducted at the Rehabilitation Medicine Outpatient Clinic at Siriraj Hospital, (Bangkok, Thailand) and the Sirindhorn National Rehabilitation Center (Nonthaburi, Thailand) after receiving an approval from the institutional review boards of both hospitals.

### Participants

Study participants were recruited by convenience sampling of patients from both hospitals. Chronic stroke patients age 18 years or older who visited one of the hospitals during 2014-2018 and received a plastic AFO to correct gait pattern for the first time and used the AFO for at least a year prior to the study were recruited. Stroke patients with documented cognitive impairment, an inability to verbally communicate, or who were unwilling to join the study were excluded. After inclusion-exclusion screening, a written informed consent to participate was obtained from all enrolled study participants.

### Procedure

All study participants' functional ability and ambulation status were assessed using the modified Barthel Index (mBI)[6] and the Functional Ambulation Category (FAC).[7] FAC has 6 levels that range from level 0 (non-functional ambulator) to level 5 (independent ambulator). The participants were then asked to complete an AFO use questionnaire specifically designed and developed for the present study. The items in the questionnaire consisted of the patient's perception of AFO, frequency of AFO use for ambulation, perceived benefits and drawbacks of the AFO, and the participant's feedback regarding ways to facilitate AFO usage. The newly designed questionnaire was tested for understandability with 10 stroke patients, including both AFO users and nonusers. Completed questionnaires were immediately checked to ensure that there was no identify missing data and request that information.

### Sample size calculation

As there have been no studies reporting patient compliance with AFO use after a stroke, the authors estimated AFO use and usage based clinical observations to calculate the sample size. Based on clinical observation and using a 95% confidence interval (CI), it was estimated that 50.0% ± 10.0% of stroke patients who received an AFO would comply with long-term AFO use recommendations. Sample size calculation indicated that a minimum of 97 subjects were needed.

### Data analysis

The data were analyzed using PASW Statistics for Windows (version 18.0; SPSS, Inc., Chicago, IL, USA).[8] Descriptive statistics were used to summarize patient characteristics, including frequency and percentage, mean and standard deviation, and range.

Patients were categorized as compliant or non-compliant on the frequency of AFO use. Compliant was defined as using an AFO for ambulation for more than 3 hours per day at least 5 days per week whereas non-compliant was defined as not using AFO at all or using it less than 3 hours per day. Patient compliance/non-compliance is reported as percentage.

Univariate analysis was performed to evaluate the differences between compliant and non-compliant patients. The chi-square test was used to compare qualitative variables, including gender, education level, presence of comorbid illness, type of stroke, side of weakness, use of walking aids, period of having an AFO, benefits and drawbacks associated with wearing an AFO, and FAC level. In the present study, FAC level 0-1 was classified as a non-functional ambulator, i.e., a stroke patient totally dependent on physical assistant to ambulate. FAC 2-3 was classified as an assisted ambulator, i.e., a stroke patient more or less in need of a person to either physically assist or supervise ambulation. FAC 4-5 was classified as an independent ambulator. The independent samples t-test was used to analyze quantitative variables (age and the modified Barthel Index score). Forward stepwise logistic regression analysis was then performed to determine which factors were significantly associated with patient compliance with AFO usage. Adjusted odds ratios and 95% CIs were estimated. A $p$-value of $< 0.05$ was considered statistically significant.

## Results

Plastic AFOs were prescribed for 230 stroke patients during 2014-2018. Of those, eighty-nine patients were unreachable, 16 patients had died, 10 patients were unable to verbally communicate, 10 patients were documented as having cognitive impairment, and 12 patients declined to participate. The remaining 93 patients (63 men and 30 women, mean age 60 years) were included.

**Table 1.** Frequency and duration of plastic ankle-foot orthosis use among chronic stroke patients after receiving a prescribed orthosis at least one year (N = 93)

| Frequency of use per week | Duration of use per day | | | Total |
|---|---|---|---|---|
| | < 1 hour | 1-3 hours | > 3 hours | |
| Not at all | ----------36 (38.7) ---------- | | | NA |
| 1-2 days | 5 (5.4) | 8 (8.6) | 4 (4.3) | 17 (18.3) |
| 3-4 days | 1 (1.0) | 4 (4.3) | 5 (5.4) | 10 (10.7) |
| 5-7 days | 5 (5.4) | 3 (3.2) | 22 (23.7) | 30 (32.3) |
| Daily | 11 (11.8) | 15 (16.1) | 31 (33.4) | --- |

Number (%); NA, not applicable

**Table 2.** Patient variables comparing compliance and non-compliance with ankle-foot orthosis (AFO) usage

| Variables | Compliant user (n=22) | Non-compliant user (n=71) | *p*-value |
|---|---|---|---|
| Gender[1] | | | |
| • Male | 17 (77.3) | 46 (4.8) | 0.27 |
| • Female | 5 (22.7) | 25 (35.2) | |
| Age (years)[2] | 55.1 (10.7) | 61.8 (11.5) | 0.018* |
| Education[1] | | | |
| • High school or lower | 10 (44.9) | 46 (64.9) | 0.085 |
| • Higher than high school | 12 (55.1) | 25 (35.1) | |
| Presence of comorbid illness[1] | 19 (86.4) | 65 (91.5) | 0.44 |
| Type of stroke[1] | | | |
| • Hemorrhagic | 12 (54.5) | 22 (31.0) | 0.045* |
| • Ischemic | 10 (45.5) | 49 (69.0) | |
| Side of weakness[1] | | | |
| • Right | 10 (45.5) | 38 (53.5) | 0.51 |
| • Left | 12 (54.5) | 33 (46.5) | |
| Use walking aids[1] | 19 (86.4) | 61 (85.9) | 1.0 |
| Duration of having AFO[1] | | | |
| • < 2 years | 13 (59.1) | 39 (54.9) | 0.73 |
| • > 2 years | 9 (40.9) | 32 (45.1) | |
| Modified Barthel Index score[2] | 17.6 (2.2) | 14.4 (4.6) | < 0.001* |
| Functional Ambulation Category[1] | | | |
| • Non-functional ambulation | 1 (4.5) | 25 (35.2) | 0.001* |
| • Assisted ambulation | 1 (4.5) | 13 (18.3) | |
| • Independent ambulation | 20 (91.0) | 33 (46.5) | |

[1]Number (%), [2]mean (standard deviation), * *p*-value < 0.05 indicates statistical significance

**Table 3.** Analysis of factors independently associated with patient compliance with ankle-foot orthosis use

| Variable | Adjusted odds ratio (95% confidence interval) | *p*-value |
|---|---|---|
| Functional ambulation category | | |
| • Non-functional ambulation | 1.0 | |
| • Assisted ambulation | 1.92 (0.11-33.30) | 0.65 |
| • Independent ambulation | 15.2 (1.90-120.62) | 0.01* |

**p*-value < 0.05 indicates statistical significance

One year or more after having received the prescribed plastic AFO, patients reported highly variable AFO use. Of the 93 patients, 23.7% were classified as compliance with AFO usage instructions, with the remainder (61.3%) were non-compliance. Of the non-compliant patients, 37.6% used the prescribed AFO for less than the recommended periods and 38.7% had discontinued use of the prescribed plastic AFO (Table 1).

Univariate analysis revealed patient compliance to be statistically significantly associated with younger age, hemorrhagic stroke, high Barthel Index, and FAC level of independent ambulator status (Table 2). Forward stepwise logistic regression analysis showed independent ambulation to be the only factor independently associated with compliance with AFO use (odds ratio: 15.2; 95% confidence interval: 1.9-120.62) (Table 3).

Regarding the benefits and drawbacks associated with wearing the prescribed plastic AFOs, compliant users reported significantly more benefits than did non-compliant users. However, there were no statistically significant differences between groups related to the drawbacks associated with wearing an AFO (Table 4).

Concerning patients' perception of AFOs, most participants (78.5%) rated wearing AFOs without shoes (85%) and the ease of donning and doffing the AFOs (80%) as the two most important factors that influenced their AFO use. Among compliant patients, Other AFO-related factors that influenced AFO use were lighter weight AFOs (68.8%) and improved AFO appearance (61.3%).

## Discussion

This is the first study in Thailand to explore chronic stroke patient compliance with the use of plastic AFOs. In the present study, the percentage of patient compliance with AFO use recommendations for at least one year was 23.7%. This percentage was lower than the 50% which had been anticipated based on previous studies of the benefits of AFOs for walking ability of stroke patients.[9-11]

Nakipoglu et al,[12] recruited stroke patients with various durations of AFO use after at least 3-months post-stroke and found that 59.4% used their lower extremity orthosis every day and 29.7% did not use their orthosis at all. In the present study, among the chronic stroke patients who had their orthosis

**Table 4.** Patient variables comparing compliance and non-compliance with ankle-foot orthosis (AFO) usage

| Variables | Compliant users (n = 22) | Non-compliant users (n = 71) | *p*-value |
|---|---|---|---|
| Benefits | | | |
| More confidence | 21 (95.5) | 45 (63.4) | 0.004* |
| Faster walking | 19 (86.4) | 34 (47.9) | 0.001* |
| Longer walking distance | 21 (95.5) | 35 (49.3) | < 0.001* |
| Improved foot clearance | 20 (90.9) | 47 (66.2) | 0.024* |
| Drawbacks | | | |
| Discomfort | 11 (50.0) | 30 (42.9) | 0.56 |
| Pain | 12 (54.5) | 49 (70.0) | 0.18 |
| Ulceration | 18 (81.5) | 60 (85.7) | 0.66 |
| Falls | 20 (90.9) | 64 (91.4) | 0.82 |

Number (%), *$p$-value < 0.05 indicates statistical significance

for at least one year earlier, 32.3% used their AFO almost every day although only 23.7% were counted as compliant based on our definition of using AFO for ambulation more than 3 hours per day and at least 5 days per week and 38.7% had stopped using their AFO. Compared to the Nakipoglu study,[12] our findings suggest that the percentage of patients who discontinue AFO use increases over time.

