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Letter from the Editor

Dear Readers,

It is with great pleasure that we present the latest issue of our journal, highlighting a diverse array of recent studies that advance our understanding across various fields of clinical research and rehabilitation.

In our first featured study, Jaroenpakdee and colleagues conducted a double-blind randomized trial assessing blood flow restriction (BFR) combined with low-load resistance exercise for individuals with knee osteoarthritis (OA). Their findings suggest that BFR can enhance knee extensor strength without worsening symptoms, offering a promising adjunctive therapy for this common condition.

Pimubol and colleagues carried out a preliminary randomized, double-blinded controlled trial examining the effects of focused extracorporeal shockwave therapy (fESWT) combined with night splints in patients with moderate carpal tunnel syndrome (CTS). Their results suggest that adding fESWT to night splint therapy is both safe and effective, with four treatment sessions potentially offering a more cost-effective approach compared to ten sessions.

Lertpanyawattanakul and colleagues conducted an ambidirectional cohort study to explore factors influencing goal attainment in children with cerebral palsy (CP). Their findings underscore that children with higher gross motor function are more likely to achieve therapeutic goals. Notably, high-functioning children may benefit from active interventions aimed at improving ambulation and hand function, whereas lower-functioning children tend to progress best through passive goals focused on preventing complications and achieving early motor milestones.

In the realm of stroke rehabilitation, Charussuriyong et al. developed a clinical predictive score to forecast functional outcomes following intensive rehabilitation. Their model, based on eight variables—including age, timing of admission, neglect, cognitive status, depression, muscle strength, and walking ability—aims to assist clinicians in patient selection and personalized treatment planning.

Tantamacharik and colleagues provided insights into patient experiences with hallux valgus treatments at Siriraj Hospital. Their cross-sectional study highlights that footwear modification remains the most utilized and preferred treatment, resulting in significant clinical improvements. They recommend further research into newer modalities, such as bunion shields and toe separators, to expand treatment options.

Finally, a retrospective study by Aueaananratthakit et al. investigated the prevalence and impact of urinary tract infections (UTIs) during inpatient stroke rehabilitation. Their findings reveal an 11.5% prevalence, higher among older patients, those with recurrent strokes, dysphagia, and urinary catheter use. Interestingly, functional gains during rehabilitation appeared more closely related to age and dysphagia than to the presence of UTI.

We hope you find these studies informative and inspiring as we continue to explore innovative approaches to improve patient outcomes.

Sincerely,

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

Original Article

Blood Flow Restriction with Low-load Resistance Exercise Improves Strength in Adults with Risk Factors for Knee Osteoarthritis: A Double-Blind Randomized Controlled Trial

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ABSTRACT

Objectives: To assess the efficacy of blood flow restriction (BFR) with Low-load Resistance Exercise improving knee extensor strength in adults with risk factors for symptomatic knee osteoarthritis (OA)

Study design: Double-blind randomized controlled trial

Setting: Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand

Subjects: Forty-four adults aged ≥ 40 years who engaged in irregular physical activity and had at least one risk factor for symptomatic knee OA were enrolled. Participants were randomly assigned to either the BFR or the control group using stratified and mixed block randomization.

Methods: The study employed a double-blind, randomized, controlled trial design. The BFR group exercised twice a week for 4 weeks, performing knee extension exercises at 30.0% of their one-repetition maximum (1RM) (15 reps × 4 sets) with cuff pressure, while the control group performed the same exercises but without using the cuff protocol. The outcomes measured included 1RM isokinetic knee extension, 1RM isokinetic leg press, 30-second chair stand test, and Knee Injury and Osteoarthritis Outcome Score (KOOS). Test results pre-exercise and post-exercise (3 days after the last exercise session) were recorded. Differences in results between groups were compared using the linear regression test.

Results: The post-test mean differences of 1RM isokinetic knee extensor, 1RM leg press, 30 second chair stand test, and KOOS between groups (adjusted mean difference, AMD) were 14.7 kg (95% confidence interval (95%CI) 4.0, 19.3; $p < 0.001$), 30.83 kg (95%CI: 18.0, 43.7; $p < 0.001$), 7.1 times (95%CI: 4.2, 10.1; $p < 0.001$) and 1.4 points (95%CI: 0.3, 2.5; $p = 0.01$) respectively, all of which were statistically significant ($p < 0.05$).

Conclusions: BFR can improve knee extensor strength in adults with risk factors for symptomatic knee OA compared to low-load resistance exercise alone without further worsening knee symptoms.

Keywords: blood flow restriction therapy, resistance exercise, knee osteoarthritis, randomized controlled trial (RCT)

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Introduction

Osteoarthritis (OA) is a degenerative disease with an incidence that is increasing each year. In 2020, more than 654 million people worldwide suffered from OA.[1] Strengthening the muscles around the knee joint, especially the quadriceps muscle, can help reduce and slow the progression of the disease in people with a history of knee OA[2]. The current recommendation is that resistive exercise at a weight level of 70.0-80.0% of the one repetition maximum (1RM) can increase muscle size (hypertrophy) and muscle strength.[3] However, adverse complications have been reported in adults exercising with resistance at this intensity, such as pain in the knee, inability to tolerate exercise, and incidence of knee injury, a factor that increases knee degeneration[4].

Blood Flow Restriction Training (BFR) is a type of resistance training that combines controlling blood flow by wrapping a tourniquet (cuff or band) around the proximal part of the muscle with weight training. BFR uses less weight to train than other systems and can increase muscle mass while reducing unwanted post-exercise effect,[5] especially in individuals who cannot tolerate high-intensity resistance training or who have limitations on performing conventional exercises. For these reasons, BFR is considered an appropriate option in terms of both safety and efficacy. Increased blood flow within the muscles (blood pool) results in a chemical reaction that causes more lactic acid to accumulate in the muscles, the primary mechanism. This change stimulates the body by transmitting signals to the central nervous system, which then prompts the body to react to the repair process by instructing it to increase growth hormone production, thereby generating more protein.[6-13] However, due to a lack of clinical

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information on the subject and the fact that physical therapy and rehabilitation medicine in Thailand have not yet widely adopted BFR, the practical application of this therapy method remains limited in that country.

A systematic review by Hughes et al.[6] highlighted significant methodological limitations in prior studies, particularly the inadequate control of confounding factors. Many studies have failed to report whether participants in either the intervention or control groups engaged in additional exercise during the intervention period. Consequently, the TESTEXT SCORE (study quality assessment) indicated a score of 0 for both items 4 (presentation of baseline characteristics) and 8 (control group activity is controlled and presented).

To address these limitations, this study aimed to evaluate adults, ranging in age from middle-aged to elderly, who had risk factors for developing symptoms of OA by assessing quadriceps muscle strength. Participants' physical activity undertaken outside of the trial was restricted and monitored using a personal research diary. Participants who engaged in regular physical activity were disqualified from the study. Given the heterogeneity of blood flow restriction (BFR) training protocols in the literature, this study also incorporated key parameters identified in prior systematic reviews, such as the minimum daily exercise duration, the number of exercise sessions per week, and the training intensity, to align with established practices in BFR research. This investigation represents the first clinical study of its kind to be conducted in Thailand.

Methods

Study design

This double-blind, randomized, controlled study was registered with the Thai Clinical Trial Registry (No. TCTR 20210903007). The project additionally obtained approval from the Maharat Nakhon Ratchasima Hospital Institutional Review Board (MNRH IRB) with approval date on June 17, 2021 (Certificate No. 063/2019). This research was conducted in accordance with the CONSORT 2010 guidelines.

Participants

The target population of this study was Thai people aged ≥ 40 years with at least one risk factor for symptomatic knee OA and who engaged in some form of irregular physical activity. All participants in the study were hospital employees with desk jobs and were recruited by viewing a poster located at the outpatient department of the Rehabilitation Clinic between February and August 2021. The sample size was determined using data from a study by Neil A. Segal et al.[14] ($Z = 1.96$, $p = 0.05$, $Z\beta = 0.84$, $\sigma^2 = 12.2$, $\mu\alpha - \mu\alpha = 11.4$) adjusted by adding 20.0% to account for possible dropouts. Forty-four individuals made up the total, with 22 individuals each in the BFR group and the control group.

Inclusion criteria

1. Age 40 years or older as of the start of research
2. Ability to understand the Thai language and consent to participate in the research
3. Ability to stand, walk, and sit normally during the test.
4. Having at least one of the following strong risk factors and symptoms for symptomatic knee OA[15,16] :
   - 4.1 Body mass index (BMI) ≥ 24 kg/m²
   - 4.2 A history of knee injuries or knee surgery
   - 4.3 A history of intermittent knee pain or stiffness lasting less than 30 minutes

Exclusion criteria

1. Engaging in regular physical activity (e.g., ≥ 2-3 times/week, ≥ 150 minutes/week of moderate intensity, or ≥ 5,000 steps/day[17,18]).
2. Having signs of infection or inflammation
3. Having undergone knee-related surgery within the previous 6 months
4. Having a film x-ray record of the knee joint showing grade 2 to 4 on the Kellgren and Lawrence classification.
5. Having contraindications to exercise according to The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) guidelines.[19]

Randomization

The participants were provided with information about the study by the researcher to enable them to make an informed decisions regarding giving verbal and written consent to participate in the study. In the trial, patients were randomly allocated to one of two groups (a BFR group and a control group) using mixed block randomization (blocks of 2 and 4) using stratified randomization to separate sex into strata. In a process hidden from the participants, a computerized randomization procedure assigned each participant a group code which was then put into a sealed envelope.

Equipment

1. B Strong™ with B-Strong BFR Cuff available in 4 sizes: S, M, L, XL for limb girth circumferences ranging between 11.25 to 37.50 inches.
2. Plate-loaded leg extension machine
3. Leg press machine (MATRIX brand, model VS-S70)
4. Automatic pressure measuring device
5. Stable 4-legged chair with backrest
6. Stopwatch
7. Biodex System 4 Dynamometer (Biodex Medical Systems, Inc., Shirley, NY, USA) with software

Procedure

When the participants arrived at the fitness center of Maharat Nakhon Ratchasima Hospital for grouping, the first sports scientist opened the envelope and provided workout instructions for 4 weeks (Table 1 and Table 2) applying the protocol from Segal's research,[20] but with the number of

repetitions in the first set reduced to 15. The pre-exercise questionnaire and the patient's baseline data were both documented by the study's author. Another physician, who was not involved in this research, measured the participants' vital signs before and after each daily workout. A second sports scientist tested the participants and recorded the results pre-test (1 day before the first exercise session) and post-test (3 days after the last session of the 4-week exercise program). 1RM was measured in kilograms (kg) using a Biodex System 4 Dynamometer.

Participants in both groups were not informed about the exercises prior to the start of the study and were also told not to discuss the exercises or the measurements until the study had been completed. Additionally, the portion of the BFR device that controlled the pressure in the thighs was covered with a black cloth, so participants could not see it during the exercise. As a result, the participants were unaware of the exact pressure level or any changes in that level during each session.

Although all participants described themselves as being physically inactive, they agreed to record any physical activity in diary books provided to them at the time they consented to join the study. They were also asked to describe their daily activities, including exercise outside the study, any complications that arose after exercise during the study, their daily food intake, and their sleep patterns. This was done to identify any potentially confounding factors, including activities outside the research, and to have a record of their having met the criteria regarding regular exercise as specified in the exclusion criteria.

Outcome measurements

1) Primary outcome: 1RM isokinetic knee extension

2) Secondary outcome: 1RM isokinetic leg press, 30-second chair stand test, Knee injury and OA Outcome Score (Thai version-KOOS; internal consistency with Cronbach's α = 0.88 (95%CI: 0.83, 0.91); Test-retest reliability with ICC = 0.87 (95%CI: 0.77, 0.92). A linear regression test was used to compare the results between groups.

Results

A total of 54 participants were screened; 10 were excluded, 9 because they were regular exercisers, and one who had a history of recurrent uncontrolled hypertension. A total of 44 participants were finally recruited and randomly assigned to either the BFR group (22 participants, comprising 9 men and 13 women) or the control group (22 participants, comprising 9 men and 13 women). No participants withdrew during the study as indicated in Figure 1. Baseline data of both groups are shown in Table 3, including gender, age, height, body mass index (BMI), and pre-exercise test results. The pre-test results of both groups, consisting of 1RM isokinetic knee extension (kg), 1RM isokinetic leg press (kg), 30-second chair stand test (times), and KOOS (points), were similar, with a *p*-value greater than 0.05, shown in Table 3.

1RM isokinetic knee extension

Before exercise, the experimental group had a mean pre-test weight of 27.7 kg (SD = 10.1 kg), and the control group had a mean of 31.0 kg (SD = 10.0 kg). After 4 weeks of exercise, the mean post-test score of the BFR group was higher than the control group, with an average of 51.1 kg (SD = 15.6 kg) and 39.4 kg (SD = 8.6 kg), respectively, shown in Table 4. The mean post-test difference between groups (unadjusted mean difference, UMD) was 11.65 kg (95%CI: 4.0, 19.3) and after adjusting for the pre-test (adjusted mean difference, AMD), it was 14.7 kg (95%CI: 9.6, 19.9), a statistically significant difference ($p < 0.001$). The difference in average weight between males in the two groups was 21.5 kg (95%CI: 15.1, 28.0), a statistically significant difference ($p < 0.001$). In females, the mean weight was 7.3 kg (95%CI: 1.2, 13.4), also a statistically significant difference ($p = 0.02$) shown in Table 5. The trend of results for both groups is presented in Graph A of Figure 2.

Figure 2. Graphs of outcomes by study group adjusted for pre-test. (A) 1RM knee extension, (B) 1RM leg press, (C) 30-second chair stand test, and (D) KOOS

Table 1. The resistance training protocol of the study

Detail	Intervention group (BFR group)	Control group
Form of exercise	Bilateral knee extension	
Number of repetitions per set	15	
Number of sets	4	
Rest time between sets (seconds)	30	
Intensity	30% of 1RM each week	
Number of sessions per week	2	
Total weeks	4	
Cuff pressure	BFR with incremental inflation pressure protocol	BFR cuff with initial pressure only (no incremental inflation pressure)

BFR, blood flow restriction; RM, repetition maximum

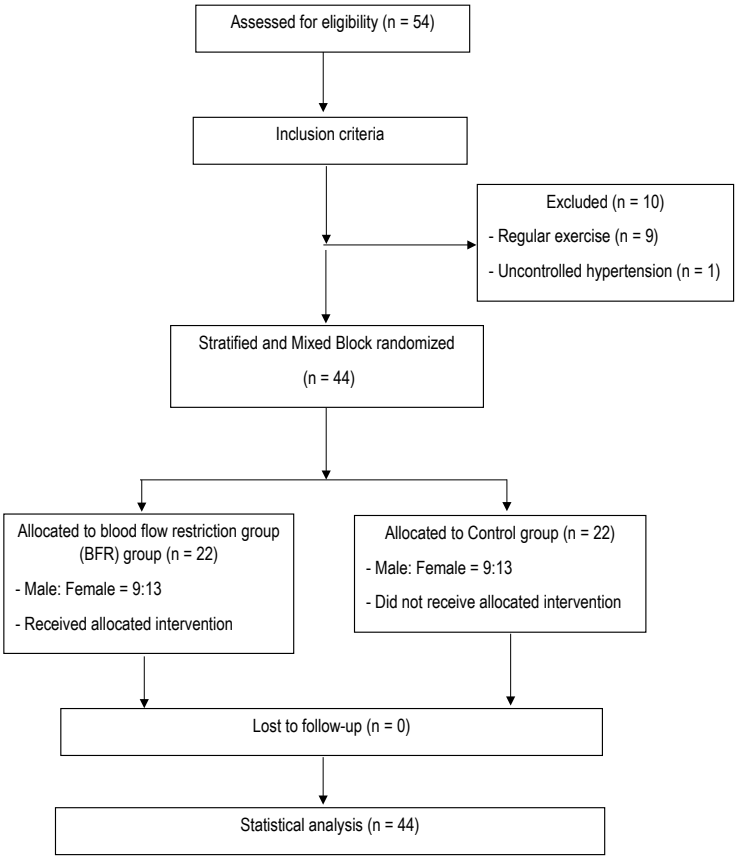

Figure 1. CONSORT diagram

Table 2. Study cuff pressure protocol

Order of week and session (Week. session)	Initial pressure (mmHg)	Incremental inflation pressure (mmHg)				
		Before 1st set	1st set	2nd set	3rd set	4th set
Pre-exercise test (1 day before the first exercise session)						
1.1-1.2	40	80	100	120	140	160
2.1-2.2	40	100	120	140	160	180
3.1-3.2	40	120	140	160	180	200
4.1-4.2	40	120	140	160	180	200
Post-exercise test (3 days after the last exercise session)						

1RM isokinetic leg press

The pre-test of the BFR group had an average of 67.1 kg (SD = 31.1), while the control group had a higher average of 76.3 kg (SD = 32.2 kg). The post-test results for the BFR group and the control group were 110.3 kg (SD = 34.8 kg) and 87.2 kg (SD = 33.1 kg), respectively, shown in Table 4. The UMD equals 23.7 kg (95%CI: 2.4, 43.7) and the AMD equals 30.8 kg (95%CI: 18.0, 43.7), which represent statistically significant differences ($p < 0.001$). When analyzed by sex, the mean weight was 32.4 kg in males (95%CI: 10.7, 54.0) ($p = 0.003$) and 25.1 kg in females (95%CI: 10.7, 39.4) ($p = 0.001$), shown in Table 5. Graph B of Figure 2 shows the trend of results for both groups.

30-second chair stand test

The test of 30-second chair standing, shown in Table 4, yielded pre-test means of 20.0 times (SD = 3.8 times) for the BFR group and 21.4 times (SD = 4.5 times) for the control group. As indicated in Table 4, the difference between UMD and AMD was statistically significant ($p < 0.001$), with UMD being 6.0 times (95%CI: 2.4, 9.6) and AMD being 7.1 times (95%CI: 4.2, 10.1). As indicated in Table 5, when the BFR and control groups were evaluated by gender, AMD was 10.5 times higher (95%CI: 6.2, 14.7) in males and 4.9 times higher (95%CI: 0.9, 8.8) in females ($p = 0.016$). Graph C in Figure 2 displays the trend of outcomes for each group.

