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Dear Readers,

It is with great pleasure that we present the latest issue of the ASEAN Journal of Rehabilitation Medicine. Before highlighting the contents of this issue, am absolutely thrilled to share a monumental milestone for our community: the ASEAN Journal of Rehabilitation Medicine has officially been accepted for indexing in Scopus. This achievement is a direct reflection of the dedication, rigor, and high standard of work contributed by our authors, reviewers, and editorial board. It represents a significant step forward in elevating the global visibility, citation impact, and reach of rehabilitation research originating from the ASEAN region and beyond.

In this milestone issue, we feature a diverse collection of research structured to showcase the value of diverse methodological designs—moving from a gold-standard prospective randomized trial and robust retrospective cohort analyses to essential regional tool validation.

We lead this issue with a prospective, randomized, double-blind controlled trial evaluating non-operative management for posterior tibial tendon dysfunction (PTTD). The authors investigate a modified total contact orthosis (modified TCO) designed specifically for indoor walking. Their findings demonstrate a significant reduction in posterior tibial tendon pain and substantial improvements in the Foot Function Index (Thai version) without serious adverse effects. Given that indoor mobility is frequently overlooked in orthotic compliance, this high-satisfaction device offers a robust, prospective benchmark for daily pain management.

Next, we dive into a series of deeply insightful retrospective studies, led by a highly sophisticated retrospective observational cohort design with propensity score matching. Researchers evaluate rehabilitation outcomes up to 24 weeks post-stroke between home-based and outpatient-based intermediate care (IMC) programs. By utilizing propensity matching to statistically control for baseline differences in historical data, the study concludes that both pathways yield broadly comparable functional outcomes. This is highly encouraging for decentralized care, especially since the home-based cohort achieved this despite a lower therapy dosage. However, a trend toward higher preventable complications at home prompts the authors to advocate for increased therapy intensity and telerehabilitation safety nets.

In our third feature, a massive retrospective observational study analyzing a 10-year institutional hip surveillance registry provides invaluable longitudinal data on 265 children with cerebral palsy (CP). Tracking the historic cumulative incidence of significant hip displacement (migration percentage > 40%) or the requirement for reconstructive surgery, the data reveals a stark, time-dependent risk: displacement progressively rose from 17.8% at 2 years to 30.5% at 4 years, reaching a striking 41.0% at 6 years. This risk was heavily concentrated in children with severe motor impairment (GMFCS levels IV–V), underscoring an urgent clinical mandate for rigorous, long-term surveillance protocols to facilitate timely orthopedic intervention.

Following this, we review a retrospective pre-and-post evaluation of an outpatient Phase II Cardiac Rehabilitation (CR) program. Reviewing historic program outcomes, the researchers demonstrate that structured CR yields excellent functional recovery, with 61.6% of participants achieving an improvement of 10% or greater in their 6-minute walk distance (6MWD). Interestingly, the greatest functional gains were derived by patients entering the program with a lower baseline capacity (< 300 meters) and moderate risk stratification, showing precisely where historical program data proves the highest clinical utility.

Our final retrospective analysis looks at robotic gait rehabilitation, measuring walking recovery via the Functional Ambulation Category (FAC) after a historic window of 10 structured sessions. The data demonstrates that more than half of the treated patients achieved at least a one-level improvement. Crucially, the retrospective analysis identifies the time interval elapsed since the initial neurological event and the patient's baseline ambulatory status as the primary predictors of success, offering clearer, data-driven criteria for prescribing high-tech robotic therapies.

Closing this issue is a vital prospective cross-cultural adaptation and psychometric validation study that introduces the Thai version of the Short Form of the Urinary Quality of Life Questionnaire (SF-Qualiveen) for spinal cord injury patients with neurogenic lower urinary tract dysfunction. Following precise linguistic adjustments, the Thai SF-Qualiveen achieved a perfect Content Validity Index (CVI) of 1.00, excellent internal consistency (Cronbach's alpha), and stellar test-retest reliability (ICC = 0.93). This psychometrically sound tool equips clinician-researchers across the ASEAN region with a highly reliable prospective instrument to measure sensitive quality-of-life impacts.

From rigorous prospective clinical trials to deep retrospective registry analyses and validated metrics, this issue balances methodological diversity with practical, regional clinical application. I am certain these papers will greatly inform your clinical practice and inspire future high-quality research across our disciplines as we enter this exciting new chapter of global indexing.

Warm regards,

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

Original Article

The Efficacy of Modified Total Contact Orthosis in Decreasing Pain While Walking Indoors in Patients with Posterior Tibial Tendon Dysfunction: A Prospective, Randomized, Double-Blind Controlled Trial

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ABSTRACT

Objectives: To evaluate the effectiveness of a modified total contact orthosis (modified TCO) in reducing pain during indoor walking among patients with posterior tibial tendon dysfunction (PTTD). Patient satisfaction, complications, Foot Function Index (Thai version), and device compliance were also evaluated

Study design: A prospective, randomized, double-blind controlled trial

Setting: The Foot Clinic at Siriraj Hospital, a tertiary care academic medical center in Bangkok, Thailand

Participants: Forty-two patients aged 45–65 years with stage I–III PTTD lasting more than 6 weeks.

Methods: Participants were enrolled between November 2023 and June 2024 and randomized into two groups. The study group received a modified TCO, whereas the control group received a sham orthosis. Both groups used the orthoses indoors for 2 weeks. Pain scores, Foot Function Index (Thai version), satisfaction, and compliance were assessed at baseline and after 2 weeks.

Results: The participants, with a mean age of 62.2 (SD = 8.9) years in the study group and 63.2 (SD = 9.5) years in the control group, were predominantly female (90.5%) and had stage II PTTD. All participants completed the study. After 2 weeks, the study group reported significantly less pain at the posterior tibial tendon and demonstrated better total foot functionality compared to the control group ($p < 0.001$ and $p = 0.03$, respectively). Both groups expressed high satisfaction with the devices, using them for more than 80.0% of the time spent indoors.

Conclusions: A modified total contact orthosis can reduce pain at the posterior tibial tendon in PTTD patients during indoor walking and can improve the Foot Functional Index without serious adverse effects.

Keywords: acquired adult flatfoot deformity, foot orthosis, flatfoot, orthotic Insoles, posterior tibial tendon dysfunction

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Introduction

Posterior tibial tendon dysfunction (PTTD) is a common condition of adult-acquired flatfoot deformity which is common in women aged 45-65 years.[1,2] Patients typically present with medial foot and ankle pain due to abnormal weight-bearing resulting from the dysfunctional foot arch. Over time, the condition can lead to foot deformities.

PTTD is classified into four stages. In stage I, symptoms may include mild pain and swelling along the posterior tibial tendon, but no deformity or sign of "too many toes" is present. The patient can perform the double heel-rise test as well as the single heel-rise test. In stage II, the posterior tibial tendon is degenerating, and foot deformities, such as forefoot abduction and hindfoot valgus, are beginning to develop but the foot remains flexible. The arch of the foot may collapse. The patient may not be able to perform the single heel-rise test, but may be able to perform the double heel-rise test. The too many toes sign is present, with no heel valgus and no foot inflammation. In stage III, the deformities become rigid and the hindfoot valgus cannot be corrected. In stage IV, the symptoms are similar to stage III, but with additional degeneration of the ankle joints, such as a tear of the deltoid ligament, leading to eversion of the ankle and degeneration of the tibiotalar joint.

Treatment options include non-pharmacological approaches, pharmacotherapy, and surgery. One non-pharmacological intervention involves shoes with total contact orthosis (TCO), which aims to reduce strain on the posterior tibial tendon and support the foot arch. These devices are recommended for continuous wear, both indoors and outdoors. Many studies[3-8] confirm that TCOs or proper foot orthoses can decrease foot pain, improve patient comfort, and help increase compliance, as demonstrated in the following research studies.

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The research by Kido M. and colleagues[3] studied the effects of foot orthotics in 8 patients with an average age of 32.1 years who had symptoms of PTTD. The patients were asked to wear sneakers with TCOs, including a 10-millimeter arch support and a 5-millimeter medial wedge. Computed tomography (CT) scans were taken to compare the weight-bearing and non-weight-bearing positions of the foot. The CT images indicated that the arch support significantly reduced the degree of foot deformity. All patients reported increased comfort while wearing the insoles.

Research by Han K. and colleagues[4] investigated biomechanical effects on rear-foot and ankle movement in 28 male patients with flat feet, with an average age of 20 years. Each patient wore three types of insoles: standard insoles, arch-supported insoles, and both arch-supported and cushioned insoles. Video recordings of the patients walking were made, with each patient walking at the same pace and speed. The analysis revealed that using insoles with arch support or insoles with both arch support and cushioning significantly reduced the degree of foot deformity compared to standard insoles.

Research by Yurt, Y. and colleagues[5] investigated the effects of different types of insoles on foot pain and the quality of life in patients with flat feet aged 18-45 years. The study found that patients using custom-made insoles, whether produced by computer-aided design (CAD-CAM) or traditional methods, experienced greater pain relief than those using standard insoles. No significant difference was observed between the insoles made using CAD-CAM and those made using conventional methods.

Research by Açak[6] studied the effects of custom-made insoles in 34 patients aged 18-28 years with flat feet. The insoles were made of 1-millimeter-thick stainless chrome steel covered with 3 millimeters of leather which included specific arch support tailored for each patient. Patients wore the insoles daily for one year, both at home and outside, although they switched to sandals for indoor use. The study found that patients experienced weight loss due to increased physical activity, reduced arch pain, improved quality of life, and enhanced physical performance, allowing them to run faster and jump higher.