In the present study, benefits of AFO were reported more frequently by compliant users than by non-compliant users. In addition, compliant users felt that ease of donning and doffing, weight, and appearance of the AFOs were strong influencing factors for AFO use. Difficulty wearing a prescribed orthosis has been reported to be a main reason for AFO discontinuation[12] which is consistent with the present study. Hung et al, studied the effects of anterior AFOs which are commonly prescribed for Taiwanese patients.[13] They found that all 52 chronic stroke patients who had had their anterior AFOs for ≥ 5 months wore their AFOs for outdoor activities; however, only half of those patients wore them at home. The benefits of AFOs have also been addressed in several other studies.[3,12,14] Notably, those studies reported that many subacute to chronic stroke patients who had discontinued the use of their AFO perceived no beneficial effect of the AFOs.

Univariate analysis in the present study revealed AFO users to be younger, more likely to have had a hemorrhagic stroke, have a higher modified Barthel Index score, and higher FAC levels compared to non-compliant users. When these variables were entered into forward stepwise logistic regression analysis, independent ambulation was found to be the only statistically significant independent predictor of patient compliance with AFO use. This finding is consistent with that of a study by Lehman[15] who reported that AFOs are worn by patients who are able to walk without them but cannot do so safely. Stroke patients who are able to walk may still have problems with their balance, which increases their risk of falling. The use of AFOs by stroke patients with muscle weakness of the ankle joints is one strategy to improve standing and walking ability by facilitating weight distribution to the affected leg,[9] improving balance,[16] and reducing the risk of falling.[17,18] These benefits were acknowledged by patients in our study. Compared to the perceptions of non-compliant users, compliant users reported that they felt significantly more confident. These same feelings of AFO-influenced patient confidence have also been reported in previous studies.[2,3] AFO users in this study also reported a significantly faster gait and longer walking distances compared to nonusers. This finding can be explained by the reported findings that AFO use can enhance step and stride length, increase walking speed,[9,14] reduce the energy cost of walking[11] and significantly increase toe clearance.[19]

The participants in the present study also commented on the problems associated with wearing AFOs such as discomfort, pain, ulceration, and falls. Interestingly, a high percentage of both the compliant and non-compliant groups reported falls related to AFO use. This should be investigated further to determine if it is true, and, if so, which types of AFO are the cause of falls as well as the circumstances under which falls commonly occur. This information could be used by prosthetists and physiatrists when they are promoting or counseling patients on AFO use. The weight, design, and appearance of AFOs were additional factors that were reported to influence AFO use by our study patients. Patients in other studies have provided similar feedback.[2,3] If these factors can be addressed, patient compliance with AFO use may be increased, improving patient outcomes and justifying the cost of providing these therapeutic lower extremity orthoses. The clinical implication from the present study is that prescribing plastic AFOs for stroke patients whose FAC could potentially reach level 4/5 could increase compliance with AFO usage.

Some limitations of this study should be mentioned. First, this study evaluated compliance in using AFOs including usage patterns, benefits, and drawbacks of AFOs among chronic stroke patients who had received their AFO at least one year earlier. A low rate of patient compliance with AFO usage might be due to our strict definition of compliance to mean more than 3 hours use of the AFO daily five days a week for ambulation. This definition may be inappropriate for chronic stroke patients as they are more sedentary than older adults[17] and the amount of walking per day or per week

by chronic stroke patients has not yet been studied. A more appropriate definition of compliance with AFO use could be determined by establishing the amount of walking activity among chronic stroke patients in a future study. Another point is the high percentage of non-compliance which is a result of inclusion of patients who used AFO for ambulation less than 3 hours per day and/or less than 5 days per week and those who discontinued using AFO. Discontinuation of AFO use might be due to severe hemiplegia and/or poor trunk balance leading to an inability to walk and inability to don and doff the AFO by oneself. In this study, severity of stroke was not assessed and recorded. Other points are that patients' perception that use of AFO is related to falls and that an inappropriate AFO prescription may be related to discontinuation of AFO use. The types of plastic AFO, both commercial and custom-made, should be explored in future studies. Such information would assist prosthetists and physiatrists to prescribe an appropriate AFO, improve patient compliance with AFO usage, and thus help make chronic stroke patients become independent ambulators. Finally, future research should include more subjects to obtain more data for analysis.

## Conclusions

Our results showed that 61.3% of chronic stroke patients continued using plastic AFOs for at least one year. The percentage of compliance with AFO use of more than 3 hours per day and at least 5 days per week was 23.7%. Being an independent ambulator was independently associated with compliance with AFO use.

## Disclosure

All authors declare no personal or professional conflicts of interest related to any aspect of this study.

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**Original Article**

# The Value of Electrodiagnostic Studies in Diagnosis and Management of Neuromuscular Disorders: A Retrospective Study from a Tertiary-Care Hospital in Thailand

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## ABSTRACT

*Objectives:* To evaluate the value of electrodiagnostic studies (EDx) in diagnosis and management of neuromuscular disorders.

*Study design:* Retrospective study.

*Setting:* Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand.

*Subjects:* New patients who were referred to EDx laboratory, Maharat Nakhon Ratchasima Hospital between January 1, 2019 and December 31, 2020.

*Methods:* General demographics, referring physician specialty, referral diagnosis, diagnosis after EDx, impact of EDx on diagnosis and management were reviewed retrospectively. The impact of EDx was classified into confirmed, changed, and no added value. Management by referring specialists after receiving EDx reports including investigation, consultation and treatment were recorded. The association between variables and change in diagnosis and management after EDx, were analyzed using multivariable analysis.

*Results:* Of 856 patients, the diagnosis was changed and confirmed after EDx in 28.4% and 69.3% respectively. EDx results led to a change in management for 29%. Referral diagnosis of radiculopathy, no referral diagnosis, female patient and neurologists' referral were major contributing factors to a change in diagnosis with odds ratios (95% CI) of 3.67 (1.52, 8.85), 2.61 (1.44, 4.73), 1.79 (1.23, 2.56) and 1.79 (1.20, 2.67) respectively. While referral diagnosis of neuromuscular junction (NMJ) disease, motor neuron disease (MND) and referred by orthopedic surgeons were the top three variables correlated with a change in management with odds ratios (95% CI) of 3.81 (1.8, 8.08), 2.85 (1.11, 7.37) and 2.24 (1.2, 4.2) respectively.

*Conclusions:* EDx is a valuable investigation that confirms (69.3%) or changes (28.4%) the diagnosis and guides the appropriate management (29%) in patients with neuromuscular disorders.

**Keywords:** electrodiagnosis, electromyography, neuromuscular diseases

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## Introduction

Electrodiagnostic studies (EDx) are commonly requested to evaluate patients with neuromuscular disorders and have been used for many decades. Such studies help to confirm the clinical diagnoses and provide information to guide subsequent investigation and management. Many previous studies have shown that EDx was useful in patients with suspected neuromuscular disorders such as polyneuropathy,[1] carpal tunnel syndrome,[2] upper extremity complaint,[3] tarsal tunnel syndrome,[4] peroneal neuropathy[5] and radiculopathy.[6] Many studies have confirmed the usefulness of EDx, such as those from the USA,[7-10] Canada[11] and Italy[12,13] that confirmed the value of the EDx study in patients with suspected neuromuscular disorders.

In Thailand, EDx is performed by a physiatrist in the Department of Rehabilitation Medicine or by a neurologist in the Department of Medicine, depending on the policy of each hospital. There is no Thai Board of Electrodiagnostic Medicine. The electromyographers perform EDx for each patient according to their clinical decision making rather than any strict guidelines. Maharat Nakhon Ratchasima Hospital is a tertiary referral hospital that has had an EDx laboratory in the Department of Rehabilitation Medicine since 2006. Patients with suspected neuromuscular disorders have been referred from orthopedic surgeons, neurologists, rheumatologists, general surgeons and other specialists for both outpatients and inpatients averaging 500 cases per year. No study of the value or usefulness of EDx has been conducted in Thailand before.

The objective of this study was to evaluate the value of EDx in diagnosis (confirmed, changed or no added value) and management (in terms of further investigation, injection or surgery) in patients with neuromuscular disorders.