Knee Injury and Osteoarthritis Outcome Score (KOOS)

The pre-test means of KOOS for the BFR group and the control group were 95.0 points (SD = 3.9) and 95.6 points (SD = 3.4 points), respectively. The post-test mean of the control group was 95.9 points (SD = 3.0 points), shown in Table 4. The UMD of the two groups was 1.1 points (95%CI:

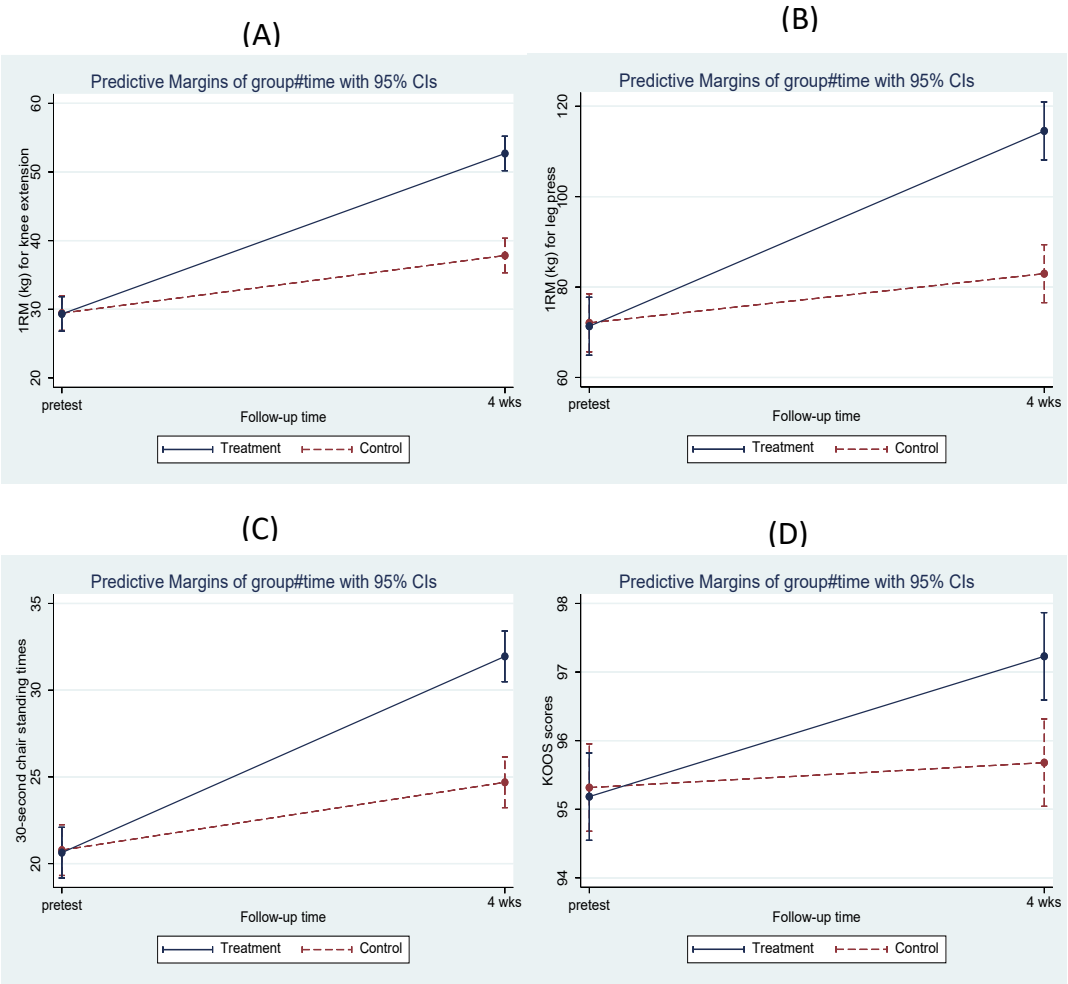

Figure 2. Graphs of outcomes by study group adjusted for pre-test. (A) 1RM knee extension, (B) 1RM leg press, (C) 30-second chair stand test, and (D) KOOS

BFR, blood flow restriction; RM, repetition maximum; KOOS, Knee Injury and Osteoarthritis Outcome Score

Table 3. General characteristics of the study population

Characters	BFR Group	Control group
Gender[1]		
Male	9 (40.9)	9 (40.9)
Female	13 (59.1)	13 (59.1)
Age, years[2]	48.9 (7.2)	50.4 (7.0)
Height, cm[2]	159.5 (8.8)	161.6 (7.9)
Body weight, kg	65.9 (15.7)	66.9 (12.5)
BMI, kg/m^2[2]	25.8 (5.14)	25.6 (4.0)
18.5 to 24.91	11 (50.0)	11 (50.0)
25.0 to 29.91	6 (27.3)	9 (40.9)
≥ 30.01	5 (22.7)	2 (9.1)
Pre-test of 1RM isokinetic knee extension, kg[2]	27.7 (10.1)	31.0 (10.0)
Pre-test of 1RM isokinetic leg press, kg[2]	67.1 (31.1)	76.3 (32.2)
Pre-test of the 30-second chair stand test, times[2]	20.0 (3.8)	21.4 (4.5)
Pre-test of KOOS, points[2]	95.0 (3.9)	95.6 (3.4)

*p < 0.05 indicates statistical significance. [1]Number (%), [2]Mean (SD),

BFR, blood flow restriction; cm, centimeters; kg, kilograms; kg/m2, kilogram per square meter; RM, repetition maximum; KOOS, Knee Injury and Osteoarthritis Outcome Score

-0.6, 2.7), which was not statistically significant, but for AMD it was 1.4 points (95%CI: 0.3, 2.5), a statistically significant difference (p = 0.010) shown in Table 4. The difference in AMD in males was 0.93 points (95%CI: -0.6, 2.4) which was not statistically significant (p = 0.226). In females, the difference was 1.8 points (95%CI: 0.3, 3.3) which was a statistically significant difference (p = 0.02), shown in Table 5. Additionally, the KOOS pain dimension for both groups after 4 weeks of exercise showed no increase in pain, shown in Table 6. Graph D of Figure 2 illustrates the trend of results for both groups.

Skin redness (32.0%) and localized fatigue (43.0% of all participants) were mild and temporary adverse effects that resolved within a short period (48 hours or less for fatigue and 15 minutes for redness). Moderate knee joint pain was reported by only one individual (2.0%) and entirely resolved after rest. There were no reported severe or long-lasting side effects.

Discussion

BFR with low-load exercise increases muscle strength more than low-load training alone by creating high metabolic stress, forcing early recruitment of fast-twitch muscle fibers, boosting anabolic hormone release, and stimulating muscle growth pathways. It mimics the effects of heavy lifting, even at light weights, making it especially useful for rehabilitation or for populations unable to lift heavy loads, as Hughes et al.[6] noted.

As in Fernandes-Bryk et al.[21] and Mattar et al.[22], the workouts in this study were conducted with BFR at 30.0% of 1RM with four sets (15, 15, 15, 15 reps, respectively), which is less than Segal et al.[22], Vechin et al.[23], and Libardi et al.[24], where individuals exercised with four sets (30, 15, 15, 15 reps, respectively) for a total of 4 weeks, which is the same length of time as research by Shimizu et al.[25] and Patterson et al.[26] Participants in this study exercised twice a week, which is similar to studies by Mattar et al., Vechin et al., Libardi et al., and Yasuda et al.[27]. Based on Brad J. et al.'s study which showed that exercising at least twice weekly can increase muscle strength and growth[28], the exercises in this study program are of a suitable length for participants to engage in regularly without skipping follow-up sessions. Jessica. et al.[29] recommend 4 weeks of continuous exercise to develop physical strength, a finding consistent with the results of this study. To ensure that factors other than exercise did not affect the post-test outcomes, we monitored the presence of confounding factors, particularly other exercises not included in this research, during the 4-week study using the participants' diary books. Additionally, there was no potential for harmful side effects while using BFR in vulnerable patients, such as those with OA.

1RM isokinetic knee extension

The exercise protocol in this study involved only knee extension, a movement that primarily targets the quadriceps muscle and increases its strength. After 4 weeks, although

Table 4. Mean (SD) of outcomes by group, unadjusted mean difference (95%CI), adjusted mean difference (95% CI), and p-value

Outcome	BFR group, Mean (SD)	Control group, Mean(SD)	Unadjusted Mean diff.[#] (95%CI)	Adjusted[##] Mean diff. (95%CI)	[*]p-value
Pre-test of knee extension weight, kg	27.7 (10.1)	31.0 (10.0)			
Post-test of knee extension weight, kg	51.1 (15.6)	39.4 (8.6)	11.6 (4.0, 19.3)	14.7 (9.6, 19.8)	< 0.001
Pre-test of leg press weight, kg	67.9 (31.1)	76.3 (32.2)			
Post-test of leg press weight, kg	110.3 (34.8)	87.2 (33.1)	23.1 (2.4, 43.7)	30.8 (18.0, 43.6)	< 0.001
Pre-test of 30-sec chair stand test, times	20.0 (3.8)	21.4 (4.5)			
Post-test of 30-sec chair stand test, times	31.3 (6.9)	25.3 (4.5)	6.00 (2.4, 9.6)	7.1 (4.2, 10.1)	< 0.001
Pre-test of KOOS, points	95.0 (3.9)	95.6 (3.4)			
Post-test of KOOS, points	97.0 (2.4)	95.9 (3.0)	1.1 (-0.6, 2.7)	1.4 (0.3, 2.5)	0.010

[*]p < 0.05 indicates statistical significance

BFR, blood flow restriction; KOOS, Knee Injury and Osteoarthritis Outcome Score, [#] BFR group – Control group, [##] adjusted pretest outcomes

Table 5. Adjusted mean difference (95%CI) and p-value of outcomes by gender

Outcome	Female; n = 13		Male; n = 9	
	Adjusted[#] mean diff. (95%CI)	p-value	Adjusted[##] mean diff. (95%CI)	[*]p-value
Knee extension	7.3 (1.2, 13.4)	0.020	21.5 (15.1, 28.0)	< 0.001
Leg press	25.1 (10.7, 39.4)	0.001	32.4 (10.7, 54.0)	0.003
30-second chair stand test	4.9 (0.9, 8.8)	0.016	10.46 (6.22,14.70)	< 0.001
KOOS	1.8 (0.3, 3.3)	0.021	0.93 (-0.6, 2.4)	0.226

[*]p < 0.05 indicates statistical significance, [#]BFR group – control group, [##]adjusted pretest outcomes

KOOS, Knee Injury and Osteoarthritis Outcome Score; N, number of participants

Table 6. Mean (SD) of pre- and post-4-week exercise scores of 5 patient-relevant dimensions of KOOS classified by demographics and gender

5 dimensions of KOOS	BFR group		Control group	
	Female n = 13	Male n = 9	Female n = 13	Male n = 9
Pain				
Pre-exercise	93.4 (4.5)	93.1 (3.3)	92.8 (5.0)	94.9 (2.6)
Post 4 week-exercise	96.8 (3.0)	94.7 (3.4)	95.85 (3.0)	95.11 (3.1)
Other disease-specific symptoms				
Pre-exercise	97.8 (3.1)	97.1 (3.0)	97.5 (3.0)	99.1 (1.8)
Post 4 week-exercise	98.77 (1.9)	97.9 (2.7)	98.2 (3.3)	98.7 (2.0)
Activities of daily living				
Pre-exercise	96.4 (4.1)	96.3 (3.4)	96.7 (3.3)	98.0 (1.2)
Post 4 week-exercise	98.2 (2.6)	97.4 (2.3)	97.3 (2.8)	97.2 (2.0)
Sport and recreation				
Pre-exercise	97.2 (4.9)	93.3 (4.3)	93.1 (6.0)	94.4 (5.3)
Post 4 week-exercise	97.7 (2.6)	96.1 (2.2)	94.2 (5.7)	95 (4.3)
Quality of life				
Pre-exercise	94.3 (7.0)	93.9 (6.2)	94.5 (5.7)	96.7 (3.2)
Post 4 week-exercise	96.3 (3.9)	95.3 (4.0)	93 (6.9)	96 (3.0)

KOOS, Knee Injury and Osteoarthritis Outcome Score; n, number of participants

the post-test values for both groups increased, the post-test and pre-test mean difference of the BFR group was significantly greater than the control group, which is consistent with the research of Matter et al., Segal et al., Yokokawa et al.[30], Karabulut et al.[31], and Abe et al.[32] This research used an exercise protocol which included the minimum intensity, number of reps, number of sets, and duration of the exercise program.

The experimental group's mean difference in BFR before and after exercise was 23.4%, which is higher than the findings of Yokokawa et al. and Karabulut et al., who reported 20.4% and 19.1%, respectively. This result is also lower than the finding of Segal et al., which was 28.3%. This study differs from Segal's in that the present study involved exercising less frequently and for a shorter period (6 minutes, 4 sets, and 15 reps per set; two times a week for a total of four weeks) compared to Segal's (7 minutes, 4 sets, and 30 reps for the first set and then 15 reps for the others; three times a week for a total of four weeks). However, this study outperformed Yokokawa et al. and Karabulut (which included just 3 sets of 30, 15, 15 reps). Based on the "Progressive Overload Principle", muscles only adapt when they are challenged beyond their current capacity. Increasing weight (intensity), reps per set (volume), or training days (frequency) provides a greater stimulus. This stimulus triggers microtrauma in muscle fibers, leading to repair and hypertrophy (muscle growth), as well as improvements in neural efficiency. Therefore, it can be inferred that increasing the intensity or amount of exercise, such as the number of reps, sets, or the frequency of training, can lead to greater strength gains from BFR exercise.

Along with other lower extremity muscles and ligaments, the quadriceps muscle stabilizes the knee joint. When the quadriceps muscle weakens, the passive components of the knee joint are subjected to increased strain, which results in increased stiffness. Strengthening the quadriceps muscles with resistance training lowers the chance of tibiofemoral joint space narrowing and cartilage loss. Therefore, it is believed that by improving knee joint stability and load absorption, resistance training that builds muscle strength also helps alleviate pain and improve function.[2]

1RM isokinetic leg press

The leg press is an exercise that uses multiple muscles, including the quadriceps, hamstrings, glutei, and gastrocnemius. In particular, the vastus medialis and vastus lateralis are the main muscles that work during the exercise. Although the protocol of this research focuses on exercises to increase the strength of the quadriceps muscle, these exercises have also been shown to increase the overall efficacy of exercises that use multiple leg muscles or the dynamic compound action of the lower limbs, as explained in a study by Shimizu et al.[25]

30-second chair stand test

The post-test study showed elevated mean values compared to the pre-test in both groups. According to a study by Abe et al. and Ozaki et al.,[33] there is a significant difference between the post-test and pre-test means of the BFR group compared to the control group. Currently, this test is used to assess fall risk in elderly individuals by evaluating their physical function and lower extremity muscle strength.[34] The BFR exercise used in this study should thus be effective in decreasing the likelihood of falls in the future because stronger quadriceps can generate greater torque at the knee joint which is critical for maintaining upright posture and adjusting to changes in body position or external forces (like being

bumped). When balance is perturbed, the quadriceps rapidly contract to extend the knee and restore the center of mass over the base of support. Stronger quadriceps also improve braking ability during descent, reducing uncontrolled motion. Strong quadriceps can also help maintain proper patellar tracking and knee joint alignment, ensuring efficient force transmission through the leg, helping to minimizing abnormal movement patterns and prevent joint wobble which can compromise balance.

The knee injury and osteoarthritis outcome score (KOOS)

The results of this research indicate that both the experimental group and the control group showed statistically significant differences. This result reflects that BFR exercise did not increase pain or make the quality of movement in daily life worse than before participating in the research, which is consistent with the research of Segal et al.[22] When analyzed by gender, this study found that males in the BFR group did not have KOOS values statistically significantly different from those in the control group, indicating that while BFR exercise increased the strength of the quadriceps muscle in males, there was no statistically significant change in pain or movement in daily life compared to the control group. The KOOS of females in the experimental group were significantly higher than that of the control group. It is possible that the female population, which currently has a higher incidence of knee OA than males, tends to use BFR more effectively than males, as suggested in a hypothesis of Segal et al.

Similar to Kevin D. Anderson et al.,[35] this study demonstrated minimal adverse effects following BFR training. The majority of those effects were classified as grade 1 adverse events, which are defined as any change from the usual therapeutic course that does not require pharmacologic, surgical, or radiological intervention. The population in this study consisted predominantly of hospital workers who met the criteria for physical inactivity or sedentary behavior, which is similar to the majority of people worldwide who are at risk for OA. Therefore, the use of BFR in this study can be extrapolated to the general population and can be considered safe, especially for individuals who prefer to use low loads during exercise.

However, the limitations on tracking confounding factors that could potentially have influenced the study's outcomes could only have been addressed through interviews and reviews of each of the participants diary books, something which could not have been monitored in real-time or in day-to-day life. Research could potentially be more reliable in the future if methods are developed for improved monitoring, e.g., incorporating wearable devices or other digital technologies. The outcomes of this trial were reported over 4 weeks, which could serve as a benchmark for future studies examining the long-term efficacy of BFR exercise and various BFR protocols. Moreover, exercising at 70.0-80.0% of 1 RM without BFR proved to be an appropriate standard recommendation. Further study may yield additional valuable information if a comparison between BFR and standard resistance exercise were feasible, particularly by including more diverse groups, e.g., moderate-to-severe OA patients or postmenopausal women.

Conclusion

Compared to the low-resistance group, adults 40 years of age and older at risk of developing symptoms of OA of the knee who performed 30.0% of 1RM resistance exercise plus BFR twice a week experienced a significant increase in quadriceps muscle strength after just 4 weeks of consistent exercise. This may be recommended as a practical supplementary approach that can potentially help slow the progression of joint degeneration in the long term.

Conflict of interest disclosure

This research did not receive any specific grant from commercial agencies or organizations for the benefit and profit.

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Data availability

The data that support the findings of this research article are available from the corresponding author, Sakolawat Jaroenpakdee, upon reasonable request.

Author contribution

Sakolawat Jaroenpakdee: conceptualization, data curation, analysis, methodology, project administration, resources, visualization,

Rachawan Suksathien: conceptualization, methodology, supervision, validation, writing - review & editing,

Pimpisa Vongvachvasin: conceptualization, funding acquisition, data collection.

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Original Article

Effects of Focused ESWT in Moderate Degree Carpal Tunnel Syndrome: A Preliminary, Randomized Double-Blinded Controlled Trial

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ABSTRACT

Objectives: To study the effects of focused extracorporeal shockwave therapy (f ESWT) combined with night splint and compare 4 and 10 treatment sessions in patients with moderate carpal tunnel syndrome (CTS)

Study design: A randomized, double-blinded, controlled trial

Setting: An outpatient rehabilitation clinic in King Chulalongkorn Memorial Hospital, Bangkok, Thailand

Subjects: Patients with a diagnosis of moderate CTS

Methods: Patients were randomly assigned to one of the two groups. The intervention group received ESWT once a week for ten consecutive weeks, while the comparison group received sham ESWT for the first four weeks and real ESWT for the subsequent six weeks. All patients were advised to wear a night splint. The Boston Carpal Tunnel Syndrome Questionnaire (BCTQ) and the electrodiagnostic study were evaluated at baseline, 4, and 10 weeks.

Results: The f ESWT group improved significantly in both BCTQ symptoms (p = 0.022) and BCTQ function (p-value 0.025), whereas the comparison group improved only in BCTQ symptoms (p = 0.028). At 4 weeks, the f ESWT group showed statistically significant improvement in distal sensory latency (p = 0.019) and sensory nerve conduction velocity across the wrist (p = 0.028) compared to the comparison group. Over the course of ten sessions of ESWT, clinical outcomes and neurophysiologic parameters continued to improve. However, the number of patients exceeding the minimal clinically important difference in BCTQ did not change after the first 4 sessions.

Conclusions: This preliminary study shows that adding f ESWT to a night splint is safe and effective for improving symptoms, function, and neurophysiologic parameters in moderate CTS. In terms of cost-effectiveness, four sessions may be more appropriate.

Keywords: carpal tunnel syndrome, extracorporeal shockwave therapy, Boston carpal tunnel syndrome questionnaire, electrodiagnosis

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Introduction

Carpal tunnel syndrome (CTS) is the most common type of entrapment neuropathy worldwide. It is caused by a compression of the median nerve at the wrist as it passes through the carpal tunnel. Patients may present with intermittent nocturnal paresthesia and dysesthesia in the median innervated territory. Later in the disease, sensory loss and thenar muscle atrophy emerge.[1] CTS is considered to have a complex etiology involving ischemic changes caused by increased intracarpal canal pressure. Nonsurgical treatments, including patient education, wrist orthosis, and oral medication, should be considered first-line treatment for mild to moderate CTS. Despite limited evidence, physical modalities are routinely employed in clinical practice for treating CTS.[2]

Extracorporeal shock wave therapy (ESWT) is a non-invasive therapy that uses an acoustic wave with a high peak pressure (100 megapascals), rapid pressure increase (10 nanoseconds), short duration (10 milliseconds), and an energy density of 0.003–0.89 megajoules/millimeter^2 (mJ/mm^2)[2,3] There are several types of shockwave generators currently available, including the piezoelectric approach, which produces shockwaves that are focused on a specific tissue area. The focused ESWT (f ESWT) concentrates acoustic energy on a specific point on the target. Applying f ESWT necessitates precise identification of the area to be treated.[4] This allows for the most favorable therapeutic effect while avoiding damage to the surrounding tissue. Furthermore, ESWT can be divided into three energy levels: low, moderate, and high.[5] There have been reports of the therapeutic effects of low-energy ESWT on peripheral nerve regeneration in animal models.[6,7] In recent years, ESWT has received significant attention as a novel and non-invasive method for treating CTS. Seok et al. in 2013 were the first to report the efficacy of ESWT in treating CTS. They concluded that ESWT can be as helpful as corticosteroid injection in relieving CTS symptoms.[8] A systemic

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review and meta-analysis in 2023 by Zhang et al. reported that ESWT can improve symptoms, functional outcomes, and electrophysiologic parameters in patients with mild-to-moderate CTS.[9] However, the mechanism by which ESWT affects entrapment neuropathy remains unclear. Moreover, no treatment protocol for ESWT has been established. Previous studies have used protocols ranging from 4 to 6 sessions, with one study extending up to 12 sessions.[9] Clinical services in our institution typically provide 10-session treatments which include using other physical modalities. The present study aimed to investigate the effect of f ESWT and compare the dose-related therapeutic effect of ten-sessions versus four-sessions of f ESWT on symptoms, function, and neurophysiologic condition in patients with moderate CTS.

Methods

Study design

This prospective, double-blinded (patients and assessors), randomized controlled trial was conducted between November 2018 and October 2019. The study was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University with approval number IRB174/61 on July 12, 2018 and followed the Code of Ethics (Declaration of Helsinki). It was registered with the clinical trials registry on August 25, 2018. (TCTR20180825002) This study was reported following the CONSORT 2010 guidelines for randomized controlled trials.

Participants

Patients with moderate CTS were recruited from a university hospital's outpatient rehabilitation clinic and electrodiagnostic lab based on criteria established by the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) guidelines.[10] Patients with comorbidities such as diabetes, rheumatoid arthritis, or cervical radiculopathy; prior carpal tunnel surgical release or corticosteroid injection; or prior treatment of f ESWT were excluded from the study.

In the present study, the cut-off points for normal electrophysiological values were as follows: 1) The upper limit of onset median distal sensory latency (DSL) was < 3.2 ms at a distance approximately 13 cm proximal to the active ring electrode at the second digit. 2) In cases of DSL between 2.8 and 3.2 ms, the combined sensory index was applied, and a value > 0.9 was considered abnormal.[11] 3) The upper limit of median motor latency was < 4.2 ms at approximately 8 cm from the active recording electrode at the abductor pollicis brevis muscle. 4) The sensory nerve action potential (SNAP) amplitude was also measured. Following AANEM guidelines, we recruited individuals with moderate CTS for our study. Mild: only prolonged DSL; Moderate: both prolonged DSL and DML; Severe: no SNAP response or a low or absent compound motor action potential (CMAP) amplitude.