Research by Karimi and colleagues[7] investigated the effect of insoles on the energy expenditure index during walking in patients with flat feet. The study involved two groups of 25 participants each. The first group consisted of patients with flat feet, while the second group comprised individuals with normal feet. The findings revealed that patients with flat feet used more energy during walking than those with normal feet due to abnormal foot alignment. Additionally, wearing insoles improved foot alignment, leading to better, faster walking and significantly reducing the energy expenditure index.

A systematic review by Gómez-Jurado, I. and colleagues[8] examined the use of supportive devices in treating patients with stage I and stage II PTTD. They reviewed four randomized control trials involving 186 participants and evaluated treatments including supportive devices, footwear, and exercise. The findings indicated that combining supportive devices with exercise yielded better outcomes than using supportive devices alone. Additionally, customized insoles with arch supports were more effective at reducing arch pain than non-customized insoles.

Other studies have found that adjusting footwear and using medial arch supports, recommended treatments for patients with PTTD, can reduce the workload on the tendon, leading to decreased pain for patients.[9,10]

The Foot Clinic at the Department of Rehabilitation, Siriraj Hospital has been in operation since 2004, serving approximately 1,000 patients annually. Many patients seek consultation for foot health issues, with adult flatfoot being a common problem that leads to foot deformities and pain, and is a significant reason for patients to visit the doctor. Surveys indicate that a large number of patients at the Foot Clinic have flatfoot due to PTTD. Once diagnosed with this condition, patients receive treatment that includes medication together with other non-pharmacological methods such as weight management, lifestyle modifications, exercise, footwear adjustments, arch supports, and custom-made TCOs. Most patients who were provided with either sports shoes or supportive footwear with custom-made TCOs experienced reduced pain while wearing them. However, nearly all patients refused to wear sports shoes or supportive footwear indoors, opting to wear them only outside the house. This resulted in alleviated pain while outside but continued pain while walking indoors, leading to suboptimal treatment outcomes. Despite recommendations to wear sports shoes or supportive footwear indoors, many patients compromised by choosing easy-to-wear sandals instead as they did not require bending over to adjust laces or straps.

According to a study by Sukthomya, S. and colleagues,[11] 46.8% of diabetic patients in Thailand walked barefoot at home, 38.5% wore sandals, 5.4% wore closed-toe shoes, and only 9.3% used other types of footwear despite receiving advice to wear shoes at all times, both indoors and outdoors, to prevent foot ulcers. Patients preferred to wear shoes only when going outside. It is the custom in Thailand to remove shoes before entering a house. The study also investigated factors influencing the choice of indoor footwear among diabetic patients. It found that 78.0% of patients preferred easy-to-wear shoes such as sandals, 76.7% wore shoes costing less than 30 USD, 71.0% preferred black shoes, 53.7% chose well-ventilated and comfortable shoes, 31.8% opted for flexible materials, and 18.9% preferred shoes with easily adjustable straps.

In response, researchers have developed a modified TCO for indoor use. These supports attach snugly to the upper foot, with extended leather sides that cover the arch and have a non-slip sole resembling a sandal which enhances comfort during indoor activities. The research team hypothesized that

the modified TCO would alleviate foot pain caused by PTTD during indoor use. In addition, the use of a sham orthosis was considered essential to compare the study and control groups, minimize the placebo effect, and ensure a more reliable evaluation of treatment efficacy.

The objectives of this study were to evaluate the effectiveness of the modified TCO in reducing posterior tibial tendon pain during indoor walking among patients with PTTD and to assess patient satisfaction, complications, Foot Function Index (Thai version), and compliance with device use.

Methods

Study design

The study was a prospective, randomized, double-blind, parallel-group, controlled trial with a 1:1 allocation ratio and a superiority framework. The trial was conducted at the Foot Clinic, Department of Rehabilitation Medicine, Siriraj Hospital, Bangkok, Thailand, between November 2023 and June 2024. The study protocol was approved by the Institutional Review Board (IRB No. 345/2566; Certification No. 464/2023, approve on June 13, 2023). The trial was registered with the Thai Clinical Trials Registry (TCTR20231026005) on October 26, 2023. The study was conducted in accordance with the CONSORT 2022 guidelines.

Participants

Patients aged over 40 years with stage I–III PTTD and intermittent pain persisting for at least 6 weeks were recruited. Eligible participants had a numeric rating scale pain score of ≥5 when not wearing shoes or while standing or walking indoors, specifically around the medial arch or along the posterior tibial tendon. All participants regularly wore appropriate shoes outdoors (TCO with a rigid heel counter, such as sneakers). Exclusion criteria included communication or cognitive impairments, use of non-steroidal anti-inflammatory drugs or discontinuation of such medications for less than two weeks within two weeks of the start of the study, regular use of proper shoes with TCO at home, foot numbness or ulceration, postural control disorders (e.g., Parkinson's disease), or planned extensive travel during the study period. A physiatrist specializing in foot disorders confirmed the diagnosis and classified the disease stage based on the clinical presentation. In participants with bilateral PTTD, the more symptomatic side, based on a numeric rating scale, was selected for analysis.

To determine the required sample size, we utilized data from Thammawijaya, A.[12] which indicated that medial arch supports in patients with plantar fasciitis reduced pain scores from 4.9 (SD = 1.66) to 2.7 (SD = 1.93). Assuming a power of 0.90, a two-sided α of 0.05, and an effect size of 1.036, a minimum of 21 participants per group was required.

Materials

The modified modified TCO (Figure 1) and the sham orthosis (Figure 2) were fabricated using an identical dual-layer construction of two 1-cm-thick ethyl vinyl acetate (EVA) soft rubber foam layers. Both devices had a similar external appearance, including a soft leather upper and a non-slip outsole, to maintain participant blinding. The modified TCO included a customized medial arch support and a medial wedge, whereas the sham orthosis lacked arch support and functioned as a flat insole.

Study protocol

Prior to enrollment, all qualifying patients underwent a recruitment and briefing process, culminating in the acquisition of their signed informed consent. Participants then completed a questionnaire assessing (1) background information, (2) the Foot Functional Index Thai Version (FFI-TH),[13] and (3) foot pain during the week prior to enrollment.

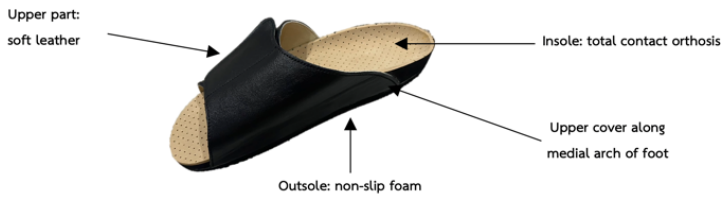

Figure 1. Modified total contact orthosis

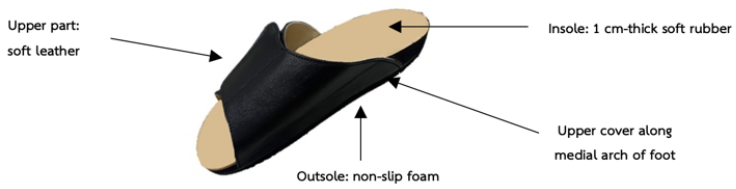

Figure 2. Sham orthosis

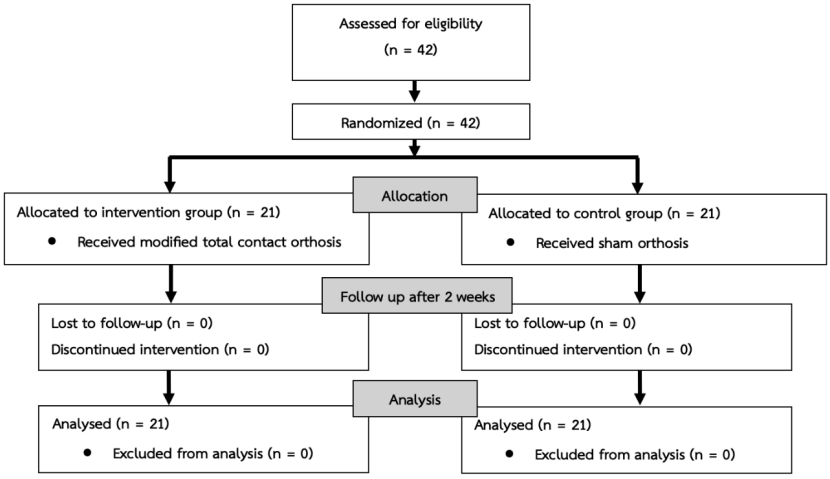

Figure 3. Flow diagram of the study

Background information included age, gender, BMI, the number of hours spent standing or walking (hours/day), and the daily duration of shoe-wearing. The duration of pain and the level of foot pain were recorded using a numeric rating scale. Questions were scored from 0 (no problem/no pain) to 10 (worst problem/worst pain). The current treatment record included activities such as taking pain-relieving medications like NSAIDs or undergoing physical therapy. After completing the questionnaire, a physiatrist conducted a physical examination to determine the stage and select the most severely affected foot.

The first investigator randomly assigned patients to two separate groups. Random permuted blocks were created using a computer-based random number generator, and allocation concealment was ensured through sequentially numbered, opaque, sealed envelopes. To ensure objectivity, this sequence was generated by an external researcher who took no part in recruiting or evaluating the participants. To prevent bias, all participants, investigators, orthotists, and outcome assessors remained blinded to the group allocations for the entirety of the study. An equal likelihood of assignment to either group was maintained for all patients.

Patients in both groups were sent to the orthotist, who made a modified TCO (study group) or a sham orthosis (control group). Both groups underwent the same foot printing procedure. After a fortnight, the patients were fitted with their devices by the orthotist. The orthotist assessed the patient to ensure the devices fit properly. In the first week after receiving the devices, patients were instructed to gradually increase the duration of wearing them. For days 1-7, they were advised to wear them for 15 minutes on the first day, 30 minutes on the second day, 1 hour on the third day, 2 hours on the fourth day, and for the entire day on days 5, 6, and 7. Afterward, patients were instructed that after day 7, they should wear the devices whenever standing or walking at home, and to wear their own sports shoes and a TCO at all times when standing and walking outside. Patients were instructed to start recording their device usage the second week after receiving the devices. For compliance measurement, patients were instructed to document the precise amount of daily usage time within a logbook. Additionally, patients were instructed to document any device-related complications in their logbooks.