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## Methods

All patients who received an electrodiagnostic study (ICD 9: 9308) between January 1, 2019 and December 31, 2020 had their data collected from the Hospital database. The author reviewed electronic medical records of each patient. Only new consultations with a referral from other physicians were included in the present study. Sample size was calculated from power of 0.8, confidence level of 0.95, with an assumed relative risk of 1.5, therefore only 110 cases were required. However, all new patients in two calendar years were recruited in this study. EDx was performed for each patient by certified electromyographers who are physiatrists with a Diploma of the Thai Board of Rehabilitation Medicine or rehabilitation medicine in-training residents under close supervision of the staff. Six physiatrists worked as electromyographers in the period of this study. Patients were referred to EDx unit from specialists in Maharat Nakhon Ratchasima Hospital and other hospitals in Nakhon Ratchasima province. For patients referred from other hospitals, the specialties of referring physicians were unknown. Therefore, only "referred from other hospitals" was recorded. Patients who were firstly diagnosed and later received EDx by the same physiatrist were excluded to decrease potential bias.

The general demographic data including gender, age, diabetes mellitus (DM), type of patient (inpatient vs. outpatient), type of health coverage scheme, referring physician specialty, referral diagnosis, details of EDx, diagnosis after EDx, impact of EDx on diagnosis and management were recorded. Diagnoses were classified into carpal tunnel syndrome (CTS), other mononeuropathies, polyneuropathy, plexopathy, radiculopathy, myopathy, neuromuscular junction (NMJ) disease, motor neuron disease (MND), and others.[11] No referral diagnosis was stated if there was no referral diagnosis or there were only symptoms noted in the medical records. Normal EDx, inconclusive results or upper motor neuron lesion (UMNL) were recorded if the electromyographers concluded those in EDx reports. Details of EDx including numbers of motor and sensory nerve conduction studies (NCS), needle electromyography (EMG), repetitive nerve stimulation studies (RNS), late response and electromyographer's name were recorded. If there was no referral diagnosis, the physiatrist's diagnosis on the day of clinical evaluation before the date of EDx was also recorded.

The impact of EDx was evaluated and classified into confirmed, changed, and no added value. The diagnosis was "confirmed" when EDx supported the referral diagnosis or diagnosis documented by the physiatrists for patients without any referral diagnosis. The diagnosis was regarded as "changed" when the diagnosis from EDx differed from the referral diagnosis or if there was no referral diagnosis and no physiatrist diagnosis then EDx provides a diagnosis. If EDx neither altered nor confirmed the referral diagnosis, "no added value" was identified. Inconclusive EDx study results or incidental diagnosis that do not correlate with the patient's clinical and referral diagnosis were classified as no added value. Management by referring physicians after receiving EDx results within 3 visits or 3 months are considered associated with EDx results. Further investigation, other than blood work, such as imaging, lumbar puncture and biopsy, consultation with other specialists, referral to another hospital and treatment, such as injection or surgery, were recorded. Orthosis or rehabilitation management were not included as management after EDx. In a changed diagnosis group, the medical records of referring physicians on the next visit after EDx performed were studied to evaluate whether referring physicians recorded EDx results or not. If there was no medical record of an EDx report, it was assumed that the referring physicians would not see EDx results. Change in management was recorded if there was at least one change in management after referring physicians had seen EDx results. Management of patients referred from other hospitals could not be evaluated. Ethics approval was obtained from the Maharat Nakhon Ratchasima Hospital Institutional Review Board (058/2021).

Statistical analysis was studied using descriptive statistics, Student's t-test and chi-square test. Association between variables and change in diagnosis and management after EDx was analyzed using logistic regression analysis. *P*-value less than 0.05 was considered to indicate significance. The odds ratio shows the magnitude of association between variables and change in diagnosis and management after EDx.

## Results

One thousand and eight patients had EDx studies within the two- year study period in the EDx laboratory. One hundred and fifty-two cases were excluded: 120 cases had EDx at a physiatrist's request (no referring physician), 21 cases were follow-up/repeat EDx, and 11 cases had incorrect ICD-9 coding. Therefore, 856 patients were included in this study. The clinical characteristics of the studied patients are shown in Table 1. The mean age was 47.5 years (range, 0-87). Half were females. Almost all patients (96%) were outpatients. Four percent were children. Eighty-six percent live in Nakhon Ratchasima province. The universal coverage scheme was used by two-thirds of the patients. Most referring specialists were orthopedic surgeons (65%), followed by neurologists (19%) and internal medicine physicians (6.5%). About 6% of the patients were referred from other hospitals. The most common referral diagnoses were other mononeuropathies (26%), CTS (22%) and plexopathy (16%). Almost 7% of the patients had more than one referral diagnosis.

The referral diagnosis from each referring specialist is shown in Table 2. Most referrals from orthopedic surgeons were other mononeuropathies (32.7%), CTS (30.5%) and plexopathy (21%) respectively. While polyneuropathy (31.6%), NMJ disease (27.5%) and myopathy (13.5%) were common referral diagnoses from neurologists. Most referrals from other hospitals were other mononeuropathies (48.2%), CTS

**Table 1.** Clinical characteristics of the studied patients (n = 856)

| Characteristics | Number (%) |
|---|---|
| Gender: female | 427 (49.9) |
| Inpatient | 33 (3.9) |
| Pediatric (age < 15) | 33 (3.9) |
| Diabetes mellitus | 80 (9.4) |
| Live in Nakhon Ratchasima province | 735 (85.9) |
| Type of health coverage scheme | |
| Universal coverage scheme | 543 (63.4) |
| Social security scheme | 150 (17.5) |
| Government officer scheme | 127 (14.8) |
| Other (cash, private insurance, veteran) | 36 (4.2) |
| Referring specialist | |
| Orthopedic surgeon | 560 (65.4) |
| Neurologist | 162 (18.9) |
| Internist | 56 (6.5) |
| Rheumatologist | 14 (1.6) |
| Surgeon (general and plastic) | 9 (1.1) |
| Otolaryngologist | 2 (0.2) |
| Specialty not specified from other hospitals | 53 (6.2) |
| More than one referral diagnoses | 57 (6.7) |

(17.9%) and polyneuropathy (12.5%). Considering 65 cases with no referral diagnosis, the percentage referred from orthopedic surgeons, neurologists, other specialists, and unspecified specialty from other hospitals were 74, 6, 15 and 5 respectively. Two cases were referred with myelitis and spinal cord lesion and were recorded as other referral diagnosis.

EDx includes motor and sensory NCS, EMG, RNS and late response. In Table 3, the mean numbers of EDx tests for each referral diagnosis are demonstrated. Almost all patients received NCS and EMG while RNS and late response were rarely used except RNS in NMJ disease. Patients with referral diagnosis of MND, myopathy, polyneuropathy and other diagnoses had more than 10 EDx tests.

CTS (26%), and other mononeuropathies (25%) were the most common diagnosis after Edx followed by polyneuropathy (14%) and plexopathy (12%). Normal or negative EDx results were noted in 114 cases (12%). Five cases (0.5%) with UMNL and 16 cases (1.7%) with inconclusive results were found. After EDx tests were performed, the diagnoses were changed in 243 cases (28.4%), confirmed in 593 cases (69.3%) and given no added value in 20 cases (2.3%).

A flow diagram showing patients with changed diagnosis after EDx is presented in Figure 1. From 243 cases with a change in diagnosis, there were 213 cases (88%) with a referral diagnosis and 30 cases (12%) with no referral diagnosis. In patients with a referral diagnosis that was changed after EDx, 43% had normal EDx results while 30% of results were normal in patients with no referral diagnosis. There was a decrease in the percentage of EDx diagnosis if the referral diagnosis was other mononeuropathies, plexopathy, NMJ disease, myopathy or MND. While CTS, polyneuropathy and radiculopathy showed similar proportions of referral and EDx diagnosis. Surprisingly, in patients with a change in diagnosis after EDx, there were 45 cases (19%) for which the medical records of the referring physicians mentioned nothing about the EDx results and the diagnosis was the same as the referral diagnosis. The referring physicians did not change the diagnosis after they had seen EDx reports in 8 patients. In some patients that had conflicting diagnosis between clinical opinion and EDx, discussion in medical records was noted.

The multivariable analysis of variables associated with change in diagnosis is shown in Table 4. Six variables that correlated with a change in diagnosis were: referral diagnosis of radiculopathy, no referral diagnosis, female patient, referred by neurologist, patient with DM and referral diagnosis of CTS with odds ratios (95% CI) of 3.67 (1.52, 8.85), 2.61 (1.44, 4.73), 1.79 (1.23, 2.56), 1.79 (1.20, 2.67), 0.52 (0.27, 0.99) and 0.48 (0.29, 0.77) respectively.