The experiment protocol was thoroughly explained to all eligible individuals. Each participant provided written informed consent prior to treatment allocation. The side of the wrist with a higher BCTQ score was recruited for each patient. An independent researcher used a computer-generated randomization with a 1:1 ratio to allocate the patients into two groups. The group assignment was not blinded to the physiatrist performing the f ESWT. Patients were unaware whether they were in the intervention or comparison group.

The sample size was calculated using the Boston Carpal Tunnel Questionnaire (BCTQ) results from a study by Vahdatpour et al.[12] with a 90% power and a 5% significance level. In addition, for the magnitude of difference (X1-X2), we used the minimal clinically important difference (MCID) of the BCTQ symptom severity subscale (0.8) and the BCTQ functional status subscale (0.5).[13] Based on this calculation, we aimed to enroll approximately 20 patients for each group.

Interventions

The patients in the intervention group received one session of f ESWT each week for ten weeks. The patients sat in a comfortable position with the hand of interest on a pillow. The size of the f ESWT gel pad applicator was chosen based on the patient's body mass index (BMI) (BMI ≤ 25 kg/m^2: size 10, BMI > 25: size 15 kg/m^2). The f ESWT probe was positioned perpendicularly on the patient's palm, over the median nerve at the carpal tunnel. Anatomic landmarks on the wrist were used to locate the median nerve (between the flexor carpi-radialis and palmaris longus tendons). Shockwaves were delivered without anesthesia using a piezoelectric generator (Swiss PiezoClast®, EMS, Dallas, USA) or a total of 1,000 shocks given at a rate of eight pulses per second. The intensity level was gradually increased to the highest level tolerated by the patient, but the energy flux density did not exceed 0.08 mJ/mm^2.

The comparison group was given sham ESWT for the first four weeks and real ESWT for the remaining six weeks, for a total of ten weeks. An identical handpiece was utilized in the sham ESWT and in the real ESWT, but a plastic sheet was placed between the gel pad and the handpiece applicator to block the wave in the comparison group. Patients in that group could hear the sound but could not feel the wave striking during treatment.

The investigator gave all subjects a commercial wrist splint to maintain basic CTS care. The wrist splint was firmly fixed in a neutral position to immobilize the affected wrist, and patients were recommended to wear it at night. The total number of nights they wore the splint throughout the 10 weeks was recorded. The average nights per week of splint wear for each patient was calculated. Patients were encouraged to avoid repetitive flexion and extension of the wrist and any other treatments from the initial screening through the duration of the trial, including analgesic drugs, acupuncture therapy, manual therapy, ultrasound, laser therapy, or any CTS treatment.

Outcome measurements

Investigators blinded to the trial evaluated the clinical outcomes, and all measurements were taken before and after the fourth and tenth treatment sessions. The Boston Carpal Tunnel Questionnaire (BCTQ), which includes a symptom severity and functional status subscales, was used as the primary outcome measure. It is widely used for clinical studies in individuals with CTS, with high internal consistency and validity.[14] The BCTQ is divided into two sections: the symptom severity subscale (BCTQ SYMPT) which consists of 11 questions with scores ranging from 1 (mildest) to 5 (most severe), and the functional status subscale (BTCQ FUNCT) consisting of eight questions with scores ranging from 1 (no difficulty with the activity) to 5 (unable to perform the activity at all). The secondary outcome measure was electrodiagnostic testing, which was carried out according to AANEM recommendations. We measured the sensory nerve action potential, distal sensory latency (DSL), distal motor delay (DML), and sensory conduction velocity across the wrist. All nerve conduction examinations were performed in the same room by the same physiatrist, who was blinded to the treatment allocation. The skin temperature of the tested limb was kept at 32°C. The median sensory nerve conduction study was performed antiheroically by stimulating the median nerve between the palmaris longus and the flexor carpi radialis tendon, approximately 13 cm proximal to the active ring electrode at the proximal phalange of the second digit. The motor nerve conduction study was performed by maximally stimulating the median nerve 8 cm proximal to the surface electrode recording at the abductor pollicis brevis muscle.

Data analysis

SPSS version 22.0 software for Windows was used for statistical analysis. A descriptive analysis was performed for the baseline characteristics of all measurements. The Fisher's exact test was used for categorical data in the between-group comparison. For continuous data, the Mann-Whitney U test was used. For within-group comparisons, the Wilcoxon signed-rank test was used. Missing data were handled using the last observation carried forward. Statistically significance was set at $p < 0.05$.

Results

Figure 1 shows the study flowchart. Ninety-four patients were assessed for eligibility, and twenty patients were recruited. Table 1 shows that the baseline characteristics are comparable between groups.

The baseline BCTQ was comparable between the two groups. Both the BCTQ severity and function subscales improved significantly from baseline in the intervention group at 4 and 10 weeks. The BCTQ SYMPT showed significant improvement in the comparison group only at 4 weeks, whereas BCTQ FUNCT showed a significant improvement at both 4 and 10 weeks. (Table 2)

Although neither group showed a significant within-group improvement in the DSL, DML, SNAP amplitude, or SNCV across in the wrist in the nerve conduction study, when the two groups were compared, only the intervention group showed a significant difference in DSL and SNCV across the wrist. We then compared the treatment sessions in the intervention group between four-session and ten-session f ESWT. After the

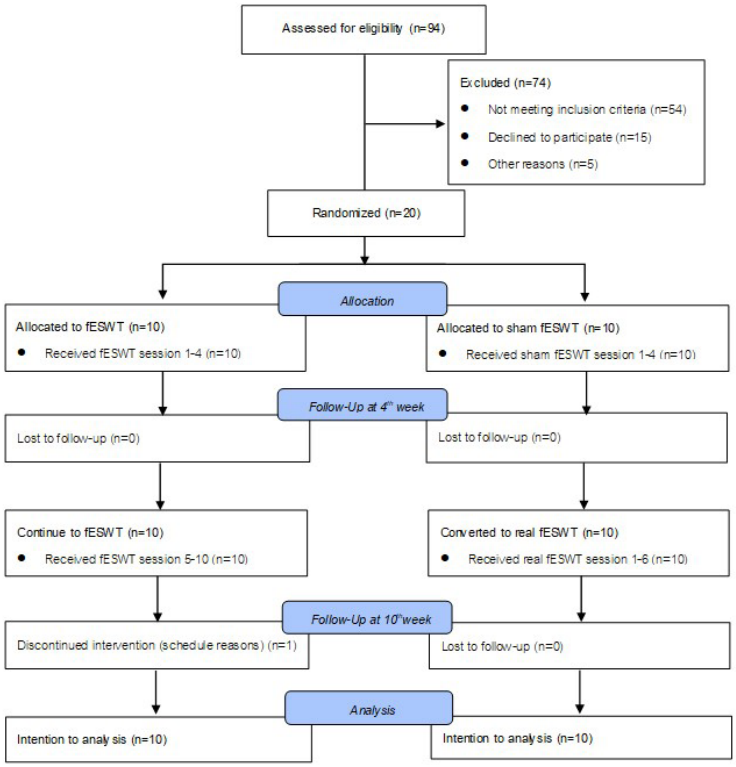

Figure 1. Flow of participants

Table 1. Baseline demographic and clinical characteristics of patients in the study

	Intervention group (n = 10)	Comparison group (n = 10)	*p*-value
Age (years)[1]	54 (15)	61 (9)	0.063
Gender (female)[1]	10 (100)	10 (100)	1.000
BMI (kg/m^2)[1]	26 (13)	22.5 (3)	0.123
Symptom duration (months)[1]	12 (21)	21 (26)	0.874
Dominant hand studied[2]	6 (60)	9 (90)	0.280
Repetitive work (hand function activity > 8 hours/day)[2]	6 (60)	6 (60)	1.000
BCTQ SYMPT[1]	2.1 (1.1)	2.0 (0.9)	0.323
BCTQ FUNCT[1]	1.6 (1.9)	1.6 (0.7)	0.311
DSL, (ms)[1]	3.8 (0.7)	3.5 (0.8)	0.063
DML, (ms)[1]	5.2 (1.5)	5.1 (2.4)	0.851
SNCV across wrists, (m/s)[1]	34.0 (6.7)	36.9 (8.5)	0.063
SNAP amplitude, (μV)[1]	22.4 (21.0)	40.8 (30.4)	0.123

[1]Median (IQR), [2]number (%)

BMI, Body mass index; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity; SNAP, Sensory nerve action potential

Table 2. Outcome variables at pre-treatment and post-treatment in each group

	Intervention group (n = 10)		Comparison group (n = 10)		between group *p*-value
	Median (IQR)	*p*-value	Median (IQR)	*p*-value	
BCTQ SYMPT					
Baseline	2.1 (1.6-2.8)		2.0 (1.3-2.2)		
4 weeks	1.6 (1.3-1.9)	0.022*	1.6 (1.1-1.9)	0.038*	0.949
10 weeks	1.5 (1.0-1.9)	0.001*	1.4 (1.0-2.0)	0.034*	-
BCTQ FUNCT					
Baseline	1.6 (1.3-2.8)		1.6 (1.2-1.9)		
4 weeks	1.4 (1.2-1.7)	0.025*	1.4 (1.1-1.7)	0.147	0.273
10 weeks	1.4 (1.2-1.6)	0.021*	1.2 (1.1-1.3)	0.025*	-
DSL (ms)					
Baseline	3.8 (3.4-4.2)		3.5 (2.9-3.8)		
4 weeks	3.6 (3.3-3.8)	0.184	3.8 (2.9-4.0)	0.041*	0.007†
10 weeks	3.4 (3.0-3.8)	0.053	3.6 (3.1-4.1)	0.066	-
DML (ms)					
Baseline	5.2 (4.7-6.2)		5.1 (4.3-6.7)		
4 weeks	5.2 (4.4-4.9)	0.100	5.2 (3.9-6.7)	0.995	0.280
10 weeks	5.0 (4.4-5.9)	0.193	4.6 (4.1-6.4)	0.251	-
SNCV across wrists (m/s)					
Baseline	34.0 (30.8-37.5)		36.9 (34.5-43.9)		
4 weeks	35.4 (34.2-39.2)	0.146	34.0 (32.1-43.4)	0.093	0.007†
10 weeks	37.6 (33.7-42.9)	0.059	36.2 (31.6-41.2)	0.043*	-
SNAP amplitude (μV)					
Baseline	22.4 (13.4-34.3)		40.8 (18.7-49.2)		
4 weeks	31.4 (25.7-49.1)	0.147	36.9 (18.7-49.2)	0.338	0.410
10 weeks	28.8 (17.7-41.7)	0.318	37.5 (24.8-47.5)	0.689	-

*Wilcoxon signed-rank test for within-group analysis; *p*-value is significant; †Mann-Whitney U test for between-group analysis of change from baseline to 4 weeks; p-value is significant

IQR, Interquartile Range; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity; SNAP, Sensory nerve action potential

fourth session, there was continued improvement in BCTQ and neurophysiologic parameters, but the improvement did not statistically significantly exceed the improvement from baseline to 4 weeks. (Table 3) Although improvement in BCQT, DSL was significantly prolonged in the comparison group, electrodiagnostic parameters improved after six sessions of real ESWT. (Table 4)

Regarding the MCID of BCTQ, there were more patients in the intervention group whose BCTQ SYMPT and FUNCT improved more than the MCID at 4 weeks, but that number of patients remained unchanged at week 10. In the comparison group, no patients exceeded the MCID of BCTQ, either

Table 3. Changes in the outcome variables from baseline to 4 weeks and 4 to 10 weeks in the intervention group

	Baseline to 4 weeks Mean (SD)	4 weeks to 10 weeks Mean (SD)	*p*-value[a]
BCTQ SYMPT	0.7 (0.8)	0.0 (0.6)	0.435
BCTQ FUNCT	0.5 (0.6)	0.0 (0.6)	0.846
DSL (ms)	0.2 (0.4)	0.2 (0.3)	0.176
DML (ms)	0.3 (0.5)	0.0 (0.6)	0.886
SNCV across wrists (m/s)	-2.3 (4.7)	-1.6 (3.5)	0.135

[a]Paired t-test for within-group analysis.

The minus value indicates increasing after treatment

SD, standard deviation; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity

Table 4. Changes in the outcome variables from baseline to 4 weeks and week 4 to week 10 in the comparison group

	Baseline to 4 weeks Mean (SD)	4 weeks to 10 weeks Mean (SD)	*p*-value[a]
BCTQ SYMPT	0.2 (0.3)	0.0 (0.6)	0.435
BCTQ FUNCT	0.2 (0.4)	0.0 (0.6)	0.846
DSL (ms)	-0.2 (0.3)	0.2 (0.3)	0.176
DML (ms)	-0.0 (0.5)	0.0 (0.6)	0.886
SNCV across wrists (m/s)	2.0 (3.4)	-1.6 (3.5)	0.135

[a]Paired t-test for within-group analysis.

SD, standard deviation; BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT, function; DSL, distal sensory latency; DML, distal motor latency; SNCV, sensory nerve conduction velocity

Table 5. The number and percentage of patients who have BCTQ scores improved above the MCID in each group (n = 10)

	Intervention group n (%)	Comparison group n (%)
Improvement of BCTQ SYMPT at the 4th week	5 (50)	1 (10)
Improvement of BCTQ FUNCT at the 4th week	4 (40)	1 (10)
Improvement of BCTQ SYMPT at the 10th week	5 (50)	4 (40)
Improvement of BCTQ FUNCT at the 10th week	4 (40)	5 (50)

Data are presented as number (%), MCID of BCTQ SYMPT = 0.8, MCID of BCTQ FUNCT = 0.5

BCTQ, The Boston Carpal Tunnel Questionnaire; SYMPT, symptoms; FUNCT

SYMPT or FUNCT, while at week 10, 40% and 50% of the patients exceeded the MCID of BCTQ SYMPT and FUCT, respectively. (Table 5)

The average duration of wearing wrist orthoses at night was comparable in both groups: 4.8 (SD = 1.5) hours per day in the intervention groups and 4.7 (SD = 1.6) hours per day in the comparison group. There were no complications in either group, and no additional medicine was required.

Discussion

This randomized, double-blind, controlled trial investigated the effect of f ESWT combined with night splints in moderate CTS patients. Beyond the fourth session of f ESWT, we discovered that the intervention group improved significantly more than the comparison group in median nerve DSL and SNCV across the wrist. These findings are consistent with recent meta-analyses indicating that ESWT exerts an excitatory effect on peripheral nerves, particularly sensory nerves.[15] Electrophysiological findings should be interpreted with caution due to the modest level of change. However, the significantly higher proportion of patients in the intervention group achieving BCTQ scores above the MCID indicates meaningful improvement in functional capacity and symptom severity. When we extended the f ESWT sessions to 10, the improvement was maintained, but the change was less than the first four sessions. Furthermore, the number of patients whose BCTQ exceeded the MCID in the intervention group remained unchanged from the previous four weeks. In contrast, in the comparison group, the number increased after sixth sessions of real f ESWT. Our results support the therapeutic effect of ESWT reported in previous studies.[8,9,12,16-18] To date, there are no clear guidelines for using ESWT in CTS patients. Few studies have investigated the effect of f ESWT using different protocols.[8,9,12] Most research, including

the present study, have employed low energy flux density, which has been proven to enhance the mechanism that promotes axonal regeneration following axotomy.[6] However, the number of shots and sessions, as well as the adjuvant treatments, in those studies have varied. Seok et al. reported that a single session of f ESWT could be as effective as a local corticosteroid injection for CTS.[8] Similarly, Aramrussameekul et al. found no significant difference in clinical efficacy between the two treatments.[19] Notably, Atthakomol et al. found that a single session of radial ESWT provided long-lasting benefits.[20] Vahdatpour et al. demonstrated that four sessions of f ESWT led to significant reductions in VAS scores and improved BCTQ and electrodiagnostic parameters.[12] Paoloni et al. reported that three sessions of f ESWT in patients with mild to moderate CTS resulted in more significant improvements compared to ultrasound and cryo-ultrasound treatments.[18]

To our knowledge, the present study is the first randomized double-blinded study to evaluate the effect of and compare the therapeutic outcomes of ESWT sessions combined with a night wrist splint. Only one clinical study conducted by Ke et al. in 2016 comparing the number of sessions of ESWT showed that three sessions of radial ESWT had a cumulative clinical effect. In contrast, a single session showed only an insignificant effect.[17] A 2019 animal model by Sagir et al. found ESWT applied to an injured nerve enhances myelin sheath thickness and promotes regeneration. That study also reported that focused ESWT performed better than radial ESWT and did significantly better when applied at lower impulses.[21] This may explain why four sessions yielded more improvement per session than 10 sessions. So far, no research has been conducted on the ceiling effect of ESWT. According to our findings, four sessions may be more cost-effective in clinical practice.

In our study, the comparison group also improved in BCQT, which may be attributed to the application of wrist splinting, a plausible mechanism of edema reduction. Manente et al. found a significant reduction in BCQT in CTS patients wearing a night wrist splint compared to a control group, but no significant difference in electrophysiologic evidence.[22] However, a meta-analysis provided inadequate data to substantiate the clinical usefulness of splints.[23] Despite BCQT improvement, in the present study we observed electrophysiologic parameter progression in the comparison group while wearing only a night splint. However, the electrophysiologic parameters were reversible after six sessions of ESWT. Park et al. showed that ESWT could inhibit the progression of CTS in an animal model. Hence, early administration of ESWT is suggested for a better outcome.[24]

Study limitations

There are several limitations in our study. First, we were able to include only about 50% of all the eligible patients, and all the participants were female both of which could limit the results' generalizability. Second, it would have been desirable to follow up for a more extended period. According to previous studies, the effect of ESWT lasts longer than 3 months and is still apparent after 6 months.[12,18] Third, imaging studies such as diagnostic ultrasonography were not performed in our study. Lastly, we used the original BCTQ and verbally translated it into Thai, but that translation was not validated for psychometric properties. Future studies should include a larger number of patients with more extended follow-up periods as well as imaging studies such as ultrasonography which might be helpful in assessing the effects of ESWT on median nerve morphological change and validating the Thai version of the BCTQ to ensure accurate and reliable outcome measurement.

Conclusion

Our preliminary findings indicate that up to ten sessions of f ESWT combined with a night splint are safe and effective for improving function and electrophysiologic parameters in patients with moderate CTS although four sessions may be more cost-effective.

Conflict of interest disclosure

The authors have no conflict of interest to report.

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Data availability

The datasets generated and analyzed during the present study are not publicly available due to ethical approval limitations involving patient data and anonymity. However, they are available from the corresponding author upon reasonable request.

Author contribution

Cherdpong Pimubol: conceptualization, investigation, formal analysis, writing- original draft,

Jirapa Champaiboon: conceptualization, investigation, writing - review & editing,

Jariya Boonhong: conceptualization, methodology, funding acquisition, supervision.

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Original Article

Factors Associated with Goal Attainment in Children with Cerebral Palsy: An Ambidirectional Cohort Study

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ABSTRACT

Objectives: This study aimed to identify factors influencing goal attainment in children with cerebral palsy (CP) while evaluating the appropriateness of established therapeutic goals.

Study design: An ambidirectional cohort study

Setting: The Rehabilitation Department, Siriraj Hospital, Bangkok, Thailand

Subjects: Patients aged 0 to 15 years with a diagnosis of cerebral palsy were eligible if they had received at least two sessions of goal-directed therapy (GDT) and a post-therapy Goal Attainment Scale (GAS) evaluation between January 2016 and March 2022.

Methods: A total of 462 goals were evaluated using the GAS. Clinical variables, including age, sex, CP type, functional classification, goals, comorbidities, and therapy frequency, were analyzed for associations with goal attainment.

Results: Clinical data were collected from 111 pediatric CP patients (51.4% female) undergoing GDT at a university hospital rehabilitation unit. The participants had a mean age of 4.7 years (SD = 2.7), with spastic CP being the most prevalent type (77.7%). The goals for high-functioning participants frequently targeted ambulation and hand function, while the goals for low-functioning groups focused on sitting, hand function, and swallowing. Overall, therapeutic goals were found to be appropriate, with a GAS T score of 50.2. The Gross Motor Function Classification System (GMFCS) levels I and II emerged as the sole statistically significant independent predictor of goal attainment (p = 0.04).

Conclusion: Children with CP who demonstrate greater gross motor function exhibit a greater likelihood of therapeutic goal attainment. The GMFCS should inform the selection of appropriate therapeutic goals. High-functioning children may benefit from active goals such as improving ambulation and hand function, while low-functioning groups progress best with passive goals centered on preventing complications and achieving early motor milestones.