Two weeks post-treatment, participants from both groups returned to complete a follow-up assessment. This survey evaluated their foot pain over the preceding week, utilizing the Foot Functional Index Thai Version [FFI-TH],[13] alongside a numeric rating scale to gauge treatment satisfaction. To maintain blinding, a physiatrist unaware of the group assignments administered this portion of the questionnaire. Afterward, individuals in the intervention group met with the orthotist to submit their logbooks. They were also interviewed to assess their willingness to use the modified TCO moving forward and to gather feedback on optimizing the device's design.

Statistical analysis

Statistical analysis was performed using SPSS version 29.0 (IBM Corp, Armonk, NY, USA). Qualitative data, including gender, current treatment, stage of disease, and side of disease involvement, are reported as numbers and percentages. Continuous variables, including age and body mass index (BMI), are expressed as mean and standard deviation (SD) or median and interquartile range (IQR), as appropriate, and compared between groups using the independent t-test or the Mann–Whitney U test, depending on data distribution. The duration of posterior tibial tendon pain and the working hours during which the patient needed to stand or walk indoors and outdoors were calculated as median (IQR). Baseline pain status during the week before the study, post-study pain, and satisfaction with the treatment, which were recorded using a numeric rating scale, are reported as median (IQR). The complications associated with the use of a modified TCO were calculated as numbers and percentages. The foot functional index was calculated as median (IQR). Compliance with the use of a modified TCO was calculated as the mean and standard deviation. An unpaired t-test was used to

explore differences in quantitative data with normal distributions, and a Mann-Whitney U test was used to explore differences in quantitative data with non-normal distributions. The Chi-Square test and Fisher's exact test were used to explore differences in qualitative data. A *p*-value of less than 0.05 was considered statistically significant.

Results

In this study, 42 patients were randomly assigned to one of two groups and all successfully completed the follow-up evaluation after a 2-week period, concluding their involvement in the research. The baseline characteristics of the subjects included in the study are presented in Table 1.

Upon analyzing the baseline measures for both groups, a similarity emerged in key factors, including age, gender, body mass index (BMI), working hours involving standing or walking indoors and outdoors, baseline pain, duration of PTTD, current treatment, side of involvement, and stage of disease. Analysis of baseline characteristics revealed no significant differences between the two groups ($p > 0.05$).

Table 2 presents the median of baseline pain status at the posterior tibial tendon, recorded on a numeric rating scale for the 2 weeks preceding the current study. Analysis of these baseline measures indicated no significant differences between the two groups ($p = 0.08$).

Primary outcome

NRS pain score at 2 weeks

As shown in Table 2, both groups had comparable baseline pain scores at the posterior tibial tendon ($p = 0.08$) prior to the intervention. After the 2-week intervention, the study group demonstrated a significantly lower pain score than the control group ($p = 0.01$). Within-group analysis revealed significant pain reduction in both groups after treatment (study group: $p < 0.001$; control group: $p = 0.03$). The reduction in

Table 1. Demographic data

Characteristics	Study group n = 21	Control group n = 21	*p*-value
Age (years)[1]	62.2 (8.9)	63.2 (9.5)	0.74[b]
Gender[2]			
Male	0.0 (0.0)	4.0 (19.0)	0.11[c]
Female	21.0 (100.0)	17.0 (81.0)	
Body mass index (kg/m^2)[1]	25.4 (3.9)	26.5 (3.9)	0.38[b]
Hours the patient needed to stand or walk in-doors (hours/day)[3]	2.0 (1.0-3.3)	1.9 (0.9-2.5)	0.55[d]
Hours for which the patient needed to stand or walk outdoors (hours/day)[3]	1.1 (0.6-2.4)	1.0 (0.4-2.0)	0.70[d]
Duration of foot problems (years)[3]	7.0 (3.0-10.0)	7.0 (3.0-17.0)	0.70[d]
Level of pain[3]	7.0 (7.0- 8.0)[a]	7.0 (6.0-7.5)[a]	0.08[d]
Current treatment[2]			
Paracetamol	1.0 (4.8)	5.0 (23.8)	0.18[c]
NSIADs	0.0 (0.0)	0.0 (0.0)	
Physical therapy	1.0 (4.8)	0.0 (0.0)	1.00[c]
Others (Norgesic®, Duocetz®)	2.0 (9.5)	6.0 (28.6)	0.24[c]
Side[2]			
Right	1.0 (4.8)	2.0 (9.5)	1.00[f]
Left	2.0 (9.5)	1.0 (4.8)	
Bilateral	18.0 (85.7)	18.0 (85.7)	
Stage[2]			
Stage I	1.0 (4.8)	0.0 (0.0)	1[f]
Stage II	17.0 (81.0)	18.0 (85.7)	
Stage III	3.0 (14.3)	3.0 (14.3)	

[1]Mean (SD), [2]Number (%), [3]Median (IQR); [a]Numeric rating scale (0: no pain, 10: worst pain), [b]Unpaired t-test, [c]Fisher's exact test, [d]Mann–Whitney U test, [f]Chi-square test with exact test, NSAIDs: non-steroidal anti-inflammatory drugs

Table 2. Comparison of pain Scores between pre-intervention and post-intervention

Pain (NRS) Median (IQR)	Study group (n = 21)	Control group (n = 21)	*p*-value between groups
Pre-intervention pain	7.0 (7.0-8.0)	7.0 (6.0-7.5)	0.08[a]
Post-intervention pain	3.0 (2.0-4.5)	5.0 (3.0-7.5)	0.01[a]
p-value within group	< 0.001[b]	0.03[b]	
Pre-post intervention difference	4.0 (4.0,5.0)	2.0 (0.0-3.0)	< 0.001[a]

NRS, numeric rating scale (0: no pain, 10: worst pain); [a]Mann–Whitney U test, [b]Wilcoxon signed-rank test

pain scores was significantly greater in the study group (p < 0.001).

Secondary outcome

Patient satisfaction

Satisfaction with the treatment was recorded using a numeric rating scale, as shown in Table 3. The questions were scored from 0 (dissatisfied) to 10 (highest satisfied). Satisfaction scores were high across all aspects in both groups. The medians (IQR) of the pain reduction satisfaction score in the study group and the control group were 9 (8.5, 10) and 7 (4.5, 9), respectively. The overall satisfaction scores in the study and control groups were 9 (8,10) and 8 (6.5,9), respectively. There were statistically significant differences in satisfaction scores for pain reduction and overall satisfaction between the two groups (p = 0.001 and 0.002, respectively).

Complications

Complications related to device use were observed in both groups. One patient (4.8%) in the study group reported pain, compared with six patients (28.6%) in the control group. Foot abrasions or blisters were reported by two patients (9.5%) in each group. Foot eczema was reported by only one patient (4.8%) in the control group.

Foot Function Index (FFI-TH)

Table 4 shows no statistically significant differences between the two groups in total scores for the FFI-Thai version[13], pain, disability, and activity limitation at baseline (p = 0.70, 0.21, 0.72, and 1.00, respectively). However, at the 2-week follow-up, significant differences were observed in total score, pain, and disability (p = 0.001, < 0.001, and 0.01, respectively). When comparing the pre- and post- intervention differences in total score of FFI-Thai version[13], pain and disability, and activities between the two groups, there was a significant difference (p = 0.001, < 0.001, and 0.004, respectively)

Compliance with device use

Table 5 presents patients' adherence to device compliance, where the percent of usage was calculated by dividing the duration of indoor device use by the duration of standing

Table 3. Patient satisfaction scores by device attributes

Type Median (IQR)	Satisfaction score		
	Study group	Control group	*p*-value[a]
Pain reduction	9.0 (8.5-10.0)	7.0 (4.5-9.0)	0.001
Cosmesis appearance	8.0 (7.0-9.0)	8.0 (6.5-8.5)	0.14
Convenience in wearing/easy to use	10.0 (9.0-10.0)	10.0 (8.0-10.0)	0.52
Maintenance	9.0 (9.0-10.0)	9.0 (8.0-10.0)	0.33
Durability	9.0 (6.0-10.0)	9.0 (6.5-9.0)	0.66
Overall satisfaction	9.0 (8.0-10.0)	8.0 (6.5-9.0)	0.002

Satisfaction was assessed using a numeric rating scale (0: no satisfaction, 10: highest satisfaction); [a]Mann–Whitney U test

Table 4. Comparison of Foot Functional Index Scores between pre-intervention and post-intervention

Subscale Median (IQR)	Study group	Control group	*p*-value
Total			
Pre-intervention	104.0 (94.5-115.0)	99.0 (78.0-127.0)	0.70[a]
Post-intervention	45.0 (35.5-60.0)	80.0 (59.5-103.0)	0.001[a]
p-value within group	< 0.001[b]	0.005[b]	
Pre-post intervention difference	54.0 (39.0-65.0)	26.0 (-1.0-46.5)	0.001[a]
Pain			
Pre-intervention	50.0 (45.0-54.0)	44.0 (40.0-57.5)	0.21[a]
Post-intervention	24 (19-29)	38 (27-48)	< 0.001[a]
p-value within group	< 0.001[b]	0.007[b]	
Pre-post intervention difference	27.0 (20.5-32.5)	15.0 (-0.5-23.0)	< 0.001[a]
Disability			
Pre-intervention	50.0 (46.0-57.5)	47.0 (41.0-64.0)	0.72[a]
Post-intervention	23.0 (17.0-32.0)	37.0 (29.5-49.0)	0.01[a]
p-value within group	< 0.001[b]	0.003[b]	
Pre-post intervention difference	25.0 (15.0-34.0)	13.0 (0.0-23.0)	0.004[a]
Activity limitation			
Pre-intervention	3.0 (0.0,7.0)	2.0 (0.0,7.0)	1.00[a]
Post-intervention	0.0 (0.0,2.0)	2.0 (0.0,5.0)	0.16[a]
p-value within group	0.002[b]	0.01[b]	
Pre-post intervention difference	1.0 (0.0-4.5)	0.0 (0.0-2.0)	0.16[a]