After the referring physicians received the EDx reports, the management changes related to EDx were studied. Two hundred and fifty patients (29%) had at least one change in management. From 434 managements, surgery was the most common form of management found in 35.7% of the patients. Carpal tunnel release in CTS (18.2%), nerve transfer or neurotization in brachial plexus injury (6.9%), and ulnar nerve transposition in ulnar neuropathy at the elbow (4.6%)

**Table 2.** Frequency of referral diagnosis from each referring specialist (n = 901)

| Referral diagnosis | Total, n (%) | Referring specialists, n (%) | | | |
|---|---|---|---|---|---|
| | | Orthopedic surgeon | Neurologist | Other specialist | Not specified |
| None (symptom) | 65 (7.2) | 48 (8.1) | 4 (2.3) | 10 (11.9) | 3 (5.4) |
| CTS | 200 (22.2) | 180 (30.5) | 4 (2.3) | 6 (7.1) | 10 (17.9) |
| Other mononeuropathies | 237 (26.3) | 193 (32.7) | 7 (4.1) | 10 (11.9) | 27 (48.2) |
| Polyneuropathy | 105 (11.7) | 22 (3.7) | 54 (31.6) | 22 (26.2) | 7 (12.5) |
| Plexopathy | 143 (15.9) | 124 (21.0) | 10 (5.8) | 5 (6.0) | 4 (7.1) |
| Radiculopathy | 25 (2.8) | 20 (3.4) | 2 (1.2) | 2 (2.4) | 1 (1.8) |
| Myopathy | 36 (4.0) | 0 (0.0) | 23 (13.5) | 13 (15.5) | 0 (0.0) |
| NMJ disease | 57 (6.3) | 0 (0.0) | 47 (27.5) | 10 (11.9) | 0 (0.0) |
| MND | 31 (3.4) | 1 (0.2) | 20 (11.7) | 6 (7.1) | 4 (7.1) |
| Others (such as myelitis) | 2 (0.2) | 2 (0.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Total | 901 (100.0) | 590 (100.0) | 171 (100.0) | 84 (100.0) | 56 (100.0) |

CTS, carpal tunnel syndrome; MND, motor neuron disease; NMJ, neuromuscular junction

**Table 3.** Number of EDx tests for each referral diagnosis

| Referral diagnosis | Motor NCS[1] | Sensory NCS[1] | Needle EMG[1] | RNS[1] | Late response[1] | Total tests[1] |
|---|---|---|---|---|---|---|
| None (symptom) | 1.6 (1.65) | 1.1 (1.29) | 2.1 (1.45) | 0 (0.0) | 0 (0.0) | 4.8 (2.10) |
| CTS | 3.55 (1.17) | 3.78 (1.48) | 0.8 (1.32) | 0 (0.0) | 0.04 (0.28) | 8.18 (2.87) |
| Other mononeuropathies | 2.23 (1.93) | 1.84 (1.87) | 3.08 (2.10) | 0 (0.0) | 0.03 (0.35) | 7.19 (3.92) |
| Polyneuropathy | 5.15 (1.85) | 4.36 (1.91) | 1.74 (2.02) | 0.01 (0.1) | 0.35 (0.87) | 11.62 (4.11) |
| Plexopathy | 0.99 (1.96) | 1.31 (1.84) | 6.34 (2.56) | 0 (0.0) | 0.07 (0.45) | 8.72 (3.95) |
| Radiculopathy | 2.72 (2.21) | 2.28 (1.74) | 3.96 (3.16) | 0 (0.0) | 0.16 (0.8 | 9.12 (5.27) |
| Myopathy | 4.61 (2.49) | 3.41 (2.03) | 2.5 (1.78) | 0.28 (0.7) | 0.19 (0.52) | 11 (4.85) |
| NMJ disease | 1.95 (1.59) | 1.14 (1.37) | 0.30 (0.83) | 1.68 (0.71) | 0.04(0.19) | 5.11(3.19) |
| MND | 4.9 (1.70) | 3.25 (1.61) | 4.65 (1.74) | 0 (0.0) | 0.26 (0.63) | 12.45 (4.01) |
| Others | 5.5 (2.12) | 2.5 (0.71) | 2.5 (3.54) | 0 (0.0) | 0 (0.0) | 10.5 (2.12) |
| More than 1 referral diagnosis | 3.39 (2.22) | 3.09 (2.07) | 2.78 (2.8) | 0.12 (0.47) | 0.05 (0.23) | 9.44 (4.48) |

CTS, carpal tunnel syndrome; EDx, electrodiagnostic study; EMG, electromyography; MND, motor neuron disease; NMJ, neuromuscular junction; RNS, repetitve nerve stimulation study

[1]Mean (SD)

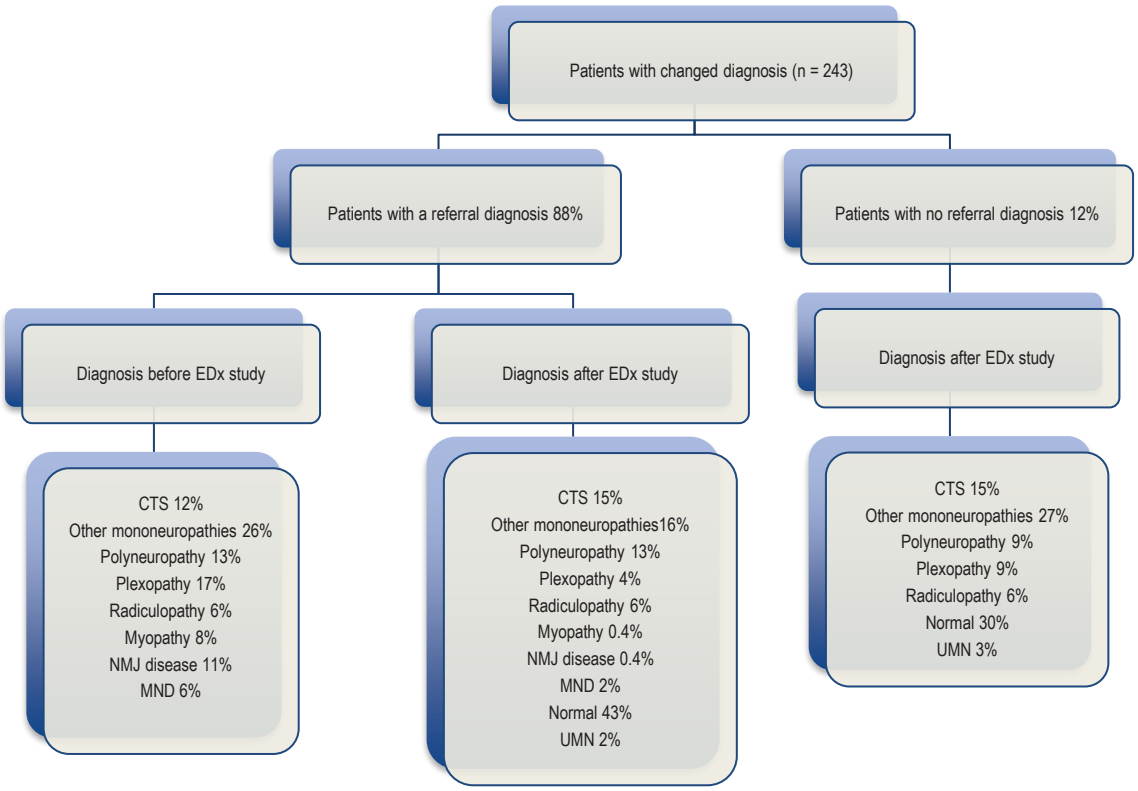


**Figure 1.** Flow diagram of patients with changed diagnosis after EDx

CTS, carpal tunnel syndrome; EDx, electrodiagnostic study; MND, motor neuron disease; NMJ, neuromuscular junction; UMN, upper motor neuron lesion

were the most common operations performed on patients. Tendon transfer in wrist and foot drop (1.6%), discectomy in radiculopathy (1.2%), thymectomy in NMJ disease (0.9%), rotator cuff repair in negative EDx of brachial plexopathy (0.7%), tendon lengthening in equinus deformity that ruled out peripheral neuropathy and tarsal tunnel release in tarsal tunnel syndrome were also informed by EDx studies (1.4%). Interestingly, EDx results indicating UMN led to subsequent imaging and two patients being diagnosed with brain tumor metastasis and hydrocephalus. Electromyographers were the first persons to note these suspicions in medical records and the EDx reports. EDx also affected the consultation, referral to other hospitals and discharge in 31%, investigation in 25% and injection in 8% of the patients. Two patients were treated with medication as appropriate to the EDx diagnosis: however the referring physicians disagree with the EDx diagnosis.

The association of variables and change in management were analyzed using multivariable analysis (Table 5). There were 8 variables that correlated with a change in management. Referral diagnosis of NMJ disease, MND, orthopedic surgeons' referral, total number of the EDx tests ≥ 15, referral diagnosis of CTS, female, referral diagnosis of other mononeuropathies and patients with DM were correlated

**Table 4.** Multivariable analysis of variables associated with change in diagnosis

| Factors | Odds ratio (95% CI) | *p*-value |
|---|---|---|
| Patient's characteristics | | |
| Age | 1.0009 (0.99, 1.01) | 0.849 |
| Female | 1.79 (1.23, 2.56) | 0.002* |
| DM | 0.52 (0.27, 0.99) | 0.047* |
| Inpatient | 0.94 (0.39, 2.26) | 0.89 |
| Referring specialists: neurologist vs. orthopedic surgeon | 1.79 (1.20, 2.67) | 0.005* |
| Referral diagnosis | | |
| No referral diagnosis | 2.61 (1.44, 4.73) | 0.002* |
| CTS | 0.48 (0.29, 0.77) | 0.002* |
| Radiculopathy | 3.67 (1.52, 8.85) | 0.004* |
| Total number of EDx tests ≥ 15 | 2.01 (1.13, 3.60) | 0.18 |