Keywords: associated factor, cerebral palsy, goal attainment, goal-directed therapy, goal setting

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Introduction

Cerebral palsy (CP), a nonprogressive neuromotor disorder stemming from disturbances in early brain development, ranks among the primary causes of childhood disability.[1,2] With a global prevalence of approximately 2.11 per 1,000 live births (1 per 1,000 in Thailand),[3,4] Children with CP often manifests as motor dysfunction, spasticity, and impaired hand function, leading to activity limitations. Further potential consequences include sensory, cognitive, communication, visual, and auditory deficits, as well as epilepsy.[1] These complications diminish the quality of life for children with CP and their families, prompting the need for diverse interventions.[1,5]

Systematic reviews support a "traffic light" classification (green, yellow, red) for CP management, endorsing goal-directed therapy (GDT) or functional training ("green light") as beneficial.[6] GDT is a collaborative approach involving the patient, family, and the rehabilitation team in setting specific, measurable, attainable, realistic, and timely (SMART) goals.[7] With its emphasis on caregiver-facilitated home programs and effective communication, GDT can improve motor function and demonstrates particular suitability for resource-limited settings such as Thailand.[8]

To optimize therapeutic outcomes, goals within GDT should be challenging yet achievable.[9] Setting precise, individualized goals requires trained and experienced therapists.[8] Typical goals in clinical practice target sitting, walking, hand function, and swallowing. However, not all clients will fully achieve their personalized goals due to various factors which can influence goal attainment. Evaluating the quality of established goals reveals their suitability and reflects the therapist's expertise, contributing to ongoing professional development.

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Extensive research has identified factors influencing treatment outcomes in children with CP. The Gross Motor Function Classification System (GMFCS) has been shown to strongly correlate with improvements in gross motor function. Additionally, CP type, cognitive impairment, communication function, manual ability, vision, age, and therapy frequency all impact functional outcomes, including activities of daily living (ADLs), handwriting, locomotion, and wheelchair use in children with CP.[10-16] These factors fall into three categories: patient, disease, and therapy. However, no clear consensus exists on factors associated explicitly with goal attainment in GDT for children with CP.

Therefore, this study aimed to (1) identify factors associated with therapeutic goal attainment in children with CP and (2) evaluate the appropriateness of established goals.

Methods

Study design

This study employed a cohort design with ambidirectional features. Written informed consent was obtained from parents or guardians during the prospective period (October 2021-March 2022). The Siriraj Institutional Review Board granted ethical approval for the study on August 5, 2021 (approval number Si-603/2021). This report followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Participants

The study leveraged data from a CP clinical tracer program implemented at a university hospital rehabilitation department in Bangkok, Thailand. Patients were eligible to participate if they had a diagnosis of CP, were aged 0 to 15 years, had received at least two GDT sessions, and had undergone a post-GDT evaluation with a GAS score between January 2016 and March 2022.

Sample size calculation

The sample size was determined a priori using an exploratory approach based on the principle of events per variable (EPV). Therefore, 10 to 15 goal attainments were required per independent variable. At least eleven variables were included in the analysis: sex, age, type of CP, GMFCS, Manual Ability Classification System (MACS), Communication Function Classification System (CFCS), epilepsy, hearing impairment, visual impairment, intellectual impairment, and frequency of therapeutic sessions. In this study, the unit of analysis in the regression model was the Goal Attainment Scale (GAS) evaluation rather than the individual participant (Figure 1). Accordingly, a sample size of at least 130 to 194 GAS evaluations was required, assuming an anticipated GDT success rate of 85.0% based on the CP tracer.

Goal setting

Attending physiatrists evaluated children with CP (aged 0 to 15 years) to determine appropriate therapeutic interventions. By employing the SMART approach, physiatrists, therapists, children, and families collaboratively established individualized, short-term (less than 12 months) therapeutic goals. Physiotherapists and occupational therapists assessed and documented goal attainment using the five-point Goal Attainment Scale (GAS) following two therapy sessions within one month. The GAS objectively measured each patient's functional progress relative to established goals.

Physical therapy (PT) goals typically targeted neck and trunk control, sitting, and ambulation, while occupational therapy (OT) focused on swallowing, hand function, cognition, and ADLs. Home programs were routinely assigned to primary caregivers, with adherence documented in a logbook. The frequency, duration, and intensity of therapy varied based on individual goals, physician appointments, therapist availability, and family convenience. Programs exceeding three physical and/or occupational therapy sessions per week were classified as intensive training.[17]

Goal evaluation and follow-up

Upon completing a course of therapy, physiotherapists or occupational therapists evaluated participants' progress toward goals using the GAS. Outcomes were documented and reported to the attending physiatrist. During follow-up, physiatrists reassessed participants and revised treatment plans, establishing new goals and continuing the GDT cycle. Individual goal attainment scores were aggregated into an overall GAS T score.

Data from participants with complicating medical conditions (such as infection or seizure), those receiving fewer than two therapy sessions, or those unable to complete sessions for GAS evaluation were excluded.

Data collection

At the beginning and completion of therapy, health professionals collected data relating to the GMFCS, MACS, CFCS, sex, goals, home program compliance (assessed via logbooks), and GAS. A physiotherapist or occupational therapist assessed the GMFCS, MACS, and CFCS data. Age, CP type, therapy session frequency, and relevant comorbidities were retrieved from medical records through a retrospective analysis to provide baseline clinical information. These data were supplemented with information collected during the prospective phase of the study. In the absence of information in the medical records, data were supplemented by phone interviews to reduce attrition bias.

Outcome measurements

Goal Attainment Scale

The GAS provides a structured method for quantifying progress toward individually established goals. It has found extensive application in pediatric rehabilitation, particularly within the context of CP. The GAS utilizes a 5-point scale (-2 to +2) to map goal achievement, assigning numeric values

to performance levels.[18] The scale's midpoint (0) represents the expected outcome. Positive scores (+1, +2) indicate outcomes that exceed expectations, while negative scores (-1, -2) signify outcomes that fall below expectations, with -2 reflecting no change from the baseline.[18] A score greater than or equal to 0 denotes goal attainment. In the present study, the GAS was selected as the primary outcome measure to evaluate the effectiveness of the GDT.

Individuals may have multiple goals, each of which receives a GAS score. These individual scores can then be combined into a single overall GAS T score, representing overall progress across all goals. To calculate this overall score, the following equation was used:

$$\text{Overall GAS} = 50 + \frac{10\Sigma(W_i X_i)}{\sqrt{(0.7\Sigma W_i^2 + 0.3(\Sigma W_i^2))}}$$

Where Xi = the GAS score and Wi = the weighting of each goal

The GAS T score had a mean of 50 and a standard deviation of 10. A mean T score of 50 indicates that goals are appropriately challenging. A T score below 50 suggests that goals may be too difficult to achieve, while a T score exceeding 50 implies that goals may be too easily attainable.[18]

Gross Motor Function Classification System (GMFCS)

The GMFCS is a standardized, five-level ordinal system used to evaluate gross motor function in children with CP aged 1-12 years. The expanded and revised GMFCS (GMFCS-E&R) further extends this classification to include adolescents aged 12-18 years. The GMFCS focuses on self-initiated movement and the use of assistive mobility devices during typical activities. Individuals at GMFCS level I can perform age-appropriate gross motor activities, potentially with minor limitations in speed and movement quality. However, individuals at GMFCS level V demonstrate significant difficulties with head and trunk control and have limited voluntary movement. The GMFCS is well established and has strong reliability and stability.[19,20]

Communication Function Classification System

The Communication Function Classification System (CFCS) is a validated, five-level ordinal system for assessing everyday communication in individuals with CP. It evaluates both the sending and receiving of information. CFCS level I individuals can communicate effectively with both familiar and unfamiliar partners. However, individuals at the CFCS level V are seldom able to communicate effectively, even with familiar people. The CFCS exhibits good test-retest and interrater reliability among professionals, with slightly lower reliability observed in parent-professional assessments.[21]

Manual Ability Classification System

The Manual Ability Classification System (MACS) provides a five-level framework to evaluate hand function in children with CP during daily activities. MACS level I indicates ease and success in object handling. Conversely, MACS level V denotes severely limited hand function, even for simple tasks. The MACS has good validity and reliability.[22]

Type of CP

The classification of CP was based on the predominant motor abnormalities. Four categories were used: spastic, dyskinetic, ataxic, and mixed.[2]

Comorbidities

Intellectual, hearing, and visual impairments were classified based on documented diagnoses in medical records.

Statistical analysis

Data analyses were performed using IBM SPSS Statistics, version 26 (IBM Corp, Armonk, NY, USA). Continuous data are reported as means and standard deviations, while categorical data are expressed as frequencies and percentages. Overall GAS T scores were calculated with equal weighting for each goal (Wi = 1), and the baseline Xi was set at -2.

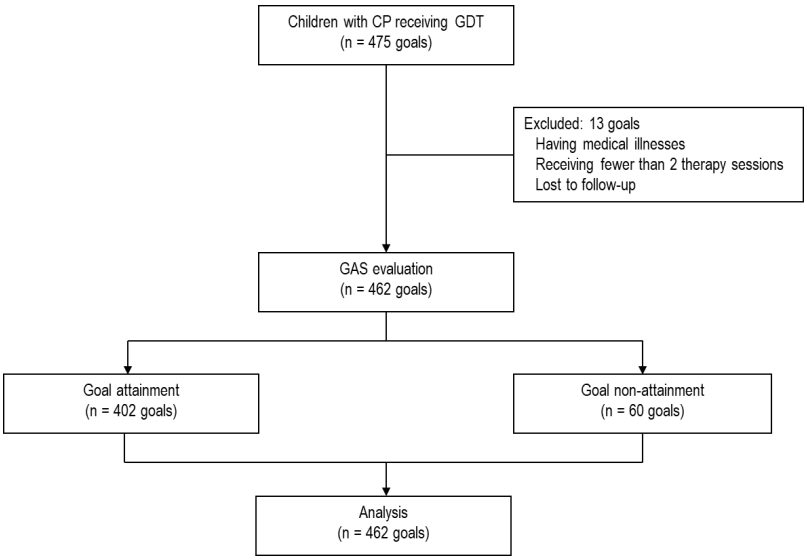

Figure 1. Flow diagram of study participants

Univariable and multivariable logistic regression analyses were employed to identify factors associated with goal attainment (a GAS score of 0 or greater). Univariable analysis included age, sex, CP type, GMFCS, MACS, CFCS, epilepsy, hearing impairment, visual impairment, intellectual impairment, and intensive training. GMFCS, MACS, and CFCS were categorized into levels I-II, level III, and levels IV-V. Variables with a $p \leq 0.2$ in the univariable analysis, along with clinically relevant factors (age, type of CP, and intellectual impairment), were included in the multivariable logistic regression model, with no evidence of multicollinearity. Variables not significantly associated with the outcome were excluded from the multivariable analysis. A significant level of < 0.05 was applied to all statistical tests. Missing data were addressed using complete case analysis.

Results

This study included 111 participants (57 females, 54 males) with a total of 462 goals. Thirteen goals (2.7%) were excluded due to participants having medical illnesses, having received fewer than two therapy sessions, or being lost to follow-up (Figure 1). The mean participant age was 4.7 years (SD = 2.7), with spastic CP being the most prevalent diagnosis (77.7%).

Participants attended a median of 5 therapy sessions (range: 2-20) over a mean duration of 72.3 days (SD = 38.2). The median compliance with the home rehabilitation program was 80.0%. However, the adherence rate exhibited a wide range (20.2%-100.0), signifying varying levels of commitment among the participants.

Table 1 provides detailed breakdowns of participant functional classifications (GMFCS, MACS, and CFCS) and comorbidities. Of the 462 goals, physiotherapy sessions represented the majority (284 goals, 61.5%), with occupational therapy targeting the remaining 178 goals (38.5%). Intensive training was utilized in only two instances (0.4%). Overall, this study demonstrated a high goal achievement rate of 87.0%. A goal quality assessment revealed that 53.2% of the goals were appropriately challenging, 25.7% were too easy, and 21.1% were too difficult. The overall GAS T score of 50.2 suggests tentatively appropriate goal difficulty.

Table 2 indicates substantial variation in goal achievement rates across therapeutic areas. Ambulation training goals demonstrated the highest achievement rate (96.8%), while cognitive training exhibited the lowest (60.0%). Ambulation, hand function, and passive goals were generally considered too easy (mean GAS T score > 50). Most other goals were classified as too difficult. Despite having the lowest achievement rate, cognitive goals appeared to be appropriately challenging, as evidenced by the wide range of GAS scores (-1 to +1).

The results highlight the relationships between CP classifications and therapeutic goals. High-functioning participants (GMFCS I-II, MACS I-II, and CFCS I-II) were most frequently assigned goals targeting ambulation, hand function, and ADLs. Conversely, low-functioning groups (GMFCS IV-V, MACS IV-V, and CFCS IV-V) primarily focused on sitting, swallowing, and neck and trunk control (Supplementary Data).

Table 1. Baseline participants' characteristics during goal-directed therapy rounds

Characteristics	n (%)
Female gender	284 (61.5)
CP type	
Spastic	359 (77.7)
Dyskinetic	1 (0.2)
Ataxic	12 (2.6)
Mixed	90 (19.5)
GMFCS level	
I	32 (6.9)
II	89 (19.3)
III	118 (25.5)
IV	116 (25.1)
V	107 (23.2)
MACS level*	
I	163 (35.3)
II	125 (27.1)
III	59 (12.8)
IV	41 (8.9)
V	58 (12.6)
CFCS level*	
I	164 (35.5)
II	80 (17.3)
III	109 (23.6)
IV	39 (8.4)
V	44 (9.5)
Associated problems	
Epilepsy	174 (37.7)
Hearing problem	14 (3.0)
Visual problem	203 (43.9)
Intellectual disability	59 (12.8)
Frequency of therapy	
< 3 sessions per week	460 (99.6)
≥ 3 sessions per week	2 (0.4)
Therapy	
Physical therapy	284 (61.5)
Occupational therapy	178 (38.5)

*There is unknown data in MACS and CFCS level due to age not applicable. CP, cerebral palsy; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System; CFCS, Communication Function Classification System

Univariable logistic regression revealed a statistically significant association between goal attainment and the following factors:

- GMFCS levels I-II and III compared to IV-V
- MACS levels I-II and III compared to IV-V
- CFCS levels I-II and III compared to IV-V
- Absence of epilepsy

Subsequent multivariable logistic regression analysis identified GMFCS levels I-II (compared to IV-V) as the sole factor independently associated with goal attainment (Table 3).

Table 2. Goal setting and attainment for participants, with overall GAS T scores

Goal	n (%)	Goal attainment (%)	Overall GAS T score
PT			
Passive	21 (4.5)	20 (95.2)	50.8
Neck and trunk control	30 (6.5)	24 (80.0)	44.1
Sitting	76 (16.4)	66 (86.8)	49.5
Ambulation	157 (33.9)	152 (96.8)	52.6
OT			
Hand function	92 (19.9)	75 (81.5)	51.0
ADLs	37 (8.0)	29 (78.4)	48.6
Swallowing	44 (9.5)	33 (75.0)	46.8
Cognition	5 (1.1)	3 (60.0)	50.0
Overall	462 (100.0)	402 (87.0)	50.2

GAS, Goal Attainment Scale; PT, physiotherapy; OT, occupational therapy; ADLs, activities of daily living

Table 3. Logistic regression: factors influencing goal attainment

Factors	Univariable logistic analysis		Multivariable logistic analysis	
	Unadjusted OR (95%CI)	*p*-value	Adjusted OR (95%CI)	*p*-value
Sex				
Male	1.69 (0.93, 3.07)	0.08	1.52 (0.76, 3.00)	0.23
Female	Reference		Reference	
Age (year)		0.78		0.47
≤ 3	0.92 (0.51, 1.65)		1.30 (0.64, 2.66)	
> 3	Reference		Reference	
Type				
Spastic	1.25 (0.66, 2.40)	0.50	0.69 (0.30, 1.55)	0.38
Dyskinetic	NA	NA	NA	NA
Ataxic	NA	NA	NA	NA
Mixed	Reference		Reference	
GMFCS				
I - II	4.45 (1.83, 10.80)	0.001*	3.18 (1.05, 9.60)	0.04*
III	2.05 (1.03, 4.07)	0.04*	1.50 (0.65, 3.45)	0.34
IV - V	Reference		Reference	
MACS				
I - II	3.55 (1.93, 6.55)	< 0.001*	1.37 (0.52, 3.61)	0.52
III	2.51 (1.01, 6.24)	0.05	2.18 (0.80, 6.71)	0.12
IV - V	Reference			
CFCS			Reference	
I - II	4.25 (2.13, 8.47)	< 0.001*	2.46 (0.66, 9.24)	0.18
III	1.60 (0.80, 3.23)	0.19	1.14 (0.40, 3.26)	0.81
IV - V	Reference		Reference	
Epilepsy				
Yes	Reference		Reference	
No	1.94 (1.12, 3.34)	0.02*	1.06 (0.45, 2.48)	0.89
Hearing impairment				
Yes	Reference		-	-
No	0.51 (0.07, 3.95)	0.52	-	-
Visual impairment				
Yes	Reference		Reference	
No	1.43 (0.83, 2.46)	0.20	1.34 (0.68, 2.64)	0.40
Intellectual impairment				
Yes	Reference		Reference	
No	0.89 (0.38, 2.06)	0.78	1.68 (0.62, 4.57)	0.31
Intensive training				
Yes	Reference		Reference	
No	6.80 (0.42, 110.13)	0.18	4.82 (0.25, 92.62)	0.29

OR, odds ratio; CI, confidence interval; GMFCS, Gross Motor Function Classification System; MACS, Manual Ability Classification System; CFCS, Communication Function Classification System

Discussion

This ambidirectional cohort study demonstrated that children with GMFCS levels I-II are highly likely to achieve therapeutic goals. These findings align with previous studies that have identified GMFCS as a key prognostic factor for gross motor function.[10,11,23] These results underscore the strong influence of the GMFCS on goal attainment, particularly the increased success observed in ambulatory children compared to non-ambulatory participants.

Prior research highlights that for individuals with CP classified as GMFCS level IV or V, the primary clinical focus is on improving range of motion and reducing muscle tone (passive goals) as primary goals of botulinum toxin A treatment.[24] Furthermore, studies indicate that severity, type of CP, and ambulation status are considered when setting individual goals for botulinum toxin injections.[25-27]

Based on these findings, the GMFCS should be regarded as an essential tool when establishing appropriate therapeutic goals in GDT for individuals with CP. In this study, high-functioning children (GMFCS levels I-III) were commonly set goals related to improving ambulation, hand function, and ADLs. In contrast, low-functioning children (GMFCS levels IV-V) prioritized goals such as improving neck and trunk control, enhancing hand function, and improving swallowing. This disparity suggests that active goals may be more suitable for individuals with higher functional levels. In comparison, passive goals—focused on preventing complications and promoting early motor milestones—may be more suitable for individuals with lower functional levels. Healthcare professionals can incorporate the GMFCS into routine clinical practice to support individualized goal setting and optimize therapeutic outcomes.

Despite a high overall goal achievement rate and generally appropriate goal setting, some specific goals remain challenging or unattainable, particularly those targeting neck and trunk control, swallowing, sitting, and ADLs. Although multidisciplinary teams may establish appropriate therapeutic goals, achieving active goals in low-functioning children presents significant challenges. However, some participants with GMFCS levels IV-V successfully achieve active goals, potentially due to their younger age at enrollment and the associated increased neuroplasticity, which enhances treatment efficacy.[28]

While prior research suggests a link between intensive therapy and improved gross motor development,[29] this study did not identify a statistically significant association between intensive training and goal attainment. This finding may be attributed to the low number of participants receiving intensive training (0.4%). This limited sample size impedes a definitive analysis of the potential influence of therapy frequency at the hospital on goal achievement rates.

To address this limitation and to potentially increase overall treatment intensity, home programs were provided to all participants for completion by caregivers. This approach aligns with studies demonstrating higher home program compliance in GDT groups.6 Notably, despite the limited use of intensive training, the high home program compliance rate (approximately 80.0%) suggests that such alternative methods can still facilitate goal attainment for most participants.

Previous research has established a link between comorbidities affecting function (cognitive, intellectual, communication or vision impairment, and epilepsy) and functional outcomes in children with CP.[9-15] Although our univariable analysis identified epilepsy and CFCS levels I-II as potential influences on goal achievement, subsequent multivariable logistic regression highlighted GMFCS as the primary determinant. This finding may be due to the fact that the GMFCS level strongly reflects CP severity, which is closely associated with both epilepsy (particularly in GMFCS levels IV-V) and CFCS levels I-II. When accounting for the influence of the GMFCS level, the independent impact of these other factors on goal attainment becomes less pronounced.

This study observed instances of nonattainment of passive goals, for which primary responsibility typically falls on caregivers. The inability to achieve these goals could be attributed to various caregiver-related factors. These include age, educational level, number of children requiring care, financial constraints, and time availability.

Furthermore, when comparing children with CP and adult stroke patients, baseline functional status as measured by motor impairment or the Functional Independence Measure (FIM) emerges as a critical predictor of rehabilitation outcomes.[30,31] Given that both CP and stroke are neurological disorders, recovery potential during rehabilitation is heavily influenced by baseline function. Therefore, comprehensive initial functional assessments should be conducted to guide goal setting and inform tailored rehabilitation planning for optimal outcomes.