[a]Mann–Whitney U test; [b]Wilcoxon signed-rank test

Table 5. Comparison of indoor mobility and device adherence between the study and the intervention groups

Composite mobility & Compliance metrics Mean (SD)	Study group	Control group	*p*-value
Duration of using indoor devices (hours per week)	26.8 (16.0)	23.1 (13.3)	0.42[a]
Duration of standing and walking indoor (hours per week)	34.6 (19.9)	30.9 (19.9)	0.56[a]
Percent of usage from duration of standing and walking	81.7 (22.4)	80.1 (24.4)	0.82[a]

[a]t-test

and walking indoors, then multiplying by 100. The mean (SD) percentage of use was high in both groups: 81.7% (22.4) in the study group and 80.1% (24.4) in the control group. There was no statistically significant difference in the duration of standing and walking indoors, the duration of using the modified TCO, or the percent of usage from the duration of standing and walking between the two groups (p = 0.51, 0.97, and 0.22, respectively).

Discussion

The use of total contact orthoses (TCO) and shoes with heel counters, such as sports shoes, for alleviating pain and optimizing physical performance among patients with posterior tibial tendon dysfunction (PTTD) is well established.[3-10] However, compliance with wearing closed heel design shoes in-house is relatively low,[11] which leads to persistent pain symptoms. Therefore, the researchers who conducted this study developed a new device, a modified TCO. This device features an open heel design, which facilitates donning. To maintain the function of the heel counter, the modified TCO was designed with an upper that covers the medial arch of the foot.

The present study was conducted specifically among patients who usually wore proper shoes outdoors and excluded those who wore proper shoes indoors, since wearing proper shoes indoors is considered the most effective treatment.

Regarding pain, the current trial found that after treatment the study group had less pain in the posterior tibial tendon than the control group. Furthermore, the study group reported a greater decrease in pain level (pre-post intervention difference). There was also an improvement in the Thai version of the Foot Functional Index in terms of pain. This result confirms that using the modified TCO can decrease pain in the posterior tibial tendon. Reasons for the better pain relief may include the following. The cause of pain in PTTD is an abnormal load on the soft tissues on the medial side of the foot, such as the posterior tibial tendon and the deltoid ligament, resulting from abnormal foot alignment (subtalar eversion) and a dysfunctional foot arch. The medial wedge and the medial arch of TCO, in conjunction with the upper part of the shoe that covers the medial arch of the foot, help maintain heel alignment and support the medial longitudinal arch.[3] As a result, these devices reduce forces acting on the posterior tibial tendon. Consequently, these devices can reduce pain.

There was a statistically significant decrease in foot pain in the control group despite the use of flat foam. This might be due to the upper part of the shoe wrapping around the medial side of the foot, acting as a medial arch support. Although the foam is unable to support the posterior tibial tendon or reduce subtalar eversion, it can act as a cushion absorbing the force causing the pain, thereby providing pain relief.

Regarding compliance and satisfaction, device usage compliance was very high. Patients in both groups rated their satisfaction high across all aspects: cosmesis, ease of use, maintenance, durability, and overall experience. Device compliance was high in both groups, with a mean (SD) of 81.7 (22.4) in the intervention group and 80.1 (24.4) in the control group, indicating that consistently wearing indoor shoes was considered beneficial. However, there was a significant difference in the satisfaction score on pain reduction between the two groups. This result establishes that using the modified TCO is the optimal solution for patients with PTTD, especially those who spend prolonged periods standing and walking indoors.

No patient had serious complications the study group had less pain. Only one patient in the study group experienced increased pain at the beginning of the study, compared with six in the control group. In the study group, the increased pain may have been due to unfamiliarity with the devices. In the control group, patients experienced progressively worsening foot pain, difficulty walking, and a sense of instability even after wearing the devices, leading them to grip the floor with their toes. In this study, the researchers instructed the patients to increase the duration of use to 15-30 minutes per day for the first week before the start of the study. However, some patients might have needed more than one week for foot accommodation. In the future, the trial period for wearing the devices should be extended beyond 1 week. Skin abrasions or blistering were found in both groups, a total of 4 patients. Only one patient from the control group developed eczema. It is recommended that patients with existing sores wear socks to help reduce the risk of complications.

The cost of the TCO was 80 USD. The labor cost for modifying the device was 10 USD, and the cost of modification materials was 5 USD per pair, a total of 95 USD per pair. The device was not difficult to fabricate. Any orthotist who could make a TCO could also easily perform the modification.

Study limitations

Several limitations affect this study. Because the research lasted only two weeks, we could not analyze the long-term outcomes. In addition, the use of subjective outcome measures may have introduced self-reporting bias. The durability of the modified TCO was also not evaluated; typically, TCO devices

last approximately 6-12 months, depending on individual use. Further studies with longer follow-up are warranted.

Conclusions

The use of an indoor modified TCO effectively reduced can effectively reduce posterior tibial tendon pain in patients with PTTD without any serious complications.

Conflicts of interest declaration

No conflicts of interest were declared by the authors concerning the research materials, authorship, or the publication of this article.

Generative AI declaration

No generative AI or large language models (LLMs) were used in the writing, editing, or data presentation of this paper. The authors only used Grammarly and QuillBot for standard copyediting and grammatical corrections.

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Data availability

To obtain the source material supporting these findings, please reach out to the corresponding author with a valid inquiry.

Author contributions

Ploypapus Rachatacharoensap: methodology, writing - original draft,

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Aphinat Chirawattanaphan: investigation, resources.

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Original Article

Improvements in Six-Minute Walk Distance and Functional Status following Phase II Cardiac Rehabilitation

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ABSTRACT

Objectives: To evaluate changes in 6-minute walk distance (6MWD) and New York Heart Association (NYHA) functional class (FC) among patients participating in an outpatient phase II cardiac rehabilitation (CR) program

Study design: Retrospective analytic study

Setting: Maharat Nakhon Ratchasima Hospital, a tertiary care hospital in Thailand

Participants: A total of 112 patients enrolled in the CR program between January 2022 and September 2024 and who had at least two 6MWD results available were included. Patients with incomplete data were excluded.

Methods: Demographics and clinical data were collected from the medical records of the patients. The 6MWD and the FC were assessed before and after CR program. The program also included exercise prescription, lifestyle and risk-factor modification.

Results: 97 patients (86.6%) had coronary artery disease, and 14 (12.5%) had congestive heart failure. Overall, 61.6% (95% CI: 52.4, 70.1) showed a ≥ 10% improvement in 6MWD from baseline. Prior to the outpatient phase II CR program, 18 patients were in FC I, 78 were in FC II, and 16 were in FC III. After the implementation of the CR program, 83 patients were classified as FC I, and none remained in FC III. In a modified Poisson regression analysis, intermediate-risk patients were 1.6 times more likely to improve than low-risk patients, while a baseline 6MWD < 300 m was independently associated with greater improvement (adjusted prevalence ratio, 1.7).

Conclusions: Participation in a structured CR program was associated with significant improvements in 6MWD and FC, with 61.6% of patients achieving ≥ 10% improvement in 6MWD from baseline. Patients with lower baseline 6MWD (< 300 m) and moderate risk stratification appeared to derive greater improvements.

Keywords: cardiac rehabilitation, 6-minute walk test, outcomes, functional status

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Introduction

Cardiac rehabilitation (CR) is a comprehensive intervention that includes physician-prescribed exercise, modification of cardiac risk factors, psychosocial assessment, and outcomes assessment.[1] There was evidence of significant improvement in functional capacity, quality of life,[2] and reduced cardiovascular mortality.[3] The European Society of Cardiology (ESC) and American Heart Association (AHA) both provide a Class IA recommendation that CR is an essential component of the treatment for patients with coronary artery disease (CAD)[4,5] and chronic heart failure.[6,7]

The Six-Minute Walk Test (6MWT) is one of the most widely used tools for assessing physical performance in CR programs. It is a simple, reliable measure that effectively reflects responsiveness to clinical changes following rehabilitation.[8] Multiple factors can influence 6MWT improvement in CR programs. Previous studies have demonstrated that the 6MWT shows improvement following CR.[9-11] Factors associated with an increase in the six-minute walk test distance (6MWD) include younger age,[12] absence of diabetes mellitus,[13] a higher number of attended rehabilitation sessions, and lower baseline physical function.[14] These findings highlight the importance of tailoring rehabilitation programs to optimize outcomes for different patient groups. According to the 2024 AHA guideline,[1] an improvement in the 6MWD of ≥ 10% from baseline is considered an appropriate clinical goal following CR.

The CR clinic at Maharat Nakhon Ratchasima Hospital was established in 2022 and has been providing CR services since then. The program included assessment, 6MWT, home-based exercise prescription, guidance on exercise precautions, and lifestyle and risk-factor modification. However, a systematic evaluation of rehabilitation patients' clinical outcomes has not yet been conducted. This study aims to assess 6 MWD and functional class (FC) after phase II CR to help develop ideas for effective rehabilitation strategies to improve service delivery in the future.

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Methods

This retrospective analytic study was conducted at the outpatient CR clinic, Maharat Nakhon Ratchasima Hospital. The study received approval from the Ethics Committee of Maharat Nakhon Ratchasima Hospital on January 22, 2026 (Project ID: 012/2026, approve January 22, 2026).