CTS, carpal tunnel syndrome; DM, diabetes mellitus; EDx, electrodiagnostic study

**Table 5.** Multivariable analysis of variables associated with change in management

| Factors | Odds ratio (95% CI) | *p*-value |
|---|---|---|
| Patient's characteristics | | |
| Age | 1.004 (0.994, 1.014) | 0.46 |
| Female | 1.61 (1.15, 2.27) | 0.01* |
| DM | 0.47 (0.25, 0.88) | 0.02* |
| Inpatient | 0.91 (0.34, 2.43) | 0.85 |
| Referring specialists: | | |
| Orthopedic surgeon | 2.24 (1.2, 4.2) | 0.011* |
| Neurologist | 0.64 (0.32, 1.29) | 0.21 |
| Other specialists (reference) | 1 | |
| Referral diagnosis | | |
| CTS | 2.07 (1.37, 3.29) | 0.001* |
| Other mononeuropathies | 0.5 (0.32, 0.78) | 0.002* |
| NMJ disease | 3.81 (1.8, 8.08) | < 0.001* |
| MND | 2.85 (1.11, 7.37) | 0.03* |
| Total number of EDx tests ≥ 15 | 2.08 (1.16, 3.73) | 0.01* |

CTS, carpal tunnel syndrome; DM, diabetes mellitus; EDx, electrodiagnostic study

with a change in management with odds ratios (95% CI) of 3.81 (1.8, 8.08), 2.85 (1.11, 7.37), 2.24 (1.2, 4.2), 2.08 (1.16, 3.73), 2.07 (1.37, 3.29), 1.61 (1.15, 2.27), 0.5 (0.32, 0.78) and 0.47 (0.25, 0.88) respectively.

## Discussion

The present study showed 97.7% of the patients with neuromuscular disorders had their diagnoses either altered or confirmed after EDx. Consistent with the previous studies of Kothari et al,[7] and Lindstrom et al,[11] that demonstrated that EDx had been helpful in confirming and changing to new clinically relevant diagnoses in almost all cases. Nardin et al,[9] studied the diagnostic accuracy of EDx in the evaluation of weakness. They showed an overall diagnostic accuracy of 91%. The percentage of confirmation and change in diagnosis in this study was 69.3% and 28.4%. As in other research, the diagnoses were confirmed in 40-63% of cases[7,8,10-12] and were changed in 12.6-59.5% of cases.[7,8,10-12]

Confirmation of the diagnosis was around 70% in this study which is more than in the other studies. The proportion of the referring specialists may explain these findings. In this study, most referring specialists were orthopedic surgeons (65%) who had mostly diagnosed entrapment or focal nerve injury rather than complex ones. The very low percentage of general practitioners (GP) who referred patients for EDx in this study may be another reason. GP referrals from other hospitals accounted for only 6%. This contrasts with Mondelli et al,[13] Lindstrom et al,[11] and Cocito et al,[12] who reported GP referrals of 66%, 54% and 25% respectively. Neurologists and internal medicine physicians could not be easily differentiated because of the consultation and residency training system in the hospital. If these two specialties were summarized into the same group and called neurologists, they would account for 25% of referrals, which is still less than in the other studies. Most of the previous studies that investigated the usefulness of EDx showed that neurologists were the specialists with the most referral for EDx: 76% in Nardin et al,[9] and 31% in Cocito et al,[12] Multivariable analysis of variables associated with change in diagnosis could confirm this hypothesis. For those patients referred by a neurologist, the diagnosis was more than 80% more likely to be changed.

Twenty-eight percent of the patients had their diagnosis changed after EDx. A referral diagnosis of radiculopathy led

to a 3.7-fold greater likelihood of being changed. But if the referral diagnosis was CTS, it was not likely to be changed (Table 4). Not surprisingly, no referral diagnosis was a potent predictor for change in diagnosis after EDx, which was 2.6-times more likely to be changed. Female patients were 1.8-times more likely to have their diagnosis changed after EDx studies. It may arise from complex complaints or pain with negative physical examination findings that made the clinicians state no referral diagnosis or radiculopathy, which these two factors were the potent predictors for change in diagnosis. This was the opposite for patients with DM, whose diagnosis was unlikely to be changed. We did not find that being an inpatient or age of the patients were associated with change in diagnosis as found in the previous study of Lindstrom et al,[11] The very small proportion of inpatients may be a reason for the lack of statistical significance in this study.

When focusing on EDx diagnoses in the changed diagnosis group (Figure 1), 43% of studies were normal in patients with a referral diagnosis compared to 30% in the patients without referral diagnosis. Unlike the previous study by Lindstorm H et al,[11] that showed 65% vs. 12% in patients with and without a referral diagnosis, the percentage that may reflect different proportions of patients with and without a referral diagnosis. The present study had 88% vs. 12% whereas Lindstorm H et al,[11] had 56% vs. 44%. Almost all patients were referred from specialists (94%) in this study compared to 46% in Lindstorm et al,[11] The overall negative or normal EDx in this study was 12%, which did not differ from the previous studies, which had 2-37.5%.[7-,12,13]

About 1 out of 30 of referrals for NMJ disease actually had NMJ disease while about 1 out of 20 of referrals for myopathy in fact had myopathy. These findings may reflect the sensitivity and quality of EDx performed by the electromyographers. The number of EDx tests correlates with the confidence to detect abnormalities. The present study showed quite a small amount of EDx tests for each referral diagnosis (Table 3); because EDx is an operator dependent procedure, this problem made us aware of the need to improve the quality of EDx. Other techniques should be performed to improve the sensitivity of EDx especially in NMJ disease such as single fiber EMG.

The management of referred patients was changed in 29% of cases after EDx, which was similar to the previous studies of Perry et al,[8] and Shepherd MM[10] at 25% and 30% respectively. In contrast to the study of Lindstorm et al,[11] in which management was changed in 63.4% of the cases. The criteria to indicate change in management were the key reasons. In this study, rehabilitation, orthosis, conventional laboratory studies such as blood work or medication did not count as a change in management; therefore, referring neurologists were unlikely to change management. In contrast, orthopedic surgeons referral showed they were 2.2-times more likely to order further management, such as imaging, injection and surgery. The referral diagnoses of NMJ disease, MND and CTS were about 4, 3 and 2 times, respectively, more likely to lead to a change in management, whereas other mononeuropathies was unlikely to cause a change to management. A total of ≥ 15 EDx tests was associated with complex cases and was 2 times more likely to result in a change in management. Female patients were likely to have management changed by 60% while patients with DM were unlikely to have management changed. Female may correlate with CTS and NMJ disease (In this study, 68% of referral diagnoses of NMJ disease were female) that made these variables also correlated with a change in management.

For future improvement of the EDx laboratory, electromyographers should be trained and qualified especially in peripheral neurological disorders other than common nerve injury. Guidelines or protocols of EDx for each diagnosis should be developed. In the period of this study, there was one year in which we had residency training in the EDx laboratory, although the presence or otherwise of residency training was not the aim of this study. However, the author believe that residency training should affect the EDx quality in a positive way. If possible, the EDx laboratory should be audited for standard procedures and reports. The results from this study showed that only 4% of patients were pediatric compared with the previous studies, which had 16%.[11] EDx skills for pediatric patients should be improved. There are two good points in this study that should be addressed. Firstly, the low numbers of patients with no referral diagnosis (7%) when compared to 25% in Lindstrom et al,[11] and 35% in Mondelli et al,[13] Secondly, the EDx conclusion with inconclusive results was very low (1.7%) when compared to 16.5% in Perry et al,[8] A further important point, 45 cases were referred for EDx but the referring physicians did not read the EDx reports. The communication between electromyographers and the referring physicians should be improved.

There were some limitations of this study. Firstly, this study was a retrospective study based on medical record reviews in a tertiary hospital. Secondly, there was only one person who reviewed the medical record and who was also the electromyographer. Thirdly, there were no standard criteria for change in diagnosis or management. The definitions used in the present study were adapted from a previous study.[11] Fourthly, this study was performed in a tertiary hospital. Referrals to the EDx laboratory are different from community hospitals or large academic EDx laboratories. Lastly, as mentioned-above, electromyographers are not certified by a specific board of EDx. However, there were some strengths of this study including the large number of patients and the variety of the diagnoses. This EDx laboratory was a tertiary hospital in the ministry of public health. Half of the study was held without academic training intervention. It may be a good reflection of the situation of EDx service in tertiary hospitals in Thailand.

## Conclusions

EDx is a valuable investigation that can confirm (69.3%) or change a diagnosis (28.4%), and guides the appropriate management (29%) in patients with neuromuscular disorders. Referral diagnosis (radiculopathy, CTS or no referral diagnosis), referring specialists (neurologist), female patient and DM are the variables associated with a change in diagnosis after EDx. While referral diagnosis (NMJ disease, MND, CTS or other mononeuropathies), referring specialists (orthopedic surgeons), total number of EDx tests ≥ 15, female patient and DM are associated with a change in management.

## Disclosure

The author declares no conflict of interest.


## Acknowledgements

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**Short Communication**

# The Effectiveness of Tongue Palatal Resistance Exercise for Increasing Suprahyoid Muscle Strength in Patients with Oropharyngeal Dysphagia: A Home Exercise Program During the COVID-19 Pandemic

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**ABSTRACT**

*Objectives:* This study aimed to assess the effectiveness of a tongue palatal resistance exercise (TPRE) home exercise program for patients with oropharyngeal dysphagia.