This study has several limitations that warrant consideration. First, as this was an observational study conducted at a single university hospital, the generalizability of the findings may be limited. Multicenter or national-level studies are needed to validate these results. Second, the absence of long-term goals in this study restricted the conclusions. Further research with long-term goal assessment is required to confirm these findings. Third, excluding participants who had a medical illness that prevented them from completing the therapy sessions introduced selection bias, as the medical illness itself could be a negative independent factor affecting the patients' ability to achieve their goals. Unfortunately, the study utilized cohort data from a routine CP clinical tracer database which employed a complete case analysis; therefore, data on drop-out patients were not available for analysis. Fourth, the use of a single therapist for both goal setting and GAS evaluation may have introduced bias. Lastly, the limited number of ataxic and dyskinetic participants prevented an analysis of factors specific to these types of CP. Further studies with more diverse and larger samples are needed to better understand the factors influencing goal attainment in children with CP.

Conclusions

Children with CP who demonstrate higher gross motor function (GMFCS levels I-II) are significantly more likely to achieve therapeutic goals. The GMFCS should guide the selection of appropriate goals for individuals with CP. High-functioning children may benefit from active goals that target ambulation and hand function. In contrast, passive goals focused on preventing complications and promoting early motor milestones may be more suitable for children with lower functioning.

Conflicts of interest declaration

The authors confirm that there is no conflict of interest related to the manuscript.

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Data availability

The data that support the findings of this study are available from the corresponding author, Teerada Ploypetch, upon reasonable request.

Author contribution

Chanapong Lertpanyawattanakul: conceptualization, data curation, analysis, methodology, project administration, writing - original draft preparation,

Teerada Ploypetch: conceptualization, methodology, funding acquisition, supervision, validation, analysis, writing - review & editing,

Wannika Nuanta: conceptualization, data collection,

Kanit Khlaijang: conceptualization, data collection,

Ruamporn Pinijpong: conceptualization, data collection.

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Original Article

A Clinical Predictive Score to Predict Functional Outcomes After Intensive Rehabilitation Programs for Patients with Stroke: A Retrospective Cohort Study

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ABSTRACT

Objectives: To develop a clinical predictive score to predict functional outcomes of intensive rehabilitation programs for stroke patients

Study design: A retrospective, observational cohort study

Setting: The inpatient rehabilitation ward of the Maharat Nakhon Ratchasima Hospital

Subjects: Stroke patients aged ≥ 18 years who had undergone admission for intensive rehabilitation

Methods: The study reviewed the demographic data, associated impairment, clinical assessment, and Barthel index (BI) at admission to and at discharge from the rehabilitation ward. The patient's functional outcome was classified based on the BI at discharge. Predictive variables were identified using stepwise multivariable logistic regression. A predictive score was constructed and validated.

Results: Among 250 patients, 81 achieved a good rehabilitation outcome. Eight variables were predictive of outcome: age < 70 years, interval from onset to intensive rehabilitation admission, neglect syndrome, cognitive impairment, depression, muscle strength of the affected distal upper extremity and proximal lower extremity ≥ grade 3, and Functional Ambulation Categories (FAC). These variables were used to construct a predictive score, resulting in a model with an area under the curve (AUC) of 0.77 (95%CI: 0.71, 0.83). The total score range was from 0 to 33. The Youden index determined a cutoff of 19.5, categorizing patients into two groups: good (> 19.5) and poor rehabilitation outcomes (≤ 19.5). The positive likelihood ratio for good rehabilitation outcomes was 2.32 (95%CI: 1.85, 2.90), while for poor rehabilitation outcomes, it was 0.27 (95%CI: 0.17, 0.44). Internal validity confirmed the model's good discrimination, calibration, and minimal overfitting.

Conclusions: Based on reliable and straightforward admission variables, the clinical predictive score presented in this study could help guide physicians in decision-making regarding selection of patients for admission to intensive rehabilitation programs.

Keywords: activities of daily living, rehabilitation outcome, stroke, predictive score

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Introduction

Stroke is a major global public health issue, ranking as the third leading cause of mortality and morbidity.[1] In addition to causing neurological deficits, it can also lead to various physical impairments. Rehabilitation is an effective method for improving patients' mobility and independence in daily activities.[2] It involves holistic care provided by a multidisciplinary team which includes patient assessment, diagnosis, goal setting, and collaborative care planning.[3]

Intensive rehabilitation involves a structured program in which patients are admitted to the hospital and receive at least three hours of rehabilitation therapy per day, five days a week, provided by a multidisciplinary team. Previous studies have shown that stroke patients undergoing intensive rehabilitation usually achieve better functional outcomes compared to those in non-intensive programs.[4] However, intensive programs have limitations, including high costs, limited accessibility, and prolonged hospital stays. Therefore, selection of patients for intensive programs is essential to maximize the benefits of intensive rehabilitation.

Maharat Nakhon Ratchasima Hospital is a tertiary care center providing intensive rehabilitation services. Approximately 200 patients receive services in the rehabilitation ward each year, with approximately 40 of them being stroke patients. A clinical model for predicting functional outcomes after intensive rehabilitation in stroke patients would be valuable. It would assist physicians to select appropriate candidates for the program and would help ensure efficient use of limited time and resources. Furthermore, this information could help encourage patients with strong potential for successful intensive rehabilitation to consider admission to maximize their recovery outcomes.

Several previous studies have developed clinical predictive models for stroke patients. The most commonly included predictors are age,[4-6] the interval from onset to intensive rehabilitation admission,[7] recurrent stroke,[6,8] functional ability at admission,[5,9,10] cognition,[5,11] neglect syndrome,[8] and aphasia.[8]

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However, most of these studies have focused on stroke patients in the acute phase, with only a few addressing those in the subacute or chronic phases. Under Thailand's regional healthcare system, stroke patients in all phases receive rehabilitation services. Furthermore, many of these predictive models were developed based on different patient populations and rehabilitation approaches, making them less directly applicable to our patient group. This study aimed to develop a clinical predictive score to predict functional outcomes after intensive rehabilitation programs for stroke patients. This tool is intended to help establish appropriate criteria for admitting patients to intensive rehabilitation programs.

Methods

Study design

This report is a retrospective cohort study and prognosis prediction research. On June 20, 2024, the Maharat Nakhon Ratchasima Hospital Institutional Review Board granted ethical approval (approval number 085/2024). This study has been reported according to the STROBE guideline for observational studies.

Participants

We recruited stroke patients undergoing intensive rehabilitation at the rehabilitation ward of Maharat Nakhon Ratchasima Hospital between May 2016 and April 2024. The inclusion criteria included the following requirements: age 18 years or over, a diagnosis of stroke, and consent to be admitted for intensive rehabilitation. The exclusion criteria included the following: unstable vital signs or neurological symptoms, underlying neurodegenerative diseases, e.g., Alzheimer's disease, Parkinson's disease, patients with complications that would prevent them from completing the rehabilitation program, and missing required information.

Intensive rehabilitation refers to a rehabilitation program in which patients are admitted to the hospital for rehabilitation training provided by a multidisciplinary team, including doctors, nurses, physical therapists, occupational therapists, speech therapists, and others. The training is provided for at least 3 hours a day, 5 days a week, for a minimum of 1 week.

Data collection

Data were collected from electronic hospital medical records, including patient characteristics, significant comorbidities, premorbid functional status, presence of a caregiver, history of stroke (including onset, type, and recurrence), the dates of admission and discharge from the rehabilitation ward, length of stay, impairments, and depression. Impairments, including hemiparesis, aphasia, dysphagia, neglect syndrome, and the presence of depression, were identified from medical records. Cognitive impairment was determined based on a Thai Mental State Examination (TMSE) score of ≤ 23 points. Clinical assessments conducted before and after the rehabilitation program were also reviewed. These assessments included muscle strength of the affected extremities, e.g., proximal upper extremity (shoulder abductor), distal upper extremity (wrist extensor), proximal lower extremity (hip flexor and knee extensor), and distal lower extremity (ankle dorsiflexor). Additional evaluations covered the ability to roll over in bed, transition from supine to sitting and sitting to standing, ambulation, sitting and standing balance, Functional Ambulation Categories (FAC) and the Barthel index (BI). The functional outcome was evaluated using BI.

Patients were classified into two groups: good rehabilitation outcome and poor rehabilitation outcome. A good rehabilitation outcome was defined as follows: for patients with a pre-rehabilitation BI score of 75 or less, an improvement of at least 40 points in the BI score or BI at discharge of 80 or higher[11,12] at discharge from the rehabilitation ward; and, for patients with a pre-rehabilitation BI score of more than 75, an improvement of at least 5 points in the BI score after undergoing intensive rehabilitation in the hospital. The study flow diagram is shown in Figure 1.

Sample size calculation

The sample size was calculated using G*Power software, with the Z-test family: the multiple logistic regression model[13] from Dušica's study,[11] which had a population similar to the present study. Based on a power of 80.0% with an alpha error of 0.05 and an R-Square of 0.4, the total sample size was 233 participants.

Outcome

The primary outcome was developing and validating a simplified clinical predictive score of functional outcome after an intensive rehabilitation program for patients with stroke based on essential statistical and clinical predictors.

Statistical methods

The data were analyzed using STATA version 14.0 statistical software. Potential predictors were selected based on prior knowledge from a literature review and previous predictive models. Categorical predictors are presented as frequency distributions and percentages. Continuous variables were categorized for analysis. Age was grouped as either < 70 or ≥ 70 years. The interval from onset to intensive rehabilitation admission was classified as < 3 months, 3-6 months, or > 6 months. Based on patient independence level, BI scores were divided into 0-20, 25-75, and > 75. Comparative analyses were performed using Fisher's exact test. A *p*-value of < 0.05 was considered statistically significant.

The independent predictors were identified using multiple logistic regression. Subsequently, some predictors were transferred into a multivariable model because of their clinical importance. The backward elimination of non-significant predictors was then conducted in a stepwise manner. After model reduction, the score transformation for each predictor variable was based on the multiple logistic regression coefficient of

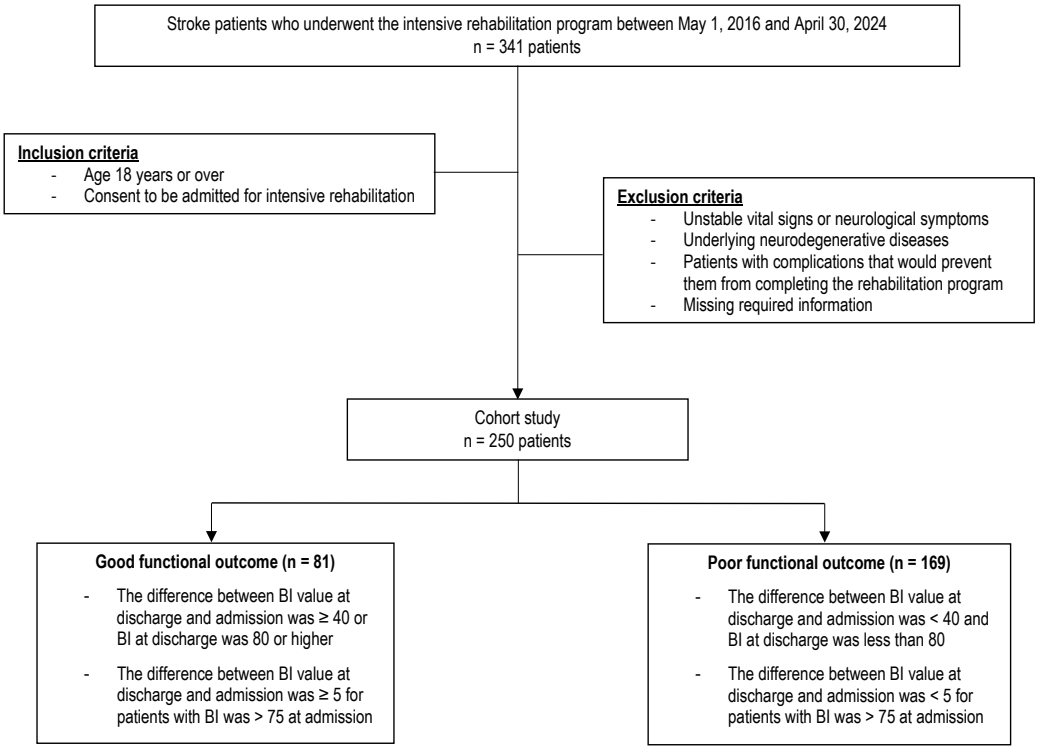

Figure 1. The study flow diagram

the variable divided by the coefficient of the variable with the smallest value. The result was then rounded to the nearest 0.5 to create a clinical predictive score for each predictor.

The score's discriminative performance was evaluated using the AuROC curve. The model's goodness-of-fit was assessed using a calibration plot. The calibration was evaluated by comparing the observed outcomes with the predicted probabilities. A polynomial of degree 2 was used to fit the calibration curve, assessing non-linear relationships between the expected and observed values. Internal validation of the clinical predictor score was performed using a bootstrapping resampling procedure with 1,000 replicates.

The total predictive scores of the patients were divided into two levels: a good rehabilitation outcome group and a poor rehabilitation outcome group. The cutoff point was determined using the Youden index. The predictive ability for rehabilitation outcomes was expressed as the likelihood ratio of a positive result and a 95% confidence interval (95%CI), with statistical significance set at a *p*-value of less than 0.05

Results

Data were collected from 250 patients, with 81 showing good rehabilitation outcomes and 169 showing poor rehabilitation outcomes. The patient's characteristics include gender, age, type of stroke, recurrent stroke, comorbidity, premorbid ambulation status, marital status, presence of a caregiver, and the interval from onset to intensive rehabilitation admission (Table 1). Statistically significant differences between the two groups in univariable analysis were found for patients over 70 years old, the presence of a caregiver, and the interval from onset to intensive rehabilitation admission.

The impairment and clinical assessment of patients were also recorded, including hemiparesis side, muscle strength (assessed using the Medical Research Council scale) on the affected side ≥ grade 3, aphasia, cognitive impairment, dysphagia, neglect syndrome, depression, sitting ability, ambulation status, BI, and FAC at admission (Table 2). The two groups showed statistically significant differences in univariable analysis for muscle strength on the affected side ≥ grade 3 in the proximal and distal parts of upper and lower extremities, cognitive impairment, neglect syndrome, sitting ability, ambulation status, BI, and FAC. FAC was categorized into three groups based on level of assistance: maximal assistance (FAC = 0), minimal to moderate assistance (FAC = 1-2), and under supervision to independent ambulation without assistance (FAC = 3-5)

Thirteen statistically significant variables in univariable analysis were included in the multiple logistic regression. Depression was added due to clinical significance. After backward stepwise selection was performed, the presence of a caregiver, muscle strength on the affected side of the proximal upper extremity and the distal lower extremity, sitting ability, ambulation status, and BI at admission were eliminated

The final predictive score was developed using two statistically significant predictors identified in our research: age < 70 years and the interval from onset to intensive rehabilitation admission, as well as six clinically significant predictors from previous studies: neglect syndrome, cognitive impairment, depression, muscle strength on the affected distal upper extremity and proximal lower extremity ≥ grade 3, and FAC. The score was calculated based on beta coefficients, resulting

Table 1. Baseline characteristics of patients with good and poor rehabilitation outcome (univariable analysis)

Variables	Good outcome (n = 81)	Poor outcome (n = 169)	*p*-value
Gender (male)[1]	61 (75.3)	117 (69.2)	0.372
Age ≥ 70[1]	4 (4.9)	28 (16.6)	0.009
Mean age (years)[2]	54.2 (11.1)	57.4 (11.4)	0.083
Ischemic stroke[1]	47 (58.0)	87 (51.5)	0.346
Recurrent stroke[1]	10 (12.4)	14 (8.3)	0.360
Comorbidity[1]			
Diabetes mellitus	25 (30.9)	43 (25.4)	0.367
Hypertension	54 (66.7)	117 (69.2)	0.771
Dyslipidemia	19 (23.5)	28 (16.5)	0.226
Atrial fibrillation	4 (4.9)	13 (7.7)	0.593
Coronary artery disease	0 (0.0)	3 (1.8)	0.553
Other	15 (18.5)	39 (23.1)	0.512
Premorbid ambulation status[1]			1.000
Independent walking without a gait aid	79 (97.5)	163 (96.5)	
Independent walking with gait aid	2 (2.5)	4 (2.4)	
Bedridden	0 (0.0)	2 (1.2)	
Marital Status[1]			0.168
Single	22 (27.2)	35 (20.7)	
Married	57 (70.4)	133 (78.7)	
Divorce	2 (2.5)	1 (0.6)	
Presence of Caregiver (yes)[1]	75 (92.6)	168 (99.4)	0.005
Interval from onset to intensive rehabilitation admission[1]			0.002
< 3 months	67 (82.7)	107 (63.3)	
3-6 months	11 (13.6)	33 (19.5)	
> 6 months	3 (3.7)	29 (17.2)	
Length of stay[2]	13.6 (10.5)	16.4 (2.3)	0.426

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

Table 2. The impairment and clinical assessment of patients with good and poor rehabilitation outcomes (univariable analysis)

Variables	Good outcome (n = 81)	Poor outcome (n = 169)	*p*-value
Right hemiparesis[1]	43 (53.0)	77 (45.6)	0.524
Muscle power of the affected side ≥ grade 3[1]			
Proximal of UE	24 (29.6)	20 (11.8)	0.001
Distal of UE	22 (27.2)	17 (10.1)	0.001
Proximal of LE	38 (46.9)	37 (21.9)	< 0.001
Distal od LE	19 (23.4)	16 (9.5)	0.006
Aphasia[1]	20 (24.7)	54 (31.9)	0.300
Cognitive impairment[1]	13 (16.1)	56 (33.1)	0.006
Dysphagia[1]	19 (23.5)	52 (30.8)	0.294
Neglect syndrome[1]	6 (7.4)	29 (17.2)	0.050
Depression[1]	3 (3.7)	18 (10.7)	0.087
Able to change body position from supine to sit[1]	54 (66.7)	67 (39.6)	< 0.001
Ambulation status at admission[1]			0.003
Walk with/without assist	31 (38.3)	31 (18.3)	
Wheelchair ambulation	8 (9.9)	18 (10.6)	
Bedbound/bedridden	42 (51.9)	120 (71.0)	
Barthel index at admission[1]			< 0.001
0-20	19 (28.3)	48 (71.6)	
25-75	45 (27.8)	117 (72.2)	
> 75	17 (80.9)	4 (19.1)	
FAC at admission[1]			0.001
0	51 (62.9)	138 (81.7)	
1-2	18 (22.2)	25 (14.8)	
> 3	12 (14.8)	6 (3.6)	

[1]Number (%), UE, upper extremity; LE, lower extremity; FAC, Functional Ambulation Categories

Table 3. The clinical predictive score of good rehabilitation outcome, odds ratio (OR), 95% confidence interval (CI), *p*-value, beta coefficient (β), and assigned item scores

Valiables	OR	95%CI	*p*-value	Beta coefficient	Score
Age < 70 years	3.35	1.08, 10.35	0.036	1.21	4.5
No neglect syndrome	2.08	0.75, 5.73	0.159	0.73	3.0
No cognitive impairment	1.82	0.87, 3.82	0.112	0.60	2.0
No depression	2.29	0.54, 9.70	0.264	0.81	3.0
Muscle strength of distal muscle of UE ≥ 3	1.95	0.82, 4.63	0.130	0.67	2.5
Muscle strength of proximal muscle of LE ≥ 3	2.06	0.97, 4.38	0.059	0.73	3.0
Interval from onset to intensive rehabilitation admission					
< 3 months	6.83	1.89, 24.70	0.003	1.92	7.5
3-6 months	2.94	0.69, 12.54	0.144	1.08	4.0
> 6 months	1.00	Reference		0.00	0.0
FAC at admission					
0	1.00	Reference		0.00	0.0
1-2	1.29	0.57, 2.94	0.530	0.26	1.0
≥ 3	2.02	0.58, 7.03	0.270	0.70	2.5

UE, upper extremity; LE, lower extremity; FAC, Functional Ambulation Categories

in a total range of 0 to 33 (Table 3). The AUC for this total predictive score was 0.77 (95%CI: 0.71, 0.83) (Figure 2). A graphical approach to assess the goodness of fit demonstrated that the model is well-calibrated, with most points falling close to the bisector. The high *p*-value of 0.89 indicates no significant miscalibration (Figure 3). From the plot, the predicted probability of good rehabilitation outcomes increases as the score increases, showing agreement between the actual rehabilitation outcomes and the predicted risks (Figure 4).

For clinical applicability, the scores were categorized into two groups based on clinical relevance: good rehabilitation outcomes (> 19.5) and poor rehabilitation outcomes (≤ 19.5). The cutoff point was determined using the Youden index. The positive likelihood ratio for good rehabilitation outcomes was 2.32 (95%CI: 1.85, 2.90), while for poor rehabilitation outcomes, it was 0.27 (95%CI: 0.17, 0.44) (Table 4). The score showed a sensitivity of 82.7% (95%CI: 72.7, 90.2) and a specificity of 64.3% (95%CI: 56.5, 71.5). The positive predictive value was 52.8% (95%CI: 43.7, 61.7), and the negative predictive value was 88.5% (95%CI: 81.5, 93.6).