Participants

All patients enrolled in the CR clinic phase II program between 1 January 2022 and 30 September 2024 were identified from the hospital database, and their electronic medical records were reviewed. Inclusion criteria were: age ≥ 18 years, a diagnosis of CAD, congestive heart failure, valvular heart disease, or complete heart block on a permanent pacemaker (NYHA-FC 1,2,3), participation in at least two CR sessions, and availability of at least two 6MWT measurements. Patients were enrolled in the CR program following medical or surgical treatment, including guideline-directed medical therapy, percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), or valve surgery, as appropriate. Patients with incomplete data were excluded, including those without available low-density lipoproteins (LDL) results or documented home-based exercise records. After the inclusion-exclusion screening, data were collected from medical records using case record forms. The pilot study showed that 20 patients (66.7%) achieved ≥ 10% improvement in 6MWD from baseline. According to the Cochran's formula Z2/2P(1-P)/d2, the significance level was set to 0.05, and the estimation error of P was 0.67, indicating that at least 98 subjects were needed. The estimated proportion (P) for sample size calculation was obtained from a pilot sample randomly selected from outpatient clinic records. The pilot sample was used for this purpose and was not included in the final analysis.

Procedure

Data were collected from medical records using case record forms, including demographic and clinical variables: age, sex, body mass index (BMI), underlying comorbidities, diagnosis, smoking status, risk stratification, and major cardiovascular events within 1 year. Baseline and final measurements of heart rate, blood pressure, FC, 6MWD, and LDL were recorded. In addition, the type and duration of the most recent exercise session as well as the frequency of exercise sessions were documented.

The 6MWT was performed at the first follow-up visit after hospital discharge, provided there were no contraindications. The final 6MWT used for analysis was the last available assessment before discharge from the CR program. New York Heart Association (NYHA) FC was determined by a physiatrist according to standardized criteria, based on patients' reported symptoms (e.g., dyspnea, fatigue) and their reported functional limitations during daily activities. The evaluation was conducted at baseline before participation in the CR program.

Risk stratification was based on the AACVPR[15] criteria using non-exercised testing findings. Patients were classified as low risk if they had a resting left ventricular ejection fraction (LVEF) ≥ 50%, an uncomplicated myocardial infarction or complete revascularization, absence of complex ventricular arrhythmias at rest, absence of heart failure, and no signs or symptoms of post-event or post-procedure ischemia. Moderate risk was defined as an LVEF of 35.0 to 49.9%. Patients who did not meet the criteria for low- or moderate-risk were classified as high risk. LVEF was assessed after the latest cardiac event and before enrollment in the CR program, and was used for risk stratification. The number of attended CR sessions was categorized into two groups (2-3 sessions and > 3 sessions). The cut-off for categorizing CR session attendance was determined based on the median distribution of attended CR sessions in the study population.

The outpatient CR program (phase II) at Maharat Nakhon Ratchasima Hospital primarily consists of an initial hospital-based assessment followed by a structured home-based exercise program. Each patient undergoes a comprehensive evaluation by physiatrists, including a 6MWT. Based on this assessment, individualized counseling is provided, covering home exercise prescription, self-monitoring of exercise intensity (using the rating of perceived exertion [RPE], consistent with the level achieved during the in-hospital assessment), exercise precautions, lifestyle and risk factor modification, and dietary guidance. Patients are advised to perform home-based exercise 3 to 5 days per week, with gradual increases in duration (approximately 10 to 20% per week or 1 to 2 minutes per session), while maintaining the prescribed intensity level. The first follow-up is scheduled 4 to 6 weeks after discharge from admission, with subsequent follow-ups at approximately 1 to 3-month intervals, depending on patient availability and clinical status. These follow-ups are conducted at the hospital to reassess functional capacity and adjust the exercise prescription as needed. Patients are instructed to stop exercise immediately if warning symptoms occur, such as chest pain, dyspnea, dizziness, light-headedness, or presyncope. Patients are discharged from the program once they can safely perform exercise and daily activities at or near their usual level, or once they have achieved the predefined goals.

Statistical analysis

Descriptive statistics were used to summarize patient characteristics, including frequency, percentage, mean, standard deviation, and median (IQR). The chi-square test was used to compare qualitative variables. The 6MWD, heart rate, and LDL levels between the first and last follow-up visits were analyzed using paired t-tests, whereas changes in FC were evaluated using Fisher's exact test with a statistical significance level set at $p < 0.05$. The differences between the improved and not-improved groups were analyzed using the

chi-square test. Modified Poisson regression was used to estimate prevalence ratios for the binary outcome of achieving ≥ 10% improvement in 6MWD. Variables that were significant in the univariable analysis and clinically relevant variables potentially associated with improvement in 6MWD were included in the multivariable model.

Result

A total of 598 patients participated in the outpatient CR program between January 1, 2022 and September 30, 2024. Of these, 65 had incomplete data, 157 had contraindications to CR or were unable to undergo 6MWT assessment, 236 had only one 6MWT measurement, and 28 were still in follow-up. The remaining 112 patients (76 men and 36 women; mean age, 59.8 years) were included. Among these patients, the diagnoses included CAD (86.6%), congestive heart failure (12.5%), and heart block (0.9%) (Table 1). Of the patients with CAD, 49 underwent post-PCI complete revascularization, 44 underwent post-PCI incomplete revascularization, and 4 underwent coronary artery bypass graft. Overall, 55.3% were classified as high-risk for CR, 11.6% as moderate-risk, and 33.1% as low-risk. 75.9% were receiving β-blockers. The duration of participation in the CR clinic was a median of 4 months (IQR: 3–6). Most patients 90 (80.4%) used walking as their exercise. 51 (45.5%) exercised for ≥ 30 minutes per day, and 107 (95.5%) exercised on ≥ 3 days per week. At the 1-year follow-up, 3.6% experienced rehospitalization, 0.89% died, and 95.5% had no cardiovascular events.

Overall, 61.6% of patients (95% CI: 52.4, 70.1) showed an improvement in 6MWD of ≥ 10% from baseline. Among patients with a pre-CR 6MWD < 300 m, 82.5% showed improvement, compared with 50% among those with 6MWD ≥ 300 m. In addition, none of the patients who exercised fewer than 3 days per week showed improvement, whereas 64.5% of those exercising ≥ 3 days per week did. These differences were statistically significant. In contrast, sex, age, diabetes mellitus, diagnosis, and risk stratification did not show significant differences. (Table 2).

After CR, 74.1% (95% CI: 65.3, 81.3) were in FC I, 25.9% (95% CI: 18.7, 34.7) were in FC II, and no patients remained in FC III. Resting heart rate significantly decreased from 76.6 (SD = 12.8) to 72 (SD = 13.6) ($p < 0.01$). The 6MWD increased significantly from 312.8 (SD = 105.3) to 377.9 (SD = 93.1) ($p < 0.01$). LDL levels decreased significantly from 118.1 (SD = 40.6) to 83.7 (SD = 28.2) ($p < 0.01$) (Table 3).

When stratified by demographic factors, no differences in mean 6MWD were observed across sex, age groups, or diagnoses. However, when stratified by risk categories, a difference was noted. The intermediate-risk group demonstrated a mean pre- to post-CR difference of 105 m (SD = 43.1), which was greater than that observed in the low- and high-risk groups, with mean differences of 50.5 m and 65.4 m, respectively (Table 4).

Table 1. Clinical characteristics of the patients (n = 114)

Characteristics	Number (%)
Age (year)[1]	59.8 (11.6)
Male	76 (67.7)
Diagnosis	
SVD	36 (32.1)
DVD	29 (25.9)
TVD	32 (28.6)
Congestive heart failure	14 (12.5)
Heart block	1 (0.89)
Cardiovascular risk factor	
DM	35 (31.1)
HT	62 (55.3)
DLP	55 (49.1)
Smoking habit	
No smoking	72 (64.3)
History of smoking	39 (34.8)
Current smoking	1 (0.89)
BMI	
< 18.5	9 (8.0)
18.5-22.9	34 (30.4)
≥ 23	69 (61.6)
Baseline LVEF	
< 35%	34 (30.3)
35-49%	32 (28.6)
≥ 50%	46 (41.1)
Baseline FC	
1	18 (16.1)
2	78 (69.6)
3	16 (14.3)

[1]Mean (SD); SVD, single vessel disease; DVD, double vessel disease; TVD, triple vessel disease; DM, diabetic mellitus; HT, hypertension; DLP, dyslipidaemia; BMI, body mass index; LVEF, left ventricular ejection fraction; FC, functional class

Univariate analysis revealed baseline 6MWD was statistically significantly associated with improvement in 6MWD. Other factors potentially associated with improvement in 6MWD, including risk stratification, the number of CR sessions attended, and age, were further evaluated using modified Poisson regression analysis. Intermediate-risk patients were 1.6 times more likely to demonstrate improvement than low-risk patients. Additionally, a baseline 6MWD < 300 meters was independently associated with greater improvement (adjusted prevalence ratio 1.7) compared with a baseline 6MWD ≥ 300 meters (Table 5).

Discussion

In this study, 61.6% of patients demonstrated improvement in 6MWD after completing CR. According to the 2024 AHA guideline,[1] an improvement in the 6MWD of ≥ 10.0% from baseline is considered an appropriate clinical goal following CR. To date, no studies have compared outcomes using this ≥ 10% threshold; therefore, this analysis is among the first to apply it. Previous studies have primarily compared absolute 6MWD values before and after CR participation.