*Study design:* One-group pre- and post-test.

*Setting:* Cipto Mangukusumo Hospital, Jakarta, Indonesia.

*Subjects:* Five patients with the following inclusion criteria: (i) oropharyngeal dysphagia, (ii) able to follow instructions, (iii) blood pressure < 160/110 mmHg, and (iv) never participated in a home oromotor exercise program.

*Methods:* The patients were trained to perform TPRE and were instructed to do 30 repetitions of the exercise per session, 3 to 5 sessions a week, for 2 weeks. Suprahyoid muscle strength was assessed using a surface electromyographic (EMG) biofeedback instrument before and then weekly after starting the home exercise program.

*Results:* The EMG activity of the suprahyoid muscle increased in all patients with a mean of 8.56 (SD 3.456) μV at baseline, 15.26 (SD 3.19) μV after the 1st week, and 17.44 (SD 3.922) μV after the 2nd week of TPRE.

*Conclusions:* A 2-week home program of tongue palatal resistance exercise can increase EMG activity, an indirect indication of increased suprahyoid muscle strength in individuals with oropharyngeal dysphagia. This home exercise program seems particularly appropriate during the current COVID-19 pandemic while hospital-based dysphagia rehabilitation services are limited.

**Keywords:** oropharyngeal dysphagia, tongue, resistance exercise, COVID-19 pandemic, rehabilitation

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## Introduction

Swallowing is an essential process for survival as a source of nutrition, hydration, and alimentation and which provides other contributions to the quality of life.[1,2] The tongue is a structure that works in mastication and is important in the formation, manipulation, and propulsion of boluses to the pharynx. It also helps in respiration and speech. Neurogenic disorders such as strokes can weaken the tongue muscles, thereby reducing mastication and reducing the ability to form boluses and divert them to the pharynx, increasing the accumulation of food residues in the oral cavity, and resulting in fluid leaks from the lips during aspiration, changes that are very significantly associated with morbidity and mortality.[3,4] Oropharyngeal dysphagia, the penetration of food, drink, or saliva into the larynx, their aspiration into the trachea and the accumulation of oropharyngeal residue,5 affects 30% of patients with a cerebrovascular injury, 52-82% of patients with a neurodegenerative disease, and more than 60% of geriatric patients.[5]

Since 2020 the world has faced a COVID-19 pandemic which has changed how patients with dysphagia are treated. Rehabilitation procedures recommended by the Dysphagia Research Society require special precautions because of aerosol production while conducting clinical evaluations of swallowing and during dysphagia management, including oromotor or cranial nerve examination, cough reflex examination, and suctioning procedures as well as swallowing exercises,[6] but it has become difficult for health care facilities to provide those services due to the pandemic.

Swallowing exercises have been demonstrated to improve swallowing and breathing functions.[1,7] One recently developed training approach for individuals experiencing swallowing disorders involving tongue weakness is tongue palatal resistance exercise (TPRE).[8] Previous studies have reported on the implementation of TPRE in a hospital setting.[3,8,9] However, during the COVID-19 pandemic, hospital services, including dysphagia rehabilitation at our hospital, have been limited, with only emergency or urgent visitations allowed. In response, we decided to modify our TPRE practice from hospital-based to home-based, and to use an electromyographic (EMG) biofeedback device only for training

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patients on how to perform the exercises correctly. At home, the patients performed the exercises by themselves, without EMG biofeedback. This study was carried out to evaluate the effectiveness of a two-week home-based TPRE program in increasing suprahyoid muscle strength in patients with swallowing problems.

## Methods

This one-group pre-test and post-test design study was approved by the Research Ethics Committee, Faculty of Medicine, University of Indonesia (20-07-0841).

After receiving informed consent, patients with oropharyngeal dysphagia which had been confirmed by a fiberoptic endoscopic evaluation of swallowing (FEES) test, were able to follow the exercise program instructions, had blood pressure controlled below 160/110 mmHg, and had never participated in a home program of oromotor exercise were recruited into the study. Exclusion criteria were uncontrolled hypertension, inability to conduct suprahyoid muscle strength measurements, and inability of the patient to carry out the exercises. The dropout criterion was not doing the exercises for more than 2 consecutive days.

TPRE is designed to produce tongue pressure by lifting the tongue against the palate near the alveolar ridge and elevating the floor of the mouth (Figure 1).[9,10] All participants were trained to perform the exercise using surface EMG biofeedback. They were then instructed to do 30 repetitions of the exercise holding each muscle contraction for 10 seconds, repeating the exercise 3 to 5 times a week for two weeks without EMG biofeedback.

EMG biofeedback measurement of tongue pressure, a representation of suprahyoid muscles strength, was done using a surface EMG biofeedback device (Chattanooga VitalStim® Plus Four Channel Electrotherapy System (Chattanooga Group, Inc., Austin, TX, USA). Surface electrodes with a diameter of 2 cm were placed over the suprahyoid area (Figure 2). During the 10 seconds of sustained contraction of TPRE, EMG activity was monitored and measured in μV,[11] representing the suprahyoid muscles strength. Baseline data was recorded during the TPRE training. A follow-up assessment was conducted at the clinic twice: after the first and second weeks of practicing the home exercise program.

The patients' demographics, clinical data including the Dysphagia Severity Scale based on FEES (1, saliva aspiration; 2, food aspiration; 3, water aspiration; 4, occasional aspiration; 5, oral problems; 6, minimum problems; and 7, within normal limits),[12] and the EMG activity measured at baseline and follow-up were recorded.

## Results

A total of 5 participants (Table 1) were followed weekly for two weeks after TPRE; there were no dropouts during the study. The majority were male (60%), with a mean age of 60.4 years (SD 6.69). All participants demonstrated increased EMG activity after the first and second weeks of TPRE (Table 2). The mean suprahyoid muscle strength was 8.56 (SD 3.456) μV at baseline, 15.26 (SD 3.19) μV after the first week, and 17.44 (SD 3.922) μV after the second week.

## Discussion

This was the first study of a 2-week home TPRE program for dysphagia patients during the COVID-19 pandemic in Indonesia. Each of the 5 patients had a different level of severity, duration, and cause of dysphagia. Increased EMG activity of the suprahyoid muscle was seen at the end of the first week, increasing further by the end of the second week of TPRE in all patients. The amount of the increase varied, but was greater in the patients with more severe dysphagia at baseline, including those with chronic dysphagia, than those with a less severe condition.

These results suggest that, even without EMG biofeedback, the home exercise TPRE program produces positive effects. Those effects might potentially be increased still further with proper TPRE training using an EMG biofeedback device.

Tongue movement against resistance while performing

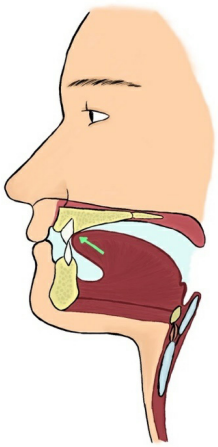

**Figure 1.** Tongue palate resistance exercise (TPRE) (modified from Bae Y, 2013)[13]

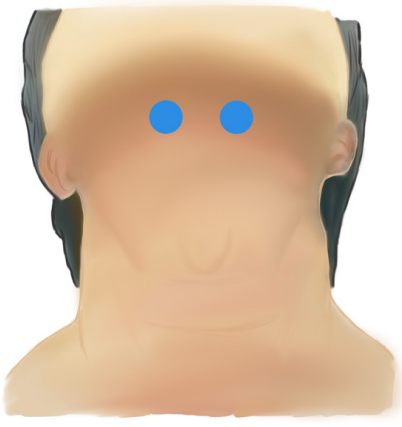

**Figure 2.** Surface electrode placement over the suprahyoid area for recording electromyographic (EMG) activity of suprahyoid muscles

**Table 1.** Baseline characteristics of participants

| Subject | Gender | Age | Underlying Disease | Tracheostomy | Dysphagia Severity Scale | Onset of dysphagia |
|---|---|---|---|---|---|---|
| I | Female | 57 | Presbyphagia | No | 2 | < 6 months |
| II | Female | 52 | Nasopharyngeal carcinoma | No | 2 | < 6 months |
| III | Male | 65 | Ischemic stroke | No | 5 | < 6 months |
| IV | Male | 69 | Ischemic stroke | Yes | 4 | 6 - 12 months |
| V | Male | 59 | Nasopharyngeal carcinoma | Yes | 1 | > 12 months |

**Table 2.** Change in electromyographic (EMG) activity over the suprahyoid area while performing tongue palate resistance exercise

| Subject | Baseline DSS | EMG activity (μV) | | |
|---|---|---|---|---|
| | | T0 | T1 | T2 |
| I | 2 | 5.0 | 18.00 | 22.80 |
| II | 2 | 8.3 | 11.80 | 12.00 |
| III | 5 | 13.0 | 18.60 | 18.90 |
| IV | 4 | 11.0 | 12.10 | 16.50 |
| V | 1 | 5.5 | 15.80 | 17.00 |

DSS, Dysphagia Severity Scale
T0, pre-exercise; T1, at the end of 1st week; T2, at the end of 2nd week

TPRE increases suprahyoid muscle function, thereby increasing the elevation of the hyoid both anteriorly and superiorly during swallowing, thus indirectly improving the pharyngeal phase.[3,9] In addition, a stronger tongue push against the palate results in moving the boluses in the oral cavity more quickly and safely toward the pharynx, and reducing pharyngeal residues and aspiration of boluses during the pharyngeal phase of swallowing.[3,9]

Because this study was conducted during the COVID-19 pandemic, there were some limitations: (1) there was only one small group with diverse causes of dysphagia and no control group, (2) the period of study was short and there was no long-term follow-up, (3) a proper device for assessing tongue muscle strength was not available in Indonesia, and (4) there was no re-assessment of dysphagia severity after completing the program. Based on the results of this study, a randomized controlled trial using appropriate outcome measurements including the comparison between exercise and non-exercise, hospital- and home-based exercise programs, as well as short and long duration exercise programs and including both subacute and chronic cases should be conducted before further clinical implementation.