To evaluate the internal validity of the derivation model, we conducted bootstrap validation with 1,000 replications. The results reflect the model's overall predictive accuracy, discrimination, and calibration performance. The scaled Brier score was 19.4% for the apparent model performance and 18.6% after optimism adjustment via bootstrap validation. The C-statistic was 0.74 (95%CI: 0.68, 0.79) for the apparent performance and 0.74 (95%CI: 0.68, 0.80) after the optimism adjustment. This result demonstrates good discrimination, showing that the model effectively differentiates between outcomes. The E:O ratio, reflecting calibration, was 1.000

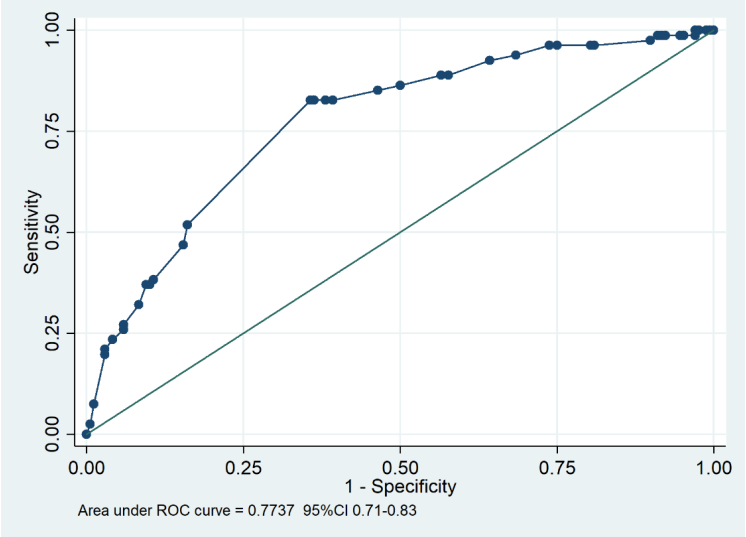

Figure 2. Area under received operating characteristic curve (AUROC) of the clinical predictive score of functional outcomes after intensive rehabilitation program for stroke patients

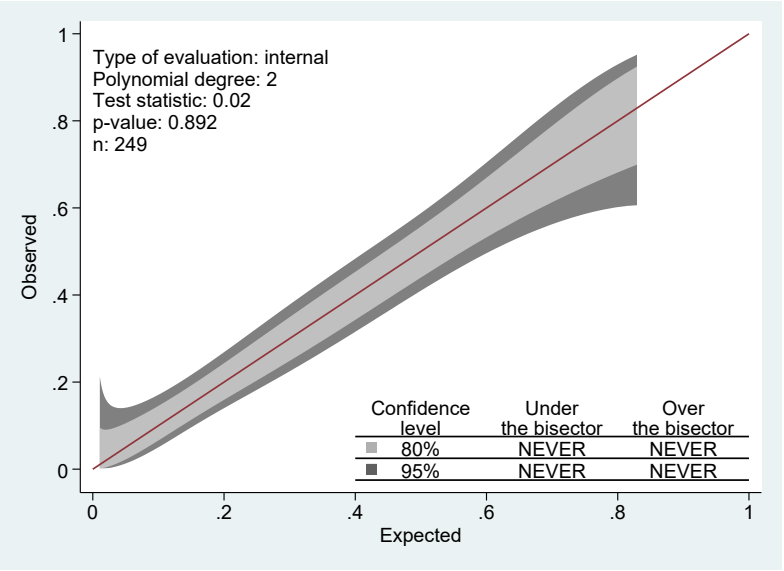

Figure 3. Calibration plot of the predicted probability of functional outcome after intensive rehabilitation program and observed functional outcome

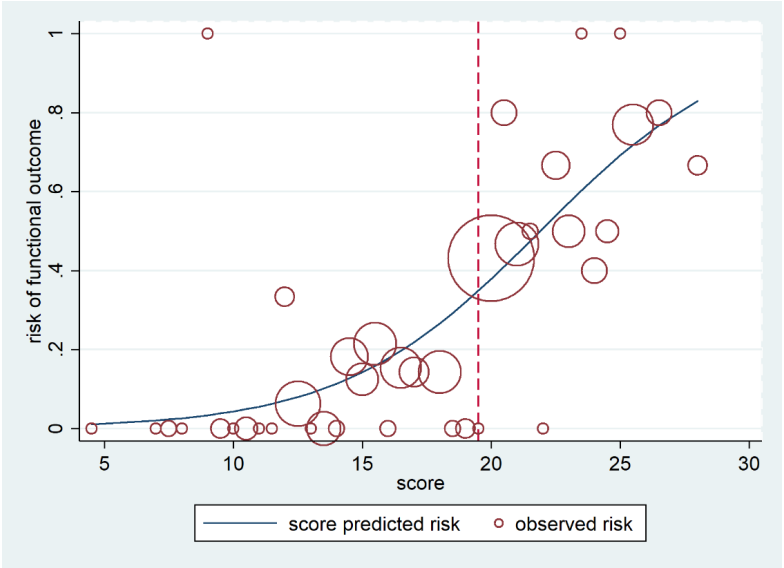

Figure 4. The risk curve analysis: observed risk of functional outcome (hollow circle) and predicted risk of the functional outcome by score (solid line), size of the circle represents the relative number of patients in each score

Table 4. Distribution of probability of functional outcome after intensive rehabilitation across the actual functional outcome

Probability categories	Score	Good functional outcome n (%)	Poor functional outcome n (%)	LR+	95%CI	*p*-value
Poor	0.0-19.5	14 (11.9)	108 (88.5)	0.27	0.17, 0.44	<0.001
Good	20.0-33.0	67 (52.8)	60 (47.2)	2.32	1.85, 2.90	<0.001

LR+, positive likelihood ratio; CI, confidence interval

for the apparent model and 1.00 (bootstrap 95%CI: 0.85, 1.16) after optimism adjustment, suggesting no significant deviation. Additionally, the heuristic shrinkage factor was 0.98 and the bootstrap shrinkage factor was 1.10, indicating minimal overfitting and further supporting the model's internal validity. These results suggest that the model demonstrates good discrimination and calibration, with minimal optimism or overfitting.

Discussion

The clinical predictive score was developed to predict the functional outcomes after intensive rehabilitation in stroke patients. The independent predictors include age < 70 years, neglect syndrome, cognitive impairment, depression, muscle strength of the affected distal upper extremity and proximal lower extremity ≥ grade 3, the interval from onset to intensive

rehabilitation admission, and FAC. The total score range is from 0 to 33 points, categorizing patients into two groups based on their scores: good rehabilitation outcomes (> 19.5 points) and poor rehabilitation outcomes (≤ 19.5 points). The model demonstrated excellent discriminative performance and good calibration, indicating it is a reliable tool for predicting rehabilitation outcomes.

From the analysis using multiple logistic regressions, two predictors were statistically significant for rehabilitation outcomes: age < 70 years and the interval from onset to intensive rehabilitation admission. These findings are consistent with previous studies.[4,6,8,10-11,14-16] Age is a key factor affecting rehabilitation outcomes, as older patients often experience cognitive decline and have more comorbidities than younger patients.[17] Additionally, neuroplasticity occurs more slowly and less effectively in older patients.[18] Pohjasvaara et al. found that stroke patients over 70 years old were more dependent and disabled compared to those aged 55-70 years.[19]

In this study, the interval from onset to intensive rehabilitation admission was categorized into three groups: less than 3 months, 3-6 months, and over 6 months. This classification is based on evidence that most functional recovery occurs within the first 6 months after a stroke,[20] with the most significant recovery occurring in the first 3 months.[21] Several studies have shown that early and intensive rehabilitation improves ADL and functional outcomes more successfully than delayed rehabilitation.[22,23] Wattanapan et al. studied the effectiveness of intensive rehabilitation in stroke patients and found that shorter onset-to-admission intervals and shorter length of stay were significantly associated with better outcomes.[4]

In addition to these factors, we included clinically important variables in the model, such as neglect syndrome, cognitive impairment, depression, muscle strength on the affected side, and FAC. Neglect syndrome has been identified as a negative predictor of poor ADL outcomes.[8,15] Chen et al. studied the impact of spatial neglect in stroke rehabilitation and found that stroke patients with neglect syndrome had poorer rehabilitation outcomes, more extended hospital stays, and a higher risk of falls.[24]

Cognitive impairment is a barrier to successful rehabilitation outcomes.[5,11,15] Patients with cognitive impairment often struggle with learning, perceiving, and understanding the rehabilitation program, making it difficult for them to follow instructions effectively. Additionally, this condition reflects severe central nervous system dysfunction, which negatively impacts neuroplasticity.[25]

Depression is a common condition among stroke patients, occurring in 20.0-40.0% of cases.[26] It can lead to problems such as sleep disturbances, fatigue, altered appetite, depressed mood, loss of interest in socialization, and limited participation in rehabilitation programs. Although univariable analysis in this study did not show a statistically significant association between depression and the outcome, this may be due to the small number of patients with depression. Additionally, this was a retrospective study; some patients may not have been assessed for depression, leading to underestimation and reduced statistical power. However, based on previous research[6,11], depression is considered an important factor that may influence the outcome. Therefore, we included this variable in the predictive model.

Muscle strength is key in predicting self-care and walking ability in stroke patients. Suksatien et al. reported that muscle strength greater than grade 2 on the affected side during the acute phase of stroke was strongly associated with good long-term functional outcomes as measured by BI.[27] In this study, we included muscle strength in our predictive model, focusing on the wrist extensor, hip flexor, and knee extensor with grade ≥ 3. The wrist extensor muscle was selected due to its critical role in performing basic daily activities.[28] The hip flexor and knee extensor muscles were chosen for their importance in walking ability,[29,30] one of the BI's components.

The final predictor we selected was FAC at intensive rehabilitation program admission. Patients were categorized into three groups based on level of assistance: maximal assistance (FAC = 0), minimal to moderate assistance (FAC = 1-2), and under supervision to independent ambulation without assistance (FAC = 3-5). The FAC is a reliable indicator of motor function and trunk balance, crucial for improving independence.[16] Patients with higher FAC at admission tended to achieve better functional outcomes following intensive rehabilitation.

While previous studies have reported BI at admission predicts functional outcomes after intensive rehabilitation,[8,10,31] our findings differ. We found that BI at admission did not discriminate and predict the rehabilitation outcomes in our study. This result may be because patients with lower BI had not undergone prior rehabilitation, allowing for more significant improvements during the program. Conversely, patients with higher BI experienced minimal changes due to a ceiling effect,[32] making it less reflective of actual improvement.

Previous studies have also identified the ability to change body position from supine to sitting[9] and ambulation status at admission[15,16] as factors influencing rehabilitation outcomes after intensive rehabilitation. However, these variables were not included in the final model in our study because their inclusion did not improve its accuracy in predicting outcomes. Furthermore, ambulation status at admission closely overlapped with the FAC, making its inclusion unnecessary.

Blanco et al. developed a clinical model based on a study of 92 intensive rehabilitation patients to predict functional outcomes. A good outcome was defined as a BI score of ≥ 85 after the program. The predictors included an initial BI > 20 at admission, prior independence before the stroke, and motor deficits without sensory deficits or homonymous hemianopia. The model correctly predicted activities of daily living (ADL) outcomes in 79.0% of cases.[10] In contrast, our model incorporates cognitive and psychological factors, whereas Blanco

et al.'s model primarily focuses on baseline functional status. Additionally, the applicability of Blanco et al. is limited as it included only patients capable of sitting independently and relied on a relatively small sample size.

Sodero et al. developed a clinical predictive model to estimate the modified Barthel Index (mBI) of subacute stroke patients (onset < 30 days) undergoing intensive rehabilitation. The study identified younger age, fewer comorbidities, higher cognitive abilities, lower stroke severity, and better motor function at admission as independent predictors of higher mBI at discharge. Similarly, our model included age, cognitive function, and motor function. However, comorbidities and stroke severity were not included, as comorbidities were not statistically significant in our analysis, and stroke severity had substantial missing data. A key strength of Sodero et al.'s model is its focus on the stroke subacute phase, allowing for more consistent outcomes. This difference is important, as the effects of intensive rehabilitation vary depending on the stroke phase. However, our study could not achieve this due to a limited sample size. Another strength of the Sodero study was the use of a continuous outcome measure for the model, which demonstrated exemplary reliability in its assessments (adjusted R-Squared = 77.2%).[33]

Several predictive models have been developed to estimate the Functional Independence Measure (FIM) in stroke patients following intensive rehabilitation. For example, Scrutino et al. predicted an FIM score greater than 61 (indicating mild stroke impairment) using predictors such as age, onset-to-admission interval, neglect syndrome, motor FIM and cognitive FIM. The model demonstrated high accuracy and reliability, with an area under the curve (AUC) of 0.86[6,15], and was externally validated by García-Rudolph et al. (AUC = 0.87).[34] Although their predictors are similar to ours, the assessment methods differ. Scrutino et al. used motor FIM for ambulation and cognitive FIM for cognition. In contrast, our model uses muscle strength of the affected lower extremity and FAC for ambulation and the Thai Mental State Examination (TMSE) for cognition. While FIM-based measures provide a more standardized evaluation of functional independence, our model incorporates more detailed clinical and neurological assessments. Additionally, the inclusion of depression provides a more comprehensive view of rehabilitation potential.

Another model, Harari et al., developed a model using standardized clinical tests to predict outcomes using a continuous score. Key predictors were admission scores on the FIM, Ten-Meter Walk Test (TMWT), and the Berg Balance Scale. Other factors included age, time from stroke onset to admission, education level, speech and language impairment, BMI, and hemorrhagic stroke. The model had good internal validation (adjusted R-Squared = 76.0% and MAE = 7.6).[16] Although the model included a wide range of demographic, clinical, and functional factors, relying on standardized clinical tests may make it less practical for routine rehabilitation. Moreover, the small sample size of 50 patients raises concerns about overfitting and limited generalizability.

This study had several limitations. First, as a retrospective study, some data were missing. Some predictors may not have been included in the clinical model. Some confounding factors could not be identified, potentially affecting the outcome. Second, the study was conducted in a single hospital, which may not represent the entire stroke population, limiting the generalizability of the results. However, the model demonstrated good calibration with minimal overfitting, and external validation is planned using datasets from ongoing prospective studies. Third, the sample size was insufficient for subgroup analysis or assessing rehabilitation outcomes across stroke phases (acute, subacute, and chronic), which may impact results. Lastly, the BI was used as the functional rehabilitation outcome but it is not the most precise assessment tool. Its broad score ranges may fail to capture small changes and can exhibit a ceiling effect in patients with high scores.[32] Despite these limitations, the BI remains a practical and straightforward tool, requiring minimal time to administer, and is widely used in regional and general hospitals across Thailand.

The strengths of this study are that all predictors used in the model are clinical data that can be easily collected in medical practice. Additionally, this study had an adequate sample size, and statistical analysis using a score calibration plot demonstrated that the model effectively predicts rehabilitation outcomes. This model helps predict rehabilitation outcomes even before patients are admitted for intensive rehabilitation. We do not intend this model to be used to discriminate between patients chosen to receive intensive rehabilitation and those not chosen, but rather to provide physicians with a valuable tool for guiding admission decisions, setting realistic functional goals, and planning appropriate rehabilitation programs. While some patients were categorized as having poor rehabilitation outcomes, most of them also had functional improvement after intensive rehabilitation.

Conclusion

Our study suggests that the clinical predictors for rehabilitation outcomes after intensive rehabilitation programs in patients with stroke are age < 70, the interval from onset to intensive rehabilitation, neglect syndrome, cognitive impairment, depression, muscle strength on the affected distal upper extremity and proximal lower extremity ≥ grade 3, and FAC at admission. It could help guide physiatrists and multidisciplinary teams in decision-making before admitting patients to intensive rehabilitation programs.

Conflict of interest disclosure

The authors declare no conflicts of interest.

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Data availability

The data supporting this study's findings are available on request from the corresponding author, Paveenrath Charussuriyong . The data are not publicly available because they contain information that could compromise the privacy of the research participants.

Author contribution

Paveenrath Charussuriyong : conceptualization, methodology, formal analysis, writing - review & editing,

Rachawan Suksathien: supervision.

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Original Article

Experience and Satisfaction with Non-surgical Hallux Valgus Treatment Among Patients in Siriraj Hospital

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ABSTRACT

Objectives: To describe patient experiences, treatments, outcomes, side effects, and satisfaction with hallux valgus treatments at Siriraj Hospital.

Study design: A cross-sectional study

Setting: Siriraj Hospital, Bangkok, Thailand

Subjects: Two hundred thirty participants aged over 18 who were diagnosed with hallux valgus by their physician for over a year and were able to communicate in Thai. Participants had to use the treatment for at least 5 hours per day, 5 days per week, for a minimum of 1 month.

Methods: Data was collected via questionnaires from July 2021 to April 2022. Proportions of experience and satisfaction with non-surgical hallux valgus treatment were calculated to measure the patient's experience and satisfaction with treatment options from the patient's perspective. Mean pain score differences before and after treatment were analyzed using a paired sample t-test.

Results: The study included 217 females (94.3%) with a mean age of 56 SD = 16.4. Fifty-six percent had bilateral hallux valgus. The most common treatment was changing footwear or shoe modification, which was used by 93.0% of participants. The most preferred treatment was changing footwear or shoe modification (65.2%), followed by insoles (20.0%) and dynamic splints (5.7%). These treatments all showed statistically significant clinical improvement ($p < 0.001$, $p < 0.001$ and $p = 0.008$, respectively). Most participants (81.3%) felt their deformity remained unchanged. The median satisfaction score was high for all treatments (8 out of 10). No serious complications were reported.

Conclusions: Changing footwear or shoe modification was the most utilized and the preferred treatment, demonstrating significant clinical improvement. Further studies are recommended to investigate the effectiveness of newer treatments and potential alternatives, e.g., bunion shields, toe separator socks, and cotton toe separators.

Keywords: hallux valgus, treatment, pain, satisfaction

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Introduction

Hallux valgus is a common forefoot deformity characterized by the abnormal angulation of the great toe lateral deviation and the first metatarsal medial deviation. This deformity progresses slowly and has several stages. To classify these stages, the investigators used the hallux valgus angle (HVA) and the intermetatarsal angle (IMA) measured through radiographic evaluation, diagnosing patients as having mild, moderate, or severe deformity.[1] The prevalence of hallux valgus is related to age. More than 50 percent of patients were over 60 years old.[2]

The etiologies of hallux valgus are multifactorial. Intrinsic factors are genetics, pes planus, gout, and rheumatoid arthritis. The main extrinsic factor is the use of improper footwear.[1,3] The prevalence of hallux valgus is higher in women than in men, with a ratio of 15:1.[1,4] However, neither obesity nor occupation are associated with hallux valgus.[3]

Clinical symptoms include first metatarsophalangeal (MTP) joint pain, bunion pain, overriding toes, ulcers from toe-toe or toe-shoe friction, and calluses. This deformity also causes plantar pain and difficulty in ambulation due to abnormal foot pressure distribution while pushing off. Additionally, patients may present with cosmetic issues or difficulty finding suitable shoes.[5]

Non-surgical treatment in patients with mild to moderate hallux valgus is suggested over surgery to avoid postoperative complications because most hallux valgus patients are elderly. Many non-surgical treatment options are currently available, but no standard clinical practice guidelines exist for hallux valgus. Physicians can prescribe most treatments, such as shoe modification, custom-made insoles, and silicone toe separators with bunion shields. However, patients can also seek treatment independently from online or medical device stores, e.g., bunion shields.[5]

A review of the literature found Australian podiatrists often recommend new footwear or modifications to existing foot-

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wear as the primary treatment for hallux valgus across all age groups. Other recommended options include orthotic devices, in-shoe padding, bunion shields, strapping, and exercise.[6] Studies have confirmed the association between hallux valgus and ill-fitting shoes. Wearing a narrow-toe box and high-heeled shoes (more than 2.5 cm) has been shown to be associated with hallux valgus, corns, calluses, and other foot pain problems.[7] Although changing footwear is recommended for treating hallux valgus, there is no published research regarding specific footwear characteristics that can help prevent deformity progression. Silicone toe separators have shown evidence of pain relief and hallux valgus deformity reduction.[8,9] While insoles and toe splints have been reported to provide pain relief, they cannot prevent or correct hallux valgus deformity.[10-14] Using hallux valgus night strap or intrinsic foot muscle exercise has been shown to not reduce pain or deformity.[15,16] Some items, like toe separator socks, bunion shields, and cotton toe separators, are used by patients despite a lack of supporting research demonstrating their efficacy.

The primary objective of this study was to describe the treatments based on patients' experiences and the preferred treatment for hallux valgus at Siriraj Hospital. Secondary objectives were to assess outcomes after using these treatments, including changes in pain score and hallux valgus deformity from the patient's perspective, side effects, and patient satisfaction. The results of this study could lead to further studies, such as randomized controlled trials, to confirm the effectiveness of treatments that as yet not supported by evidence.