Table 2. General characteristics and patient variables comparing patients with ≥ 10% and < 10% improvement following CR

Variables	≥ 10% improvement (n = 69)	< 10% improvement (n = 43)	*p*-value
Age (year)			0.54
< 60	28 (58.3)	20 (41.7)	
≥ 60	41 (64.1)	23 (35.9)	
Diagnosis			0.32
CAD	62 (63.9)	35 (36.1)	
Congestive heart failure	7 (50.0)	7 (50.0)	
DM			0.15
Yes	25 (71.4)	10 (28.6)	
No	44 (51.1)	33 (42.9)	
Risk stratification			0.21
Low	19 (51.4)	18 (48.7)	
Intermediate	10 (76.9)	3 (23.1)	
High	40 (64.5)	22 (35.5)	
Pre-CR 6MWD			< 0.01
< 300	33 (82.5)	7 (17.5)	
≥ 300	36 (50.0)	36 (50.0)	
Functional class			0.25
1	9 (50.0)	9 (50.0)	
2	52 (66.7)	26 (33.3)	
3	8 (50.0)	8 (50.0)	
Number of attended CR sessions			1.00
2-3	44 (61.9)	27 (38.1)	
> 3	25 (61.0)	16 (39.0)	
Exercise adherence (days/week)			< 0.01
< 3	0 (0.0)	5 (100.0)	
≥ 3	69 (64.5)	38 (35.5)	

CAD, coronary artery disease; DM, diabetic mellitus; CR, cardiac rehabilitation; 6MWD, six-minute walk distance

Table 3. Clinical outcomes pre-CR and post-CR

Variables	Pre-CR, mean (SD)	Post-CR, mean (SD)	*p*-value
SBP	130 (21)	129.7 (19.4)	0.89
DBP	76.1 (11.8)	75.3 (11.9)	0.44
HR	76.6 (12.8)	72 (13.6)	< 0.01
6MWD	312.8 (105.3)	377.9 (93.1)	< 0.01
Functional class			< 0.01
1	18 (16.1)	83 (74.1)	
2	78 (69.6)	29 (25.9)	
3	16 (14.3)	0 (0.0)	
LDL	118.1 (40.6)	83.7 (28.2)	< 0.01

CR, cardiac rehabilitation; SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; 6MWD, 6-minute walk distance; LDL, low-density lipoprotein

A systematic review[16] found strong evidence that the 6MWT was responsive to change in clinical status following CR, with an estimated mean difference in 6MWD of 60.4 m (95% CI: 54.6, 66.3 m; $p < 0.01$). This is consistent with our study's findings, which showed a mean improvement of 65.1 m (SD = 7.4, $p < 0.01$).

Analysis of factors associated with improvement revealed that patients with a baseline 6MWD of less than 300 meters demonstrated greater improvement, likely due to their lower baseline functional capacity. In addition to pharmacological therapy, participation in exercise-based CR contributed to improved exercise capacity. Beyond central cardiac recovery, exercise-based CR provides additional benefits through peripheral and skeletal muscle adaptations. These adaptations include improved peripheral vascular function, increased oxidative muscle fiber composition, and reduced skeletal muscle wasting. Peripheral adaptations, particularly within skeletal muscle, are considered the primary mechanisms underlying improvements in peak oxygen consumption.[17] In contrast, patients with a baseline 6MWD of ≥ 300 meters did not demonstrate a clear improvement, consistent with the categorization proposed by Wicks JR.[12]

However, those with a pre-6MWT distance ≥ 300 meters showed a pre- to post-6MWD increase of 14.2 to 18%, although individual comparisons to their own baseline were not performed. In addition, the 6MWT is a submaximal exercise test, which may limit the detectable change in patients with already high baseline 6MWD values.

Patients who exercised at least 3 days per week were more likely to show improvement in 6MWD than those who exercised less frequently, suggesting a potential dose–response relationship between exercise adherence and functional improvement. This finding is consistent with recommen-

Table 4. 6MWD according to demographic characteristics

Variables	Pre-CR 6MWD, mean (SD), m	Post–CR 6MWD, mean (SD), m	Mean change in 6MWD, mean (SD), m
Male	332.4 (100.6)	394.2 (82.9)	61.8 (44.6, 79.0)
Female	271.6 (104.4)	343.6 (104.7)	72 (43.3, 100.7)
Age			
< 60	351 (99.2)	416.2 (77.2)	65.2 (40.8, 89.6)
≥ 60	284.2 (101.6)	349.2 (94.2)	65 (46.4, 83.6)
Diagnosis			
CAD	309 (107.4)	376.1 (94.2)	67.2 (51.5, 82.8)
Congestive heart failure	336 (92.8)	390.4 (90.9)	54.4 (4.5, 104.3)
Risk stratification			
Low	320.6 (121.7)	371.1 (98.4)	50.5 (24.5, 76.5)
Intermediate	311.9 (119.7)	416.9 (117.9)	105 (61.9, 148.1)
High	308.4 (92.5)	373.8 (83.5)	65.4 (45.6, 85.3)

6MWD, Six-minute Walk distance; CR, cardiac rehabilitation; CAD, coronary artery disease

Table 5. Factors associated with patients' improvement in 6MWD

Factors	Unadjusted PR (95%CI)	Adjusted PR (95%CI)	*p*-value
Risk stratification			
Low	1	Ref.	
Intermediate	1.5 (1.0, 2.3)	1.6 (1.0, 2.5)	0.04
High	1.3 (0.9, 1.8)	1.3 (0.9, 1.8)	0.16
Pre-CR 6MWD			
≥ 300	1	Ref	
< 300	1.7 (1.3, 2.2)	1.7 (1.3, 2.3)	< 0.01
Number of attended CR sessions			
2-3	1	Ref	
> 3	1.0 (0.7, 1.3)	1.0 (0.8, 1.4)	0.82
Age			
< 60	1	Ref	
≥ 60	1.1 (0.8, 1.5)	0.9 (0.7, 1.3)	0.60

6MWD, Six-minute Walk distance; CR, cardiac rehabilitation

dations from the AHA guideline,[1] which advocates regular aerobic exercise 3 to 5 days per week to improve cardiovascular fitness and functional capacity.

Although most patients were classified as high-risk based on LVEF, the majority were in FC II. This apparent discrepancy is not unexpected, as LVEF reflects underlying cardiac systolic function, whereas FC represents patients' symptomatic status and functional capacity. Consequently, patients with reduced LVEF may still present with relatively mild symptoms, particularly in stable or optimally managed conditions.

Regarding FC, improvements were observed, with patients moving to FC I–II. This is consistent with previous findings showing that patients participating in CR achieved NYHA class II.[18] Resting heart rate (RHR) significantly decreased from 76.6 (SD = 12.8) to 72 (SD = 13.6) bpm ($p < 0.01$), consistent with previous studies[19] showing that regular exercise leads to RHR reduction.[20] However, 75.9% of patients were receiving β-blockers, which also contributed to the observed decrease in RHR through titration of β-blocker therapy. The observed reduction in LDL can be attributed to both exercise[21] and concurrent statin therapy. In patients with acute coronary syndrome, those with baseline LDL levels greater than 55 mg/dL all received statin treatment.

During CR visits, patients received counselling on home-based exercise with self-monitoring; follow-ups were scheduled approximately every 1 to 3 months. Because many patients lived far from the centre and were unable to attend weekly follow-ups for exercise titration as per a centre-based program, monitoring safety after the home-based program was crucial. At the 1-year follow-up, 3.6% of patients experienced rehospitalization, and 0.89% died. When comparing the risk of total mortality with home-based CR, the number of deaths was 24 per 1,000 (95% CI: 13, 43) during follow-up of up to 1 year, showing no significant difference.[22] In addition, there were 4 rehospitalizations among 108 patients (3.7%),[23] which is comparable to the findings of our study.

In the intermediate-risk patient group, greater improvements were observed compared with the low-risk group because they were already in the middle range. This is likely

due to their baseline EF being within the moderate range; after CR and medical therapy, their symptoms improved, allowing for greater gains. In contrast, patients in the low-risk group already had good baseline 6MWD, so the difference was smaller, while those in the high-risk group had more limited improvement post-CR due to higher baseline risk.

Access to CR services: A total of 598 patients were included, of whom 236 (39.5%) had only one 6MWT measurement, indicating suboptimal follow-up for outcome collection. Some patients missed scheduled follow-ups, consistent with previous reports[19], which showed 41.4% of patients missing follow-ups. Inadequate follow-up in CR remains a challenge worldwide. A study in Thailand identified barriers to CR attendance, including family and work commitments, transport-related factors, and the costs of attending CR.[24] These barriers were addressed in our program by providing a home-based exercise approach, allowing patients to exercise and titrate at home. Additional follow-up beyond the provided program could include the use of telemedicine to reduce barriers related to cost and transportation.

Regarding diagnoses, 86.6% of patients had CAD, 12.5% had congestive heart failure, and among CAD patients, 4.1% had undergone CABG following referral by cardiothoracic surgeons. This proportion was lower than that of post-PCI or CAG patients, whom cardiologists referred. The differences in referral proportions may be explained by the initiation of the CR program at Maharat Hospital, where the CR team conducted conferences to present the program to Cardiologists, securing their cooperation in referring cases to CR. Follow-up care for CABG cases, however, remained relatively low, which is consistent with previous research showing that a lack of communication related to CR between health care providers themselves and with patients contributed to poor CR uptake.[24]

The main limitations of our study include its retrospective design based on medical record review. In addition, we were unable to fully exclude potential confounding factors, such as receipt of standard medical therapy and recovery following interventional procedures, which may have influenced some of the observed outcomes. We were unable to systematically exclude all comorbid conditions that may affect gait or exercise capacity. Based on available data, a small number of patients had a history of stroke with full recovery (n = 7) and osteoarthritis (n = 1), while data on spinal canal stenosis were not available. These conditions may act as confounding factors and could influence 6MWT performance, thereby limiting the extent to which observed changes reflect purely cardiovascular improvement. This study included only patients with at least two 6MWT results. As a result, patients who were unable to attend the second assessment or dropped out early were excluded, which may introduce selection bias. This may limit the generalizability of the findings and potentially overestimate the observed improvements.