## Conclusions

A 2-week home program of tongue palate resistance exercises demonstrated improvement in suprahyoid muscle strength. Further studies are needed to confirm the effectiveness of those exercises in improving swallowing function.

## Disclosure

The authors declare no conflicts of interest.


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# Foot Drop as an Unusual Presentation of Plexiform Neurofibroma: A Case Report of an Otherwise Healthy Female

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**ABSTRACT**

*Objectives:* To describe an unusual presentation of plexiform neurofibroma in an otherwise healthy female patient.

*Study design:* Case report.

*Setting:* Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital, Bangkok.

*Subjects:* A 46-year-old otherwise healthy female presenting with right foot drop.

*Methods:* Not applicable.

*Results:* An electrodiagnostic study was performed by a physiatrist to determine the cause and evaluate the severity of the foot drop and to reveal any evidence of abnormalities extending to the sacral plexus. The evidence discovered lead to further investigation, including magnetic resonance imaging (MRI) of the plexus, which confirmed the diagnosis of plexiform neurofibroma. The patient had no skin lesions and no family history of neurofibroma. The tumor was removed and a biopsy confirmed an intraneural neurofibroma. A plastic ankle foot orthosis was prescribed to assist ankle dorsiflexion and improve walking. Six months after surgery, power of the involved muscles showed no significant improvement.

*Conclusions:* Foot drop in healthy individuals can result from plexiform neurofibroma even without a definitive diagnosis of neurofibromatosis type 1. Electrodiagnostic study should be the first step before undertaking further investigation, e.g., MRI. MRI is prescribed to confirm the diagnosis and location of the lesion.

**Keywords:** foot drop, plexopathy, plexiform neurofibroma, electrodiagnosis, rehabilitation

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## Introduction

Foot drop is common presentation leading patients to visit a physiatrist for a definite diagnosis and proper appropriate management. Foot drop can result from central, peripheral, and other metabolic causes. Injury at any point of along the peripheral nerve, especially a peroneal nerve injury, is the most common cause of foot drop.[1]

Electrodiagnostic study commonly involves an investigation to locate the lesion and to evaluate the cause and severity of the foot drop. Neurofibromas are benign nerve tumors that contain multiple nerve fascicles.[2] They are commonly poorly circumscribed and locally invasive.[3] Plexiform neurofibroma is generally believed to present exclusively in patients diagnosed with neurofibromatosis type I and is a pathognomonic sign.[3] There are few case reports of neurofibroma involving the lower extremities.[2, 4-6] For that reason, we report this rare case of an otherwise healthy female presenting with foot drop which was later diagnosed as plexiform neurofibroma.

## Case presentation

A 46-year-old female presented with right foot drop at the rehabilitation out-patient department. She recognized the foot drop in her right foot from difficulty climbing stairs and frequent falls for a year before this visit. She also had numbness at the anterolateral part of her right leg and the dorsum of her right foot. She denied any underlying disease or traumatic events. She had history of frequent alcohol drinking while sitting crossed-legged. Right foot drop with steppage gait, muscular atrophy at both anterior and posterior aspects of the right lower leg as well as the posterior thigh were observed. There were no skin lesions or brown freckling spots (cafe-au-lait macules), brown dome shape lesions (neurofibromas) or brown pigmentation in the eye (Lisch nodules). The pin-prick sensation was diminished at the anterolateral aspect of the right leg and dorsum of the right foot. Muscle power of the upper extremities was normal but some muscles of the lower extremities were severely weak or paralyzed as shown in Table 1. Tinel's sign was positive at the right fibular head area with a tingling sensation down to the right foot. Deep tendon reflexes (DTRs) were 1+ for all extremities. Electrodiagnostic study was performed by a physiatrist.

An electrodiagnostic study, including a nerve conduction study and needle EMG, were performed and the findings are shown in Tables 2, 3 and 4. The diagnosis was incomplete right L5-S1 sacral plexopathy with signs of chronic degeneration at the L4-5 level and active degeneration at the S1 level. Further investigation of cause of the sacral plexopathy was suggested.

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**Table 1.** Muscle power of the lower extremities according to the Medical Research Council (MRC) grading

| Muscles | Hip flexors | Hip extensors | Knee flexors | Knee extensors | Hip abductors | Ankle dorsiflexors | Ankle plantar flexors | Tibialis posterior | Peroneus longus | Extensor hallucis longus |
|---|---|---|---|---|---|---|---|---|---|---|
| Right | 5 | 3 | 5 | 5 | 5 | 1 | 5 | 5 | 1 | 0 |
| Left | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |

**Table 2.** Findings and interpretation of sensory nerve conduction study

| Nerve - site of stimulation | Onset latency (ms) | Peak amplitude (microV) | Peak-Peak amplitude (microV) | Duration (ms) | Distance (cm) | Velocity (m/s) |
|---|---|---|---|---|---|---|
| Sural nerve - lateral malleolus | | | | | | |
| Left | 2.4 | 18.4 | 15.7 | 2.03 | 10 | 40.9 |
| Right | 2.6 | 9.7 | 6.6 | 1.93 | 10 | 38.4 |
| Superficial peroneal | | | | | | |
| Left | 2.7 | 6 | 5.1 | 2.45 | 12 | 44.3 |
| Right | | | | | | |
| Saphenous - Ankle | | | | | | |
| Left | 2.8 | 6.1 | 1.5 | 1.56 | 12 | 43.5 |
| Right | 2.7 | 5.1 | 0.59 | 1.30 | 11 | 41.4 |

| Interpretation of sensory nerve conduction study | |
|---|---|
| Right sural nerve | Low SNAP amplitude, normal latency and velocity |
| Right superficial peroneal nerve | No response |
| Right saphenous nerve | Normal latency, amplitude and velocity |
| Left sural nerve | Normal latency, amplitude and velocity |
| Left superficial peroneal nerve | Normal latency, amplitude and velocity |
| Left saphenous nerve | Normal latency, amplitude and velocity |

SNAP, sensory nerve action potential; ms, millisecond, microV, microvolt; cm, centimeter; m/s, meter/second

**Table 3.** Findings and interpretation of sensory nerve conduction study

| Nerve - site | Latency (ms) | Amplitude (mV) | Distance (cm) | Velocity (m/s) |
|---|---|---|---|---|
| Left Common peroneal nerve - EDB | 5 | 6.2 | | |
| | 12.66 | 5.4 | 35 | 45.7 |
| Right Common peroneal never - EDB | 7.55 | 0.1 | | |
| | 19.74 | 0.1 | 30 | 24.6 |
| Left Tibial nerve - AH | 3.54 | 21.1 | | |
| | 11.77 | 15.1 | 38 | 46.2 |
| Right Tibial nerve - AH | 3.96 | 19.4 | | |
| | 13.07 | 15.4 | 36.5 | 40 |

| Interpretation of motor nerve conduction study | |
|---|---|
| Right common peroneal nerve | Low CMAP amplitude, prolonged latency and slow velocity |
| Right tibial nerve | Normal latency, amplitude and velocity |
| Left common peroneal nerve | Normal latency, amplitude and velocity |
| Left tibial nerve | Normal latency, amplitude and velocity |

CMAP, compound muscle action potential; ms, millisecond; mV, millivolt; cm, centimeter; m/s, meter/second; EDB, extensor digitorum brevis muscle; AH, abductor hallucis muscle

When the electrodiagnostic findings suggested plexopathy, the physiatrist requested a magnetic resonance imaging (MRI) of the sacral plexus to identify and locate any lesions of the lumbar and sacral plexus. The MRI showed a 1.1x3.4x4.5 cm ill-defined elongated shape heterogenous enhancing lesion located anteriorly to the right sacral alar and extending into the right sciatic foramen along the right L5 nerve root, probably a plexiform neurofibroma (Figure 1). In addition, it revealed lumbar spondylosis with degenerative discs and central disc herniations causing stretching of the bilateral L5 traversing nerve roots (predominantly on the left) and an extraforaminal left L5 exiting nerve root. At this stage, a neurosurgeon and a neurologist were consulted to do a workup on neurofibromatosis and treatment of plexiform neurofibromas.