Methods

Study design

This cross-sectional study received ethical approval from the Siriraj Institutional Review Board (COA No. Si 523/2021) on February 28, 2022. The study was conducted in accordance with the STROBE guideline for observational studies.

Participants

Two hundred and thirty patients with hallux valgus who visited the foot clinic and the outpatient rehabilitation clinic at Siriraj Hospital from July 2021 through April 2022 were recruited for this study. Inclusion criteria included age over 18 years, having been diagnosed with hallux valgus by a physician for more than 1 year, being able to communicate in Thai to answer the questionnaire, having used any hallux valgus treatment for at least 5 hours per day, 5 days per week, for at least 1 month, and being capable of giving informed consent. Exclusion criteria included having active arthritis, a history of rheumatoid arthritis, or a history of foot bone fractures. Sample size calculation was based on a review of the literature.[6] The sample size was calculated based on the percentage of the most widely recommended treatment for hallux valgus, i.e., provision of advice on different footwear or existing footwear modification (equal to 92.0%). Using the nQuery Advisor program, we set 0.92 as the expected proportion and the accepted distance from proportion to limit = 0.035 (5% type I error, 2-sided, 95% confidence interval (95%CI) = 1.96). Two hundred and thirty participants were calculated to be required for this study.

Materials and data collection

An information sheet with verbal explanations of the study was provided to all participants. Signed informed consent was obtained prior to the study. Participants completed the questionnaire themselves independently; if they could not write or read Thai, they answered the questions verbally, and their relatives or doctors helped fill in the case record form.

Three-part case record form

Part I: General information about the participants, including age, gender, weight, height, occupation, daily lifestyle (sitting or walking, wearing shoes or barefoot), onset and side of hallux valgus.

Part II: Patient experience with hallux valgus treatment. Participants specified all treatments they had received from a provided list (they could select more than one treatment). The names of the different treatments were supplemented by colored pictures following each options as shown in Appendix 1. The list of treatments included changing to different footwear or shoe modification, using prefabricated or custom-made insoles, a static splint, a dynamic splint, a bunion shield, a silicone toe separator with bunion shield, a single piece silicone toe separator, a cotton toe separator, a hallux valgus strap, toe separator socks, taping of toes, intrinsic foot muscle exercise (strengthening and/or stretching), surgery among others. Participants also chose the best treatment for hallux valgus from their perspective, which they must have used regularly for at least 5 hours per day, 5 days per week, for at least 1 month.

Part III: The most preferred treatment from the patient's perspective. Participants reported the duration and frequency of use (hours per day, days per week, and total period of use), how they learned about and where they received the treatment, and their scores before and after treatment for each of five common foot problems that usually occur with hallux valgus. The five common foot problems were first MTP joint pain, bunion pain, plantar pain, difficulty walking, and toe friction. Scores were chosen using a numeric rating scale from 0 to 10 where zero means no pain or no symptoms in that domain of the foot problem and ten means maximal pain or the most disturbance from that foot problem. Next, they rated the change of hallux valgus deformity (self-assessed with no radiographic confirmation). They could answer "Less" meaning having a lower degree of the big toe deviation, "More" meaning having a higher degree of big toe lateral deviation, or "Unchanged" as having no change of the big toe deformity from the participant's perspective. Finally, participants rated their overall satisfaction using a numeric rating scale which

ranged from 0 (most dissatisfaction) to 10 (most satisfaction). Additionally, participants were asked to write down any side effects.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 23. Categorical variables are presented as frequencies and percentages. Normally distributed continuous variables are presented as means and standard deviations (SD). Non-normally distributed continuous variables are expressed as medians with first and third quartiles. For the most preferred hallux valgus treatment chosen by participants, a paired sample t-test was used to analyze the mean difference in pain scores before and after using the treatments. A *p*-value of less than 0.05 was considered statistically significant.

Results

Two hundred and thirty participants were enrolled in this study. Table 1 displays participant demographic information. The mean age was 56, and the average body mass index was 24.1 kg/m^2. Most participants (94.3%) were female. Ninety-eight participants (42.6%) were teachers. More than half (73.0%) usually walked with shoes in their daily lifestyle. Seventy-nine participants (34.3%) had been diagnosed with hallux valgus for one to five years, and one hundred and twenty-nine participants (56.1%) had bilateral hallux valgus.

Table 1. Demographic information of 230 participants

	n (%)
Age (years)[1]	56.2 (16.4)
BMI (kg/m^2)[1]	24.1 (4.6)
Gender[2]	
Female	217 (94.3)
Male	13 (5.7)
Occupation[2]	
Teacher	98 (42.6)
Healthcare workers	28 (12.2)
Merchant	23 (10.0)
Chef	12 (5.2)
Accountant	11 (4.8)
Housekeeper	8 (3.5)
Soldier/policeman	5 (2.2)
Other	45 (19.6)
Lifestyle[2]	
Usually sit	51 (22.2)
Usually walk with shoes	168 (73.0)
Usually walk barefoot	11 (4.8)
Diagnosis as hallux valgus[2]	
One to five years	79 (34.3)
Five to ten years	29 (12.6)
Ten to twenty years	60 (26.1)
More than twenty years	62 (27.0)
Side of hallux valgus[2]	
Right	52 (22.6)
Left	49 (21.3)
Bilateral	129 (56.1)

[1]Mean (SD), [2]number (%)
BMI; body mass index

Primary outcome

Figure 1 shows experiences of the 230 patients with hallux valgus treatment at Siriraj Hospital. Participants chose all the options that they had experienced. The most frequent treatment was changing to different footwear or modifying existing shoes (214 participants, 93.0%).

Figure 2 displays the proportion of participants' selection of the best hallux valgus treatment. Participants were asked to choose their best treatment for hallux valgus. The most frequently chosen option was changing to different footwear or modifying existing shoes, selected by 150 participants (65.2%).

Participants were asked who recommended their most preferred treatment and where they obtained that treatment.

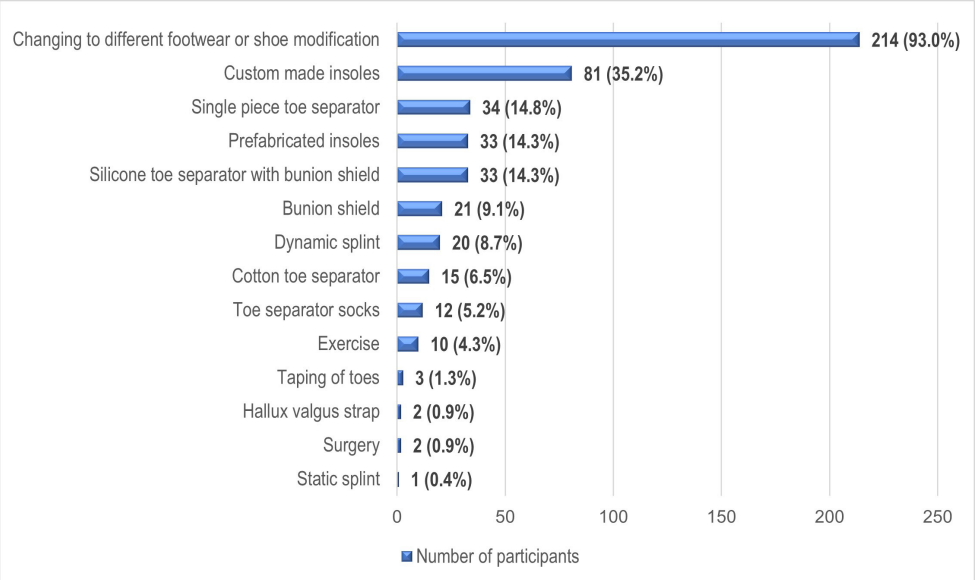

Figure 1. Patient experience with hallux valgus treatment. (Participants could choose more than one treatment.)

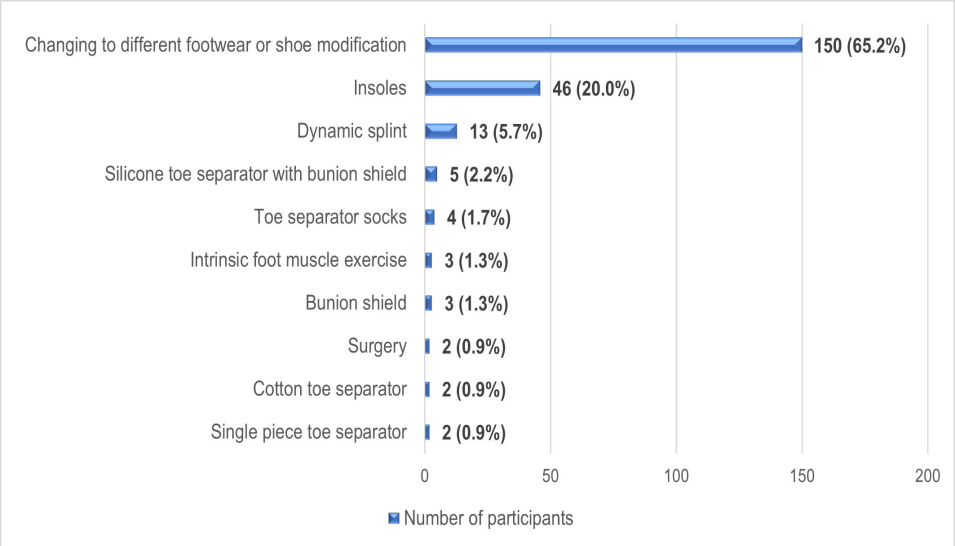

Figure 2. Participant's opinion of the best treatment for hallux valgus

Table 2. Outcome and satisfaction score after using the most preferred hallux valgus treatment

Option n (%)	First MTP pain	Bunion pain	Plantar pain	Difficulty in walking	Toes friction	Satisfaction score Median [IQR]	Reduction in the severity of the deformity n (%)
Different footwear or shoe modification 150 (65.2)							
Pre, mean (SD)	1.12 (2.29)	1.79 (2.70)	2.16 (2.85)	1.19 (2.52)	0.60 (1.55)	7 [5-9]	
Post, mean (SD)	0.38 (1.05)	0.38 (1.17)	0.76 (1.45)	0.41 (1.34)	0.20 (0.93)		6 (26.1)
Mean diff (95%CI)							
Δ Pre-post,	0.74 (0.45, 1.04)	1.41 (1.03, 1.78)	1.40 (1.05, 1.75)	0.79 (0.47, 1.11)	0.40 (0.21, 0.59)		
p-value*	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001		3 (13.0)
Custom-made/ prefabricated insoles 46 (20.0%)							
Pre, mean (SD)	1.74 (2.97)	2.59 (3.01)	4.98 (3.28)	2.28 (3.18)	0.87 (1.73)	8 [8-10]	6 (26.1)
Post, mean (SD)	0.52 (1.59)	0.8 (1.94)	0.76 (1.74)	0.30 (1.26)	0.52 (1.47)		
Mean diff (95%CI)							
Δ Pre-post,	1.22 (0.52, 1.92)	1.78 (1.11, 2.46)	4.2 (3.33, 5.11)	1.98 (1,14, 2.82)	0.35 (0, 0.69)		
p-value*	0.001	< 0.001	< 0.001	< 0.001	0.048		
Dynamic splint 13 (5.7)							
Pre, mean (SD)	4.15 (3.31)	4.77 (3.63)	3.54 (3.53)	1.31 (2.18)	1.46 (2.82)	8 [7-8]	
Post, mean (SD)	2.15 (2.99)	3 (3.42)	2.23 (2.92)	0.46 (1.39)	0.85 (2.15)		
Mean diff (95%CI)							
Δ Pre-post,	2 (0.63, 3.37)	1.77 (0.15, 3.39)	1.31 (0.04, 2.58)	0.85 (-0.2, 1.89)	0.62 (-0.56, 1.80)		
p-value*	0.008	0.035	0.044	0.102	0.275		

* P-value from paired sample t-test

MTP, metatarsophalangeal; IQR, interquartile range

Most treatment options, such as insoles and dynamic splints, were recommended by the hospital healthcare workers and were obtained from hospitals. Some participants were recommended by healthcare workers to use a silicone toe separator with bunion shield and a single piece silicone toe separator which the patient obtained from a hospital and/or drug stores. Changing to different footwear and using toe separator socks were treatments recommended by friends; patients obtained these items from shoe stores and/or online shopping. Two participants were recommended to use cotton as a toe separator by friends. Additionally, three participants learned about intrinsic foot muscle exercises online and performed the exercises regularly on their own.

Secondary outcome

Table 2 shows the outcomes and satisfaction scores after using their most preferred treatment. The treatment outcome focuses on the change in score (mean difference) between before (pre) and after (post) using the treatment regularly for five common foot problems associated with hallux valgus, i.e., first MTP joint pain, bunion pain, plantar pain, difficulty in walking and toe friction. The results showed statistically significant pain score reductions in all five domains after changing to different footwear or modifying shoes and using insoles ($p < 0.001$). A dynamic splint significantly was reported to reduce first MTP joint, bunion, and plantar pain ($p = 0.008$, 0.035, and 0.044, respectively). However, the numbers of participants using each method (toe separator socks, bunion

shields, silicone toe separators with bunion shields, single-piece silicone toe separators, intrinsic foot muscle exercises, surgery, and cotton toe separators) were too small to find a statistically significant difference.

Most participants (187 participants, 81.3%) felt their deformity remained unchanged after regularly using their most preferred treatment. Table 2 also shows the number and percentage of participants who felt their deformity improved in terms of severity from their perspective (no radiographic confirmation). Twenty-three participants (10.0% of participants) felt their hallux valgus deformity decreased after changing new shoes or modifying shoes (6 participants, 26.1%), using a dynamic splint (6 participants, 26.1%), using insoles (3 participants, 13.0%), using a bunion shield (3 participants, 13.0%), using a single-piece silicone toe separator (2 participants, 8.7%), having surgery (2 participants, 8.7%) and using a silicone toe separator with a bunion shield (1 participant, 4.4%). In contrast, a few participants felt their deformity progressed after changing to new footwear (15 participants), using insoles (3 participants), using a dynamic splint (1 participant), and using a silicone toe separator (1 participant). The median satisfaction score (7 to 8 out of 10) for all each of the participants' most preferred hallux valgus treatment was high.

Side effects and complications

Participants complained that plastic dynamic splints were uncomfortable and unwearable with shoes during the day. They also reported pain, irritability, and easy displacement while wearing silicone toe separators with bunion shields or single-piece silicone toe separators with shoes. Additionally, these items were easily torn and became dirty. The bunion shields often rolled over and fell off while being worn with shoes, causing patients to feel tight and uncomfortable. No serious complications were reported.

Discussion

Changing to different footwear or modifying shoes was chosen as the most used and preferred management method for hallux valgus among the 230 participants. Hallux valgus is slow and progressive and can result in different clinical presentations. As it is slowly progressive, some patients did not seek early treatment because they were asymptomatic. In cases of mild deformity, patients may have difficulty finding shoes because of the bunion. As the deformity progresses, pain such as first MTP joint pain, bunion pain, or toe friction can occur, leading patients to visit a physician for consultation. However, some patients avoid consulting a physician and seek treatment themselves.

Changing to different footwear or modifying shoes significantly reduced pain scores across all five common foot problems associated with hallux valgus. The statistical analysis showed that the pre-mean pain score for this group's five-foot problems was mild. Therefore, changing footwear or modifying shoes was selected as the first choice since it was easily accessible and provided good results in pain reduction. Most participants learned about this treatment from friends and healthcare providers. They could get new footwear from shoe shops based on their preference or the physician's advice. If they could not find proper shoes that fit their foot deformity, they would get their existing shoes modified, as prescribed by the physician at the hospital. Shoe modifications could include bunion release or padding to reduce friction with shoes.

According to previous research, the effectiveness of hallux valgus deformity correction or prevention remains controversial. One study confirmed the association of hallux valgus with ill-fitting shoes. Wearing narrow-toe boxes and high-heeled shoes more than 2.5 cm was associated with hallux valgus, corns, calluses, and other foot pain problems.[7] Consequently, physicians recommend that hallux valgus patients avoid these types of footwear; however, most participants felt their hallux valgus deformity remained unchanged from their perspective. Participants were satisfied with this treatment as their best hallux valgus option, even though changing footwear did not reduce the deformity. Once the pain was reduced, participants continued using these shoes and did not seek other treatment options for hallux valgus.

Previous research has indicated that insoles can significantly relieve pain, especially plantar pain, in hallux valgus patients, but show no significant improvement in the hallux valgus angle (based on radiographic evaluation).[10,11] The outcome of this study aligns with previous studies showing that using insoles can significantly reduce all five-foot problems, and that a few participants felt the deformity was reduced in severity after using this item. The mechanism of insoles with hallux valgus remains controversial. All participants who chose insoles as their most preferred hallux valgus treatment also used them in combination with new shoes, typically sneakers. Thus, the results showed a similar outcome to both changing footwear and using insoles. However, participants who chose insoles as their most preferred hallux valgus treatment had a higher pre-treatment mean score for plantar pain. Thus, participants with hallux valgus who also had plantar pain preferred insoles with proper shoes to relieve this foot problem.

Previous research has reported no positive outcome from using dynamic splints for hallux valgus.[12-14] In this study, the pretreatment mean pain score for participants who chose dynamic splints as their best hallux valgus treatment was higher than for those who chose changing to different footwear or using insoles. Participants with mild to moderate pain sought options other than changing shoes to treat their hallux valgus pain. The results showed that dynamic splints significantly improved the first MTP joint, bunion, and plantar pain from the patient's perspective. Additionally, six participants (26.1%) felt their hallux valgus deformity decreased after using dynamic splints. The positive outcome encouraged participants to continue using this item, making it a good alternative

treatment for hallux valgus. It can also be used as a night splint to avoid the discomfort of wearing it during the daytime. Further research on dynamic splints for hallux valgus is needed to confirm their effectiveness.

Previous studies have reported on the efficacy of silicone toe separators and single-piece toe separators for hallux valgus in pain relief and deformity correction.[8,9] However, the present study found that silicone toe separators with bunion shields and single-piece silicone toe separators were not desirable from the patient's perspective. These items were used by only 14.0% of participants, and less than 2.0% chose them as their best hallux valgus treatment. Despite studies confirming their efficacy, the main reason for discontinuing these options were side effects such as pain, irritation, and easy displacement while wearing shoes.

Toe separator socks, bunion shields, and cotton toe separators were new items that participants chose as their most preferred hallux valgus treatment. However, the sample size within these groups was too small to find significant differences in pain reduction and improvement in hallux valgus deformity. Further studies, such as randomized controlled trials, are needed to confirm the effectiveness of these options which are low-priced and easily accessible.

Study limitations

The scoring was based on participants' perspectives. The difference in the pain score outcome for each treatment option was not categorized by the severity of hallux valgus deformity. Therefore, the conclusion regarding which items were the most preferred treatment for mild or severe hallux valgus remains controversial. Additionally, changes in hallux valgus deformity were not confirmed by radiographic evaluation. The results of this study could only serve as a guideline to develop further studies to confirm the effectiveness of these treatment options.

Conclusion

Based on the experience of patients at Siriraj Hospital, changing footwear or shoe modification was the most used treatment for hallux valgus. Moreover, the best treatment options in the opinion of participants were changing footwear or shoe modification, insoles, and dynamic splints. These options brought significant clinical improvement from the patient's perspective. Some new items, such as bunion shields, toe separator socks, and cotton toe separators, will require further studies to investigate their effectiveness in hallux valgus treatment as these items might be good alternative treatment options.

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Conflict of interest declaration

The authors confirm that there is no conflict of interest related to the manuscript.

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Data availability

The data that support the findings of this study are available upon request from the corresponding author, [Navaporn Chadchavalpanichaya]. The data are not publicly available due to containing information that could compromise the privacy of research participants.

Author contribution

Paweena Tantamacharik: conceptualization, methodology, resources, formal analysis, data curation, investigation, validation, writing - original draft, writing - review & editing,

Navaporn Chadchavalpanichaya: conceptualization, methodology, resources, formal analysis, data curation, investigation, supervision, validation, writing - original draft, writing - review & editing,

Thanitta Thanakiatpinyo : conceptualization, methodology, writing - original draft, writing - review & editing,

Sumana Srisoongnern: conceptualization, methodology, writing - original draft, writing - review & editing.

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Original Article

Prevalence, Characteristics, and Impacts of Urinary Tract Infection on Functional Outcomes: A Retrospective Study of Inpatient Stroke Rehabilitation at Siriraj Hospital, Thailand

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ABSTRACT

Objectives: To investigate the prevalence, characteristics, associated factors, and impacts of urinary tract infections (UTI) on the Barthel Index (BI) during inpatient stroke rehabilitation.

Study design: Retrospective study

Setting: Inpatient Rehabilitation Unit, Department of Rehabilitation Medicine, Siriraj Hospital, Bangkok, Thailand

Subjects: Inpatients with stroke, aged ≥ 18 years old, admitted to the Rehabilitation Ward, Siriraj Hospital during 2019-2021

Methods: Demographic, clinical, and functional data of eligible patients were retrieved from the rehabilitation admission medical records in the hospital information system.