Future studies should prospectively analyse and focus on expanding access to CR services, including the integration of telemedicine and the development of reimbursement models that support telemedicine-based care.

Conclusions

Participation in a structured CR program was associated with significant improvements in 6MWD and FC, with 61.6% of patients achieving ≥ 10% improvement in 6MWD from baseline. Patients with lower baseline 6MWD (< 300 m) and moderate risk stratification appeared to derive greater improvements, suggesting that CR may be beneficial even in those with limited initial exercise tolerance. Future controlled trials are needed to definitively isolate the benefits of the CR program from the natural history of patient recovery.

Conflicts of interest declaration

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

Generative AI declaration

The authors confirm that no large language models (LLMs) or artificial intelligence (AI) tools were used in the creation of this manuscript, including the writing, editing, or preparation and tables, with the exception of Grammarly for basic spell-checking.

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Data availability

The authors confirm that the data supporting the findings of this study are available within the article.

Author contributions

Panida Poolpipat: conceptualization, methodology, investigation, data curation, writing-original draft,

Rachawan Suksathien: supervision, validation, writing-review & editing.

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Original Article

Incidence and Risk Factors for Hip Displacement in Thai Children with Cerebral Palsy under a 10-Year Surveillance Program: A retrospective analytical study at Queen Sirikit National Institute of Child Health

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ABSTRACT

Objectives: To evaluate the cumulative incidence of significant hip displacement, defined as a migration percentage (MP) > 40% or the requirement for hip reconstructive surgery among children with cerebral palsy (CP) enrolled in a 10-year institutional hip surveillance program, and to identify independent clinical predictors of displacement.

Study design: Retrospective cohort study

Setting: Queen Sirikit National Institute of Child Health

Participants: Children with cerebral palsy (CP) undergoing their first surveillance radiograph with baseline MP ≤ 40.0%.

Methods: This retrospective cohort study at Queen Sirikit National Institute of Child Health, a national tertiary referral center in Thailand (2016 to 2025), analyzed children with CP having baseline MP ≤ 40.0%. The primary outcome was the cumulative incidence of hip displacement (MP > 40% or surgery), estimated using Kaplan-Meier analysis. Multivariable Cox regression was used to identify risk factors, adjusting for Gross Motor Function Classification System (GMFCS) level, CP subtype, and epilepsy.

Results: A total of 265 patients were included. The cumulative incidence of significant hip displacement of the patients progressively increased over time: 17.8% at 2 years of follow-up, 30.5% at 4 years of follow-up, reaching 41.0% at 6 years of follow-up. Among the children who developed significant hip displacement during the surveillance period, the mean age at the time of initial documentation of displacement was 5.0 (SD = 2.2) years. Multivariable analysis identified GMFCS levels IV-V as the strongest independent predictor (adjusted Hazard Ratio [aHR] 3.09; 95% CI: 1.24, 7.70; p = 0.015) compared to levels I-III. Non-spastic CP subtypes were associated with a significantly lower risk (aHR 0.22; p = 0.017) compared to spastic diplegia. Epilepsy was not found to be an independent risk factor after adjusting for motor severity (aHR = 0.76; p = 0.407).

Conclusions: The cumulative risk of hip displacement in this surveillance cohort is high, particularly among children with severe motor impairment (GMFCS IV-V), reaching 41.0% at 6 years of follow-up. These findings underscore the necessity for rigorous, long-term surveillance stratified by GMFCS level and provide crucial data for prognostic counseling to facilitate timely interventions.

Keywords: cerebral palsy, hip displacement, hip surveillance, incidence, risk factors, Gross Motor Function Classification System

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Introduction

Hip displacement is the second most common musculoskeletal deformity in children with cerebral palsy (CP), following equinus,[1-3] with an overall incidence of approximately 35.0% among the entire CP population.[2] If left untreated, this condition typically progresses to hip dislocation[1,4] resulting in severe complications such as chronic pain, scoliosis, impaired function, and a significant deterioration in the quality of life for both the child and their family.[1,2,4,5]

Most children with CP are born with anatomically normal hips. However, spasticity and muscle imbalance around the hip joint create abnormal and uneven forces on the femoral head and acetabulum. These forces stimulate gradual bony remodeling during growth. This phenomenon is often referred to as “silent subluxation” because, in the early stages, there are usually no pain or obvious clinical signs, making early diagnosis difficult when relying solely on physical examination.[1,2,6] Consequently, early diagnosis and monitoring of hip displacement relies on the measurement of the migration percentage (MP) (Reimer’s Migration Percentage/Index). This is a widely accepted, reliable, and commonly used radiological measurement.[2] An MP greater than 30.0% is considered indicative of a hip at risk for dislocation.[2,5]

Over the past 15 years, the role of hip surveillance in children with CP to detect “hips at risk” early has been recognized as a crucial step in preventing hip dislocation.[7] Successful surveillance programs in several countries, including Sweden

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(Cerebral Palsy Follow-Up Program, CPUP), Australia, and Scotland, have demonstrated a significant reduction in the incidence of hip dislocation and the need for salvage surgery.[2,6-9] The most significant clinical factor associated with hip displacement is the functional motor level, classified by the Gross Motor Function Classification System (GMFCS). A linear relationship has been observed between GMFCS level and the risk of hip displacement.[2,3] In addition to GMFCS, previous studies have demonstrated that the presence of epilepsy is highly associated with overall disease severity, while CP topography (subtype) is directly correlated with the risk and progression of hip displacement.[10,11]

Recognizing the importance of surveillance, the Queen Sirikit National Institute of Child Health (QSNICH) implemented the Clinical Practice Guideline for Hip Dysplasia in CP in Thailand in 2016.[12] An effective international standard prevention program consists of surveillance and screening systems, clinical assessment, radiological monitoring, spasticity management, physical therapy, criteria for referral to orthopedic surgeons, and follow-up.[7] A review of the institute's practices indicates that the following components are comprehensively utilized: early hip X-ray screening based on GMFCS risk is conducted together with non-operative treatment, which covers spasticity management, stretching, strengthening exercises, positioning, and the use of orthoses. Following the program's implementation, the rate of radiological screening before age 2 increased from 66.7% in 2015 to 74.1% between 2016 and 2019, and the mean age at first screening significantly decreased. Furthermore, the program demonstrated efficacy in maintaining hip stability, with 84.8% of followed patients maintaining a MP of less than 40.0%.[5] However, while short-term results are promising, there is a lack of long-term data to confirm the program's sustained efficacy in preventing severe hip displacement until skeletal maturity. Additionally, the variation in follow-up durations among patients has not been accounted for, which may lead to an underestimation of the true cumulative risk.

Furthermore, there is a lack of long-term hip surveillance data in Southeast Asia, including Thailand. Outcomes in this region may differ from Western registries due to variations in healthcare resources, delayed referrals, and the recent implementation of national guidelines. Therefore, understanding outcomes in this specific context is crucial.

This 10-year retrospective study aims to utilize data from the medical records of pediatric patients who underwent their first hip X-ray at the QSNICH between 2016 and 2024. The objectives are to evaluate the cumulative incidence of significant hip displacement, defined as a MP exceeding 40.0% or a requirement for hip reconstructive surgery among children with CP enrolled in a 10-year institutional hip surveillance program. In this study, a MP > 40.0% was selected as the primary endpoint for defining significant hip displacement. This threshold marks the point at which orthopedic evaluation and corrective measures are mandated under the current institutional guidelines. Furthermore, we sought to identify independent clinical predictors of hip displacement, specifically determining the adjusted hazard ratio (aHR) associated with different GMFCS levels, CP subtypes, and the presence of epilepsy, to better understand the long-term risk profile in this population. The findings will help refine the institute's clinical practice guidelines to be more specific and effective.

Methods

Study design

This retrospective cohort study evaluated the incidence and risk factors for hip displacement in children with CP who underwent their first hip X-ray at the QSNICH between 2016 and 2024. The study protocol was approved by the Institutional Review Board (IRB) of the QSNICH (REC No. 008/2569) on February 9, 2026 (Clinical Trial Registration: TCTR20260223011). This study has been reported according to the STROBE (STrengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies.

Participants

The study enrolled patients who underwent their first surveillance radiograph at the Department of Rehabilitation Medicine, QSNICH, Thailand, between January 2016 and December 2024.

The inclusion criteria included the following requirements: (1) a clinical diagnosis of CP of any subtype; (2) undergoing an initial anteroposterior (AP) pelvic radiograph for surveillance enrollment during the study period; and (3) having complete medical records available for analysis, including demographic data, GMFCS level, and radiographic images suitable for measurement. The exclusion criteria included the following: (1) a history of hip or pelvic surgery prior to the initial surveillance radiograph; (2) the presence of other neuromuscular conditions affecting hip pathology, e.g., myelomeningocele or arthrogryposis; and (3) severe hip displacement (MP > 40.0%) detected at the initial baseline assessment.

Data collection and measurement

Data were collected from hospital medical records and the Picture Archiving and Communication System (PACS), including patient characteristics, age at enrollment, history of epilepsy, type of CP, and GMFCS level. Clinical parameters, including the specific CP subtype (spastic, dyskinetic, ataxic, or mixed) and topographical distribution (hemiplegia, diplegia, or quadriplegia), were identified from medical records.

Radiographic assessments conducted during the surveillance period were also reviewed. These assessments included the MP of both hips measured from standard AP pelvic radiographs using Reimers' method.[13] For statistical analysis, only the hip with the higher MP value was selected for each patient. Measurements were performed by experienced rehabilitation physicians using digital tools within the PACS.