**Table 4.** Needle EMG summary table

| Muscles of the right lower extremity | Insertional activity | Fib | PSW | Amp | Dur | PPP | Recruitment pattern |
|---|---|---|---|---|---|---|---|
| Rectus femoris | Normal | None | None | Normal | Large | Normal | Normal |
| Tibialis anterior | Increased | 2+ | 2+ | Normal | Normal | Normal | Discrete |
| Gastrocnemius (medial head) | Normal | None | None | Normal | Normal | Normal | Normal |
| Peroneus longus | Increased | 2+ | 2+ | Normal | Normal | Normal | Discrete |
| Tibialis posterior | Normal | None | None | Normal | Normal | Normal | Reduced |
| Biceps femoris (short head) | Normal | None | None | Normal | Normal | Normal | Reduced |
| Gluteus maximus | Increased | 2+ | 2+ | Normal | Normal | 2+ | Reduced |
| Lumbar paraspinal muscles (L5-S1) | Increased | None | None | Normal | Normal | Normal | N/A* |

Abbreviations: EMG, electromyography; MUAP, motor unit action potential; Fib, fibrillation potential, PSW, positive sharp wave; Amp, amplitude; Dur, Duration; PPP, polyphasic potential; N/A, not applicable

* Recruitment pattern was not evaluated at paraspinal muscles

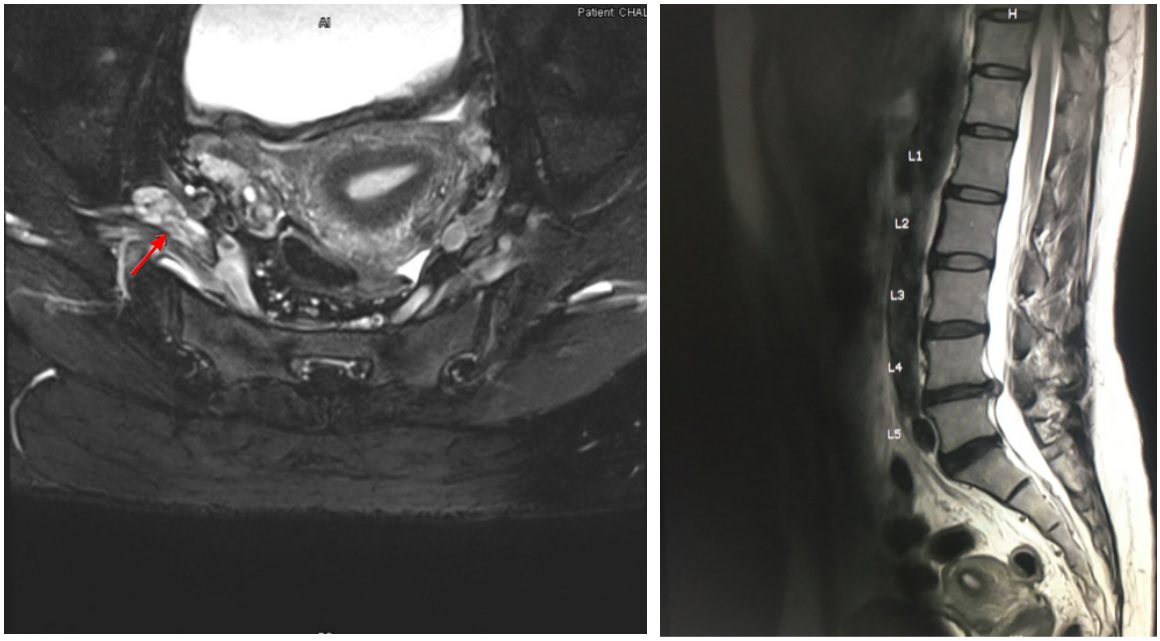


**Figure 1.** Magnetic resonance imagining (MRI) of the sacral plexus. The red arrow points to a mass located anteriorly to the right sacral alar

While waiting for surgery, the physiatrist prescribed an outpatient rehabilitation program which consisted of range of motion and strengthening exercises and electrical stimulation (ES). In addition, the patient was instructed to apply home-use ES at the weak/paralyzed muscles once or twice a day. A plastic ankle foot orthosis was also prescribed so the patient could ambulate comfortably.

The surgery, a transabdominal retroperitoneal approach for tumor removal, was done by a neurosurgeon. Pathology examination of the mass confirmed the diagnosis of intraneural neurofibroma. There were no changes in muscle power after the surgery.

A follow-up MRI at 6 months after surgery revealed no enhanced neurofibroma of the right L5 or other lumbar nerve roots, indicating probable total removal of the tumor; however, There was no neurological improvement after surgery and the patient continued to complained of fatigue after walking long distances.

## Discussion

This is a rare case of an otherwise healthy woman presenting with foot drop due to plexiform neurofibroma without a diagnosis of neurofibromatosis type I. Neurofibromatosis type I (NF type I) was first described by Frederich von Recklinghausen in 1882.[7] NF type I is a relatively common neurocutaneous disease with an autosomal-dominant inheritance pattern.[4] About 50% of individuals with NF type I have no family history of the disease is, indicating the disease is due to de novo mutations in the 17.q11.2 chromosome. Diagnostic criteria of neurofibromatosis were established by the National Institutes of Health (NIH) Consensus Development Conference on Neurofibromatosis in 1998 and are shown in Table 5. In this case, the patient met only one criterion, a single plexiform neurofibroma, which was not compatible with the NIH criteria for a definitive diagnosis of neurofibromatosis type 1. Plexiform neurofibroma is one of the non-malignant features that can also be found in patients with NF type I.[4,7,8]

**Table 5.** The National Institutes of Health (NIH) criteria for neurofibromatosis type 1 (From the NIH consensus development conference 1998)[7]

| |
|---|
| Clinical diagnosis based on presence of two of the following: |
| 1. Six or more café-au-lait macules over 5 mm in diameter in prepubertal individuals and over 15 mm in greatest diameter in post pubertal individuals. |
| 2. Two or more neurofibromas of any type or one plexiform neurofibroma. |
| 3. Freckling in the axillary or inguinal regions. |
| 4. Two or more Lisch nodules (iris hamartomas). |
| 5. Optic glioma. |
| 6. A distinctive osseous lesion such as sphenoid dysplasia or thinning of the long bone cortex, with or without pseudarthrosis. |
| 7. First-degree relative (parent, sibling, or offspring) with NF-1 by the above criteria |

Neurofibromas may occur anywhere along a nerve from the dorsal root ganglion to the terminal nerve branches.[2] Plexiform neurofibroma without neurofibromatosis type I is uncommon and rarely presents in combination with foot drop.[4] There are few case reports published about neurofibroma involving the lower extremity. In 1994, Nagel et al,[5] reported on an athletic patient who presented with a non-traumatic peroneal neuropathy which failed to resolve after a period of rest. In that case, finally imaging showed a multilobulated mass along the course of the common peroneal nerve consistent with a plexiform neurofibroma. Another report described the case of a patient who suffered from chronic anterior leg pain that failed to respond to medical treatment, including multiple injections.[6] In that case, electromyography identified abnormal findings in the accessory peroneal nerve branch in the discomfort area. Finally, MRI results showed a hyperintensity signal and perifascial hyperintensity superficial to the anterior musculature with a nodular-like signal measuring about 6 mm.

A review of the literature found that the presenting symptoms usually include pain, soreness or a tingling sensation at the tumor area as well as weakness in the legs and difficulty walking or running. Chang et al,[2] reported a case of neurofibromatosis type 1 with a painful palpable mass, about 10 cm in diameter, in the right leg for 1 year. MRI revealed low-to-intermediate signal intensity between the anterior tibia, peroneus longus, and brevis muscles on T1-weighted images (T1WI), and high signal intensity on T2-weighted images (T2WI). The T2WI images were characterized by a low-density center and a hyperintense rim. After a tumor removal operation, the patient's soreness, tingling sensation, and tolerance of long periods of standing improved dramatically.

Treatment of plexiform neurofibromas is usually conservative owing to the high rate of recurrence and significant morbidity associated with surgical resection requiring sacrifice of the parent nerve.[3,4,7,9] In the present case, the patient was operated on and the tumor seems to have been totally excised without further weakness but with no recovery of strength. This might be due to the patient having been seen late, one year after the onset and when, prior to the surgery, the involved muscles had become completely or nearly completely paralyzed. At 6 months after surgery, power of the involved muscles still had not changed. ES seemed not to provide benefit in this case due to the severe muscular atrophy, but it did irritate the patient's skin. Plastic AFO, range of motion and strengthening exercises of the muscles around the hip and ankle were beneficial. The patient could walk safely and comfortably with a plastic AFO in her daily activities.

## Conclusions

This study presents a rare case of a woman presenting with foot drop without any underlying disease. A physiatrist provided comprehensive care, including complete history taking, physical examination, an electrodiagnostic study and proper rehabilitation treatment. After the electrodiagnostic study, further imaging was indicated which revealed the true cause of foot drop.

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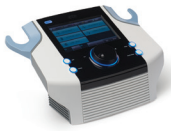

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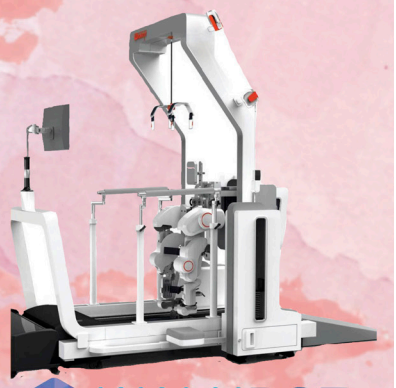

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