Results: Of 399 stroke patients identified, 11.5% had been diagnosed with UTI. Of these, 30.4% had catheter-associated UTIs (CAUTIs), while 69.6% had non-CAUTIs. *Escherichia coli* was identified as the most common pathogen. UTI was significantly associated with advanced age ($p < 0.001$), indwelling catheter use ($p < 0.001$), recurrent stroke ($p = 0.031$), and dysphagia ($p < 0.019$). Patients with UTI exhibited a statistically significant reduction in BI normalized gain per 21-day length of stay (BIg21days) ($p = 0.033$) and experienced longer rehabilitation length of stay (LOS) ($p = 0.002$). Using forward stepwise linear regression, only age and dysphagia, but not UTI, were found to be statistically significantly associated with BIg21days.

Conclusions: The prevalence of UTI is 11.5%, with higher rates in older individuals, those with recurrent stroke, dysphagia, and those using urinary catheters. Functional gain per 21 days of rehabilitation admission is associated with age and dysphagia, but not with UTI.

Keywords: prevalence, inpatients, rehabilitation, stroke, urinary tract infection

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Introduction

Stroke is a common health problem worldwide, including in Thailand.[1] The prevalence of stroke is increasing, particularly among individuals over 45 years old. The mean age of stroke onset is 65 years.[2] Although acute stroke treatment has advanced and improved, stroke survivors still face impairments and disabilities. Intensive rehabilitation programs are an important component of management to reduce impairments and disabilities in stroke patients and can also improve their quality of life.[3]

Urinary tract infection (UTI) is one of the most frequent infectious complications encountered in post-stroke patients.[4,5] Its prevalence varies, ranging from 3.7% to 19.0% in hospitalized stroke patients.[4,6-9] Many factors contribute to UTI, including the retention of indwelling catheters. Studies have suggested a link between indwelling catheters and poor clinical outcomes after stroke.[7] UTI is also associated with poor stroke outcomes, such as increased mortality, longer length of stay (LOS), and poorer functional outcomes as measured by the Barthel Index (BI).[10] Nevertheless, several factors may affect the BI in post-stroke patients admitted for intensive rehabilitation, including age, previous stroke history, dysphagia, and admission functional level.[11]

However, no prior studies have examined the prevalence of UTI during inpatient stroke rehabilitation at Siriraj Hospital. Therefore, this study aimed to determine the prevalence of UTI, their characteristics, and related factors, as well as to assess their impacts on functional outcomes during inpatient stroke rehabilitation at Siriraj Hospital. These findings are expected to enhance the prevention and management of UTI during stroke rehabilitation. This study was reported according to the STROBE guidelines for observational studies.

Methods

After receiving approval from the Siriraj Institutional Review Board (SIRB), the Faculty of Medicine, Siriraj Hospital, Mahidol University (Si 529/2022), on July 13, 2022, this retrospective study was conducted by reviewing the medical records of inpatients admitted to the rehabilitation ward at Siriraj Hospital from January 1, 2019, to December 31, 2021.

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Patient informed consent was not required, as the data retrieved did not include the patient identification. The medical records of patients meeting the following criteria were included: aged 18 years or older and those with a stroke diagnosis. Patients missing required data, such as the BI or other information necessary for the study, were excluded. The sample size calculation was based on the prevalence reported by Kitisomprayoonkul et al.,[12] using a 95% confidence interval (95%CI) and a 3.75% allowable error. The calculated sample size was 400. A total of 399 patients met the inclusion criteria and were included in the study (Figure 1).

The diagnosis of UTI was defined according to the diagnostic criteria established by the Centers for Disease Control and Prevention (CDC) and National Healthcare Safety Network (NHSN) 2021. UTI diagnosis required meeting all three of the following criteria: [13,14]

Criteria 1:

- Catheter-associated urinary tract infection (CAUTI): Indwelling urinary catheter > 2 consecutive days or removed the day before the event

- Non-CAUTI: Indwelling urinary catheter ≤ 2 consecutive days or no indwelling urinary catheter the day before the event

Criteria 2: At least one of the following symptoms: fever >38.0 °C, suprapubic tenderness, costovertebral angle pain or tenderness, urinary urgency, urinary frequency, dysuria

Criteria 3: Positive urine culture ≥ 10^5 colony-forming units/ml (≤ 2 species) or positive urinalysis (nitrite positive and/or leukocyte esterase positive and/or bacteria positive and/or WBC in urine > 4/high power field)

Only UTI diagnosed during admission to the rehabilitation ward were included in the data analysis.

Demographic, clinical, and functional data of eligible patients were obtained from the rehabilitation admission medical records within the hospital information system.

Functional outcomes after inpatient rehabilitation were assessed using BI gain, calculated as the BI score at discharge minus the BI score at admission. The maximum possible BI gain was defined as the full BI score (20) minus the admission BI score. To evaluate program effectiveness, the normalized BI gain (g) was calculated as the ratio of the absolute BI improvement to the maximum possible score change. The normalized gain scores were classified into three categories: high (g > 0.7), medium (0.3 ≤ g ≤ 0.7), and low (g < 0.3) gain.[15] The typical LOS for stroke rehabilitation at Siriraj Hospital is 21 days, approximately equivalent to the standard LOS of 23.5 days established by the National Health Security Office for neuromuscular inpatient rehabilitation. For comparative analysis, the BI normalized gain per LOS 21 days (BIg21days) was employed to evaluate each patient's functional improvement relative to the duration of their rehabilitation program.

Rehabilitation program interruption was defined as program suspension or discontinuation.

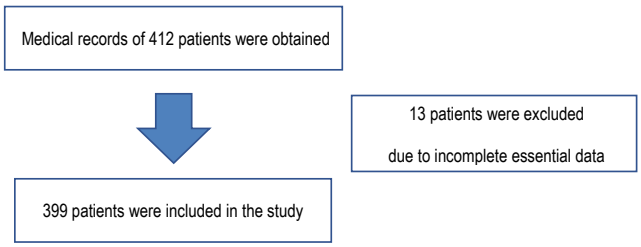

Figure 1. Flow diagram showing study recruitment

Statistical analysis

IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Descriptive statistics were used to compare characteristics of patients with UTI and those without UTI. Normally distributed continuous variables were summarized as mean and standard deviation and analyzed using an unpaired t-test. Non-normally distributed continuous variables were summarized as median and interquartile range and were analyzed using the Mann-Whitney U test. The categorical variables were summarized as numbers and percentages and were analyzed using the Chi-square test. Statistical significance was accepted if $p < 0.05$. Three linear regression models were evaluated to identify factors associated with the BI normalized gain: (1) a univariable analysis for UTI, (2) a multivariable analysis using forward stepwise selection for model 2, and (3) a multivariable analysis including UTI and the variables retained from model 2. In the stepwise selection, variables with a p-value of < 0.05 were included and those with *p*-value of > 0.1 were removed.

Results

Table 1 shows the demographic, stroke characteristics, and relevant clinical data of the 399 stroke patients recruited into the study. The overall prevalence of UTI was 11.5% (95%CI: 8.8, 15.0). Of the 46 UTI patients, 30.4% had CAUTI and 69.6% had non-CAUTI. When comparing patients with and without UTI, there was a significant difference in urinary catheter use between the UTI and non-UTI groups ($p < 0.001$) (Table 1). The mean age of patients with UTI was 71.7 years (SD = 9.9), which was significantly older than those without UTI at 65.2 years (SD = 14.0) ($p < 0.001$). There were no statistically significant differences in any comorbidities except for a history of previous stroke ($p = 0.031$), particularly previous ischemic stroke ($p = 0.042$).

The three most common UTI symptoms were fever, dysuria, and increased urinary frequency (Figure 2). *Escherichia coli* was the most common pathogen, followed by *Klebsiella pneumoniae*; both pathogens were isolated from patients with UTI in the rehabilitation ward. *Escherichia coli* showed 100.0% susceptibility to nitrofurantoin, cefepime, piperacillin/tazobactam, imipenem, meropenem, and ertapenem, but only 23.0% susceptibility to ciprofloxacin (Figure 3). Regarding treatment, 12 patients (26.1%) received ciprofloxacin, while

Table 1. Patients' demographics, stroke characteristics, relevant clinical data, and comparison between patients with urinary tract infection (UTI) and those without UTI (non-UTI)

	Total (n = 399)	UTI (n = 46)	Non-UTI (n = 353)	*p*-value
Age (years)[1]	65.9 (13.7)	71.7 (9.9)	65.2 (14.0)	< 0.001*
Sex (male)[2]	245 (61.4)	31 (67.4)	214 (60.6)	0.375
Type of stroke (ischemic)[2]	300 (75.2)	36 (78.3)	264 (74.8)	0.608
Duration from onset to rehabilitation admission (days)[1]	220 (690)	109 (176)	234 (729)	0.750
Length of stay (days)[3]	20 (15-22)	21 (17-26)	20 (15-22)	0.016*
Interruption of rehabilitation program[2]	37 (9.3)	17 (36.9)	20 (5.7)	< 0.001*
Bedside rehabilitation program[2] (less intensive)	28 (7.0)	13 (28.3)	15 (4.3)	< 0.001*
Able to communicate[2]	336 (84.2)	38 (82.6)	298 (84.4)	0.751
Ambulatory status (non-ambulatory)[2]	219 (54.9)	29 (63)	190 (53.8)	0.237
Catheterization, indwelling catheter during admission[2]	34 (8.5)	14 (30.4)	20 (5.7)	< 0.001*
Urinary retention[2]	27 (6.8)	19 (41.3)	8 (2.3)	< 0.001*
Urinary incontinence[2]	114 (28.6)	18 (39.1)	96 (27.2)	0.092
Post-stroke consequences/complications				
Cognitive impairment[2]	176 (44.1)	25 (54.3)	151 (42.8)	0.137
Dysphagia[2]	170 (42.6)	27 (58.7)	143 (40.5)	0.019*
Pressure sore[2]	15 (3.8)	3 (6.5)	12 (3.4)	0.397
Comorbidities				
Diabetic mellitus[2]	162 (40.6)	20 (43.5)	142 (40.2)	0.673
Hypertension[2]	339 (85.0)	41 (89.1)	298 (84.4)	0.400
Dyslipidemia[2]	253 (63.4)	33 (71.7)	220 (62.3)	0.212
Chronic kidney disease[2]	38 (9.5)	5 (10.9)	33 (9.3)	0.788
Previous stroke[2]	82 (20.6)	15 (32.6)	67 (19)	0.031*
Ischemic[2]	70 (17.5)	13 (28.3)	57 (16.1)	0.042*
Hemorrhagic[2]	16 (4.0)	3 (6.5)	13 (3.7)	0.412

[1]Mean (SD), [2]number (%), [3]median (IQR); *Statistical significance $p < 0.05$
IQR, interquartile range

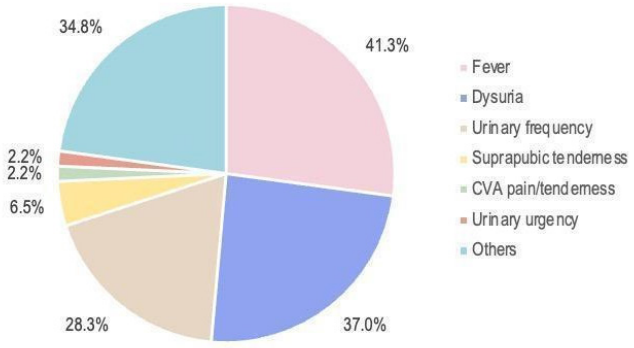

Figure 2. Symptoms of urinary tract infection

25 patients were initially treated with intravenous antibiotics and 21 patients with oral antibiotics. Eight patients required switching to more susceptible antibiotics.

Regarding LOS, the median LOS was 21 days (interquartile range, IQR = 17-26) in the UTI group and 20 days (IQR = 15-22) in the non-UTI group, with a statistically significant difference between groups ($p = 0.016$). Rehabilitation program interruptions occurred in 36.9% of patients in the UTI group compared to 5.7% in the non-UTI group. Consequently, bedside rehabilitation was required for 28.3% of patients in the UTI group and 4.3% in the non-UTI group. The percentages of interruptions and bedside rehabilitation programs in the two groups were statistically significantly different ($p < 0.001$). Furthermore, urinary retention was documented in 27 patients, occurring significantly more frequently in the UTI group ($p < 0.001$) (Table 1). No patients had a diagnosis of neurogenic bladder.

Dysphagia was identified as another significant factor associated with UTI in our study ($p = 0.019$). A statistically significant association was also found between dysphagia and urinary catheterization ($p = 0.002$).

Table 2 compares mean BI scores at admission and discharge, and BI normalized gain between patients with and without UTI during rehabilitation admission. The mean scores at admission and discharge were lower in the UTI group than in the non-UTI group. However, only the mean discharge BI score was statistically significantly different between the groups ($p = 0.034$). The mean BI gain and BI normalized gain were also lower in the UTI group but without statistically significant differences. However, the mean BIg21days in the UTI group was statistically significantly lower than that in the non-UTI group ($p = 0.033$)

Using linear regression analysis as shown in Table 3, age and dysphagia were identified as significant factors associated with BIg21days, while UTI did not demonstrate a significant decrease in BIg21days. In the adjusted model, the significant negative associations persisted for age ($p < 0.001$) and dysphagia ($p = 0.006$), but the association between BIg-21days and UTI remained not statistically significant ($p = 0.323$).

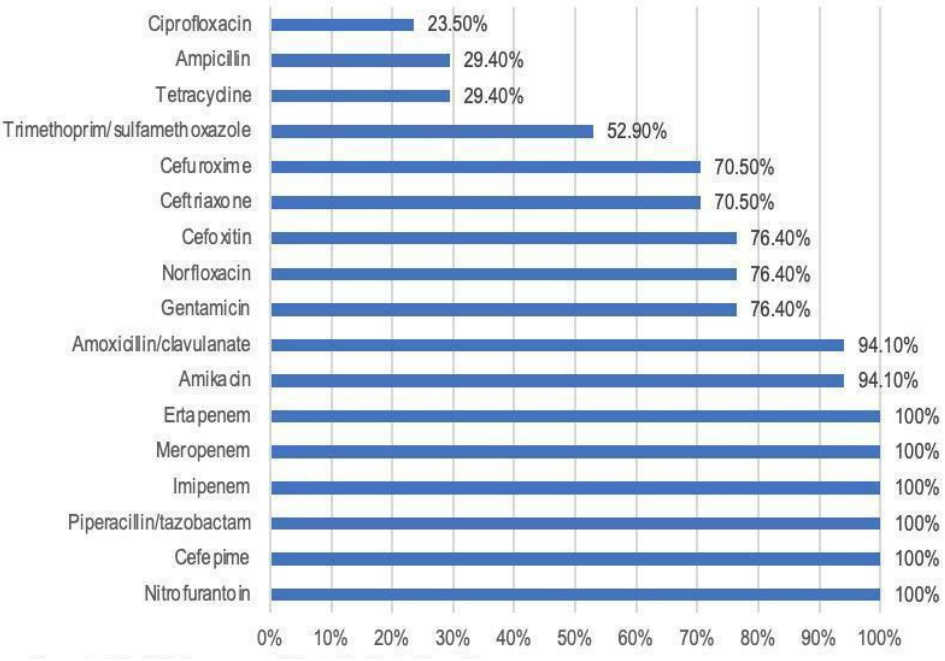

Figure 3. Antibiotics susceptibility to *Escherichia coli*

Table 2. Comparison of Barthel Index (BI) scores at admission and at discharge plus BI normalized gain between those with urinary tract infection (UTI) and without UTI (non-UTI) during rehabilitation admission

Variables	Total (n = 399)	UTI (n = 46)	Non-UTI (n = 353)	*p*-value
Barthel index				
Admission[1]	8.10 (5.21)	6.85 (4.99)	8.26 (5.22)	0.084
Discharge[1]	12.40 (6.05)	10.63 (6.11)	12.63 (6.01)	0.034*
Mean difference BI gain[1]	4.29 (3.59)	3.78 (3.48)	4.36 (3.61)	0.302
Barthel index normalized gain[1]	0.44 (0.34)	0.36 (0.32)	0.45 (0.34)	0.110
Low gain[2]	166 (41.60)	23 (50.00)	143 (40.50)	
Medium gain[2]	116 (29.10)	13 (28.30)	103 (29.20)	
High gain[2]	117 (29.30)	10 (21.70)	107 (30.30)	
Barthel index normalized gain per LOS 21 days[1]	0.5 (0.55)	0.37 (0.37)	0.55 (0.57)	0.033*

[1]Mean (SD), [2]number (%); *Statistical significance $p < 0.05$

Barthel index normalized gain: low gain < 0.3, medium gain = 0.3-0.7, high gain > 0.7

Table 3. Association between the Barthel index normalized gain per length of stay 21 days and statistically significant urinary tract infection (UTI)-related factors

Variables	Model 1	Model 2	Model 3
UTI	-0.184 (-0.350, -0.010), $p = 0.033$*	-	-0.081 (-0.241, 0.080), $p = 0.323$
Age	-	-0.010 (-0.013, -0.006), $p < 0.001$*	-0.009 (-0.013, -0.006), $p < 0.001$*
Dysphagia	-	-0.149 (-0.252, -0.046), $p = 0.005$*	-0.146 (-0.249, -0.043), $p = 0.006$*

Coefficients (95% confidence interval), *p*-value; *Statistical significance $p < 0.05$

CI, Confidence interval

Model 1: UTI enter method linear regression analysis; Model 2: Forward stepwise linear regression

Model 3: Adjusted UTI into model 2

Discussion

This retrospective study found that the prevalence of UTI during inpatient stroke rehabilitation, with an LOS of approximately 3 weeks, was 11.5%, which falls within the range of previously reported rates (3.7-19.0%) in hospitalized stroke patients.[4,6-9] The UTI rate was higher in patients using urinary catheters than those without catheters (41.2% and 8.8%), consistent with finding reported by Bogason et al. (2017), who demonstrated that Foley catheter use was associated with increased risk of UTI in ischemic stroke patients.[7]

Similar to findings from Mukapa et al. (2022) at a teaching hospital in Zimbabwe[16] and the National Antimicrobial Resistant Surveillance in Thailand (NARST) (2022),[17] *Escherichia coli* was the most common pathogen isolated from infected urine samples in our study. This organism demonstrated high susceptibility to nitrofurantoin but resistance to ciprofloxacin, emphasizing the importance of considering antibiotic resistance patterns when physiatrists select optimal UTI treatment during inpatient rehabilitation.

The univariable analysis in our study identified several significant factors associated with UTI, including older age, a history of previous stroke(s), dysphagia, and urinary catheter use. These finding are consistent with previous studies.[4,8,18,19] Moreover, a meta-analysis by Westendorp et al.[6] concluded that stroke severity affects the probability of UTI occurrence. A recent study also reported an association between post-stroke dysphagia and UTI, suggesting that dysphagia increases dehydration risk, which may contribute to UTI development. Additionally, patients with severe stroke and dysphagia are more likely to require urinary catheterization.[19] Stepwise linear regression analysis in our study further revealed that both increased age and dysphagia significantly impacted BIg21days.

Regarding the impact of UTI on stroke rehabilitation outcomes, our study found that UTI was significantly associated with lower BI score at discharge, less BIg21days, one day longer rehabilitation LOS, and higher rates of rehabilitation program interruption, reflecting the negative impact of UTI on functional outcomes. Although the mean BI normalized gain was higher in the non-UTI group than in the UTI group, the highest percentage of patients in both groups fell within the low-gain class, and these differences were not statistically significant. The linear regression analysis confirmed that UTI alone significantly contributed to decrease BIg21days. Similar associations with the BIg21days have been reported for both increased age and dysphagia. However, in the present study, a significant association between UTI and BIg21days was not observed after adjusting for age and dysphagia. Therefore, the statistically significant findings observed in the entire sample should be interpreted cautiously due to potential confounding effects of factors such as age and comorbidities.

The significant limitations of our study were using a retrospective review of medical records from a single tertiary hospital and using BI, a generic tool for functional assessment, rather than the National Institute of Health Stroke Scale (NIHSS), which has been demonstrated to be a predictor of functional outcomes in stroke patients.[20,21] Consequently, our findings may not be applicable to other populations receiving care at different facilities. Furthermore, we could not exclude confounding factors that may have influenced some of our findings. Future studies should prospectively analyze additional potential risk factors for UTI and factors associated with BI outcomes, including other functional measurements.

Conclusions

UTI is common during stroke rehabilitation, occurring in 11.5% of inpatients. It occurs more frequently in older patients, those with recurrent strokes, dysphagia, and those requiring urinary catheters. UTI negatively impacts functional outcomes by interrupting rehabilitation program and increasing rehabilitation LOS. *Escherichia coli* was the most commonly identified pathogen. In the linear regression model, age and dysphagia, but not UTI, were identified as factors associated with BI gain per 21 days.

Conflict of interest disclosure

The authors report no conflicts of interest.

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Data availability

The data that support the findings of this study are available from the corresponding author, Kamontip Harnphadungkit, upon reasonable request.

Author contributions

Patcharee Aueaananratthakit: conceptualization, methodology, investigation, writing - review & editing,

Kamontip Harnphadungkit: conceptualization, methodology, investigation, writing - review & editing.

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