The clinical outcome was evaluated based on the progression of hip displacement. The primary endpoint was defined as the occurrence of significant hip displacement, characterized by an MP > 40.0%, or the requirement for hip reconstructive surgery during the surveillance period.

The study enrolled patients who underwent their first surveillance radiograph between January 1, 2016 and December 31, 2024. This enrollment cutoff was selected to ensure that all participants had a potential follow-up period of at least one year. Data collection covered a 10-year period ending on December 31, 2025, and each participant was followed from their enrollment date until the earliest of the following endpoints: December 31, 2025, the occurrence of a primary outcome event, or their last recorded visit in cases of loss to follow-up. The detailed clinical pathway and screening intervals according to our institutional protocol are illustrated in Appendix Figure A1.

Sample size calculation

The sample size was calculated to detect a clinically significant difference in hip displacement outcomes using survival analysis and the Cox proportional hazards model. The calculation was based on a two-sided significance level of 0.05 and a power of 80%. We assumed a HR of 2.5 for patients with severe motor impairment (GMFCS levels IV-V) compared to those with mild to moderate impairment (GMFCS levels I-III).

Based on a presumed sample distribution of 60% for the high-risk group (GMFCS IV-V) and an overall event rate of 22% as reported by Kentish et al.[7], a total of 39 events were required, corresponding to an initial sample size of approximately 178 subjects. To account for a potential dropout rate or incomplete data of approximately 30% based on preliminary institutional data,[5] the final sample size was adjusted to include at least 255 participants.

Outcome

The primary outcome was the cumulative incidence of significant hip displacement or the requirement for hip reconstructive surgery. Significant hip displacement was defined as the first radiographic detection of a MP exceeding 40.0% in either hip, the established clinical threshold for a high risk of dislocation. Surgical intervention was defined as bone reconstructive surgery performed to manage hip displacement.

The secondary outcomes included identifying independent clinical predictors of the primary outcome. Specifically, the study aimed to determine the aHR for different GMFCS levels, CP subtypes, and the presence of epilepsy.

Statistical analysis

Data analysis was performed using standard statistical software (STATA18). Descriptive statistics were used to summarize baseline characteristics and clinical parameters. Continuous quantitative variables were tested for normality. Data are presented as mean (standard deviation, SD). Categorical variables are expressed as frequencies and percentages.

Comparisons of variables between the successful and unsuccessful hip outcome groups were performed. Continuous variables were compared using the Independent t-test. Categorical variables were compared using the X^2 test.

The cumulative incidence of hip displacement was estimated using the Kaplan-Meier method, and differences between groups were compared using the Log-rank test. To identify independent predictors and to control for confounding, a multivariable Cox proportional hazards regression model was employed. Results are reported as aHR with 95% confidence intervals (CI). A p-value of < 0.05 was considered statistically significant.

To handle missing data, a complete-case analysis approach was employed; patients with incomplete baseline medical records or missing key variables were excluded from the final analysis. For the time-to-event analysis, patients who did not experience significant hip displacement or who were lost to follow-up before the end of the study period were right censored at the date of their last clinical or radiographic evaluation.

Bias minimization

To minimize bias, we recruited consecutive eligible patients and excluded those with baseline severe displacement (MP > 40.0%) to address selection and prevalence-incidence bias. Measurement bias was reduced by using standardized digital radiographic tools. Multivariable survival analysis was employed to control for confounding, while time-to-event analysis accounted for attrition and censored data.

Results

A total of 334 patients were identified from the medical records. We excluded 22 patients due to incomplete data and 47 patients due to baseline severe hip displacement (MP > 40.0%). Consequently, 265 patients were included in the final analysis. (Figure 1)

The study consisted of 213 patients (80.4%) in the successful outcome group and 52 patients (19.6%) in the unsuccessful outcome group. Among the children who developed significant hip displacement during the surveillance period, the mean age at the time of documented displacement was 5.0 years (SD = 2.2). There were no statistically significant differences between the two groups regarding age at initial X-ray, gender distribution, BMI, history of epilepsy, or the duration of follow-up (p > 0.05). The mean age at enrollment was 34.7 months (SD = 23.2) in the successful group and 31.2 months (SD = 16.1) in the unsuccessful group (p = 0.306).

However, significant differences were observed in functional gross motor severity, CP subtype, and initial radiographic measurements. Patients in the unsuccessful outcome group had a significantly higher proportion of severe motor impairment (GMFCS levels IV-V) compared to the successful group (88.5% vs. 62.0%, p < 0.001). Similarly,

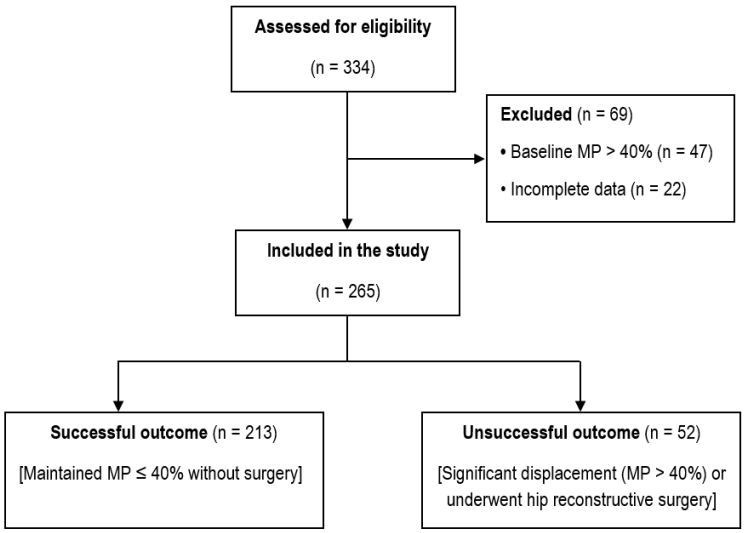

Figure 1. The study flow diagram

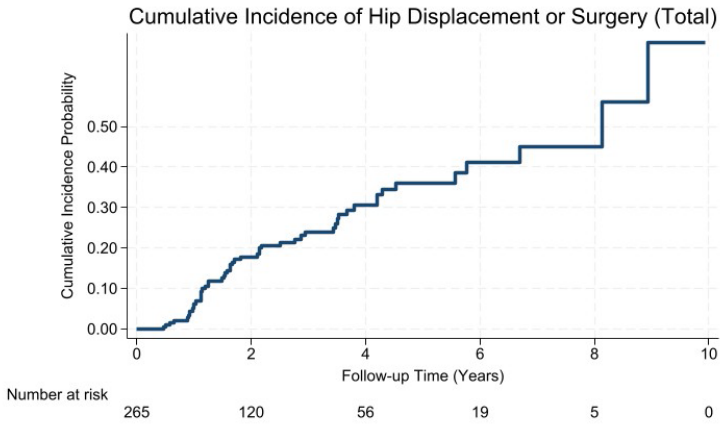

Figure 2. Kaplan-Meier cumulative incidence of significant hip displacement or surgery

the distribution of CP subtypes differed significantly between groups ($p < 0.001$), with spastic quadriplegia being markedly more prevalent in the unsuccessful group (48.1%) compared to the successful group (24.9%).

Regarding radiographic parameters, the unsuccessful group had a significantly higher mean baseline MP than the successful group (29.9% (SD = 9.7) vs. 21.3% (SD = 12.4), $p < 0.001$). Additionally, the annual MP progression rate was notably higher in the unsuccessful group (6.39% per year) compared to the successful group (0.89% per year) (Table 1).

The primary outcome was the cumulative incidence of significant hip displacement (MP > 40.0%) or the requirement for hip reconstructive surgery. Kaplan-Meier analysis demonstrated a progressive increase in the cumulative risk over the surveillance period (Figure 2). The estimated cumulative incidence was 17.8% (95% CI: 12.7%, 24.7%) at 2 years of follow-up and rose to 30.5% (95% CI: 23.3%, 39.3%) at 4 years of follow-up. By 6 years of follow-up, the cumulative incidence reached 41.0% (95% CI: 31.3%, 52.5%), and at 8 years, it was estimated to be 44.9% (95% CI: 33.6%, 58.2%) Kaplan-Meier cumulative incidence (Figure 3) demonstrated distinct risk stratification. Patients with severe motor impairment (GMFCS IV-V) exhibited a steeply rising cumulative incidence curve, diverging sharply from the flat trajectory of those with mild-to-moderate impairment (GMFCS I-III). Similarly, spastic quadriplegia and diplegia showed higher cumulative risks compared to hemiplegia and non-spastic types. In contrast, survival curves for epilepsy overlapped throughout the surveillance period, indicating no significant unadjusted difference.

After adjusting for covariates (Table 3), GMFCS level remained the strongest independent predictor. Children with GMFCS levels IV-V had a three-fold increased risk of hip displacement compared to levels I-III (aHR = 3.09; 95% CI: 1.24, 7.70; $p = 0.015$).

Regarding CP subtypes (reference: spastic diplegia), non-spastic CP was associated with a significant 78% risk reduction (aHR = 0.22; 95% CI: 0.07, 0.76; $p = 0.017$). Notably, the elevated risk for spastic quadriplegia seen in univariate analysis lost statistical significance in the adjusted model (aHR = 1.44; $p = 0.306$), suggesting that the risk is largely mediated by motor severity rather than the subtype itself.

Moreover, multivariable analysis demonstrated that epilepsy is not an independent risk factor for hip displacement.

Table 1. Baseline characteristics and outcomes of patients with cerebral palsy, stratified by hip surveillance outcome

Variables	Successful hip outcome (n = 213)	Unsuccessful hip outcome (n = 52)	*p*-value
Age at first X-ray (month)[1]	34.7 (23.2)	31.2 (16.1)	0.306[a]
Gender[2]			
Female	101 (47.7)	25 (48.1)	0.932[b]
Male	112 (52.6)	27 (51.9)	
BMI (kg/m^2)[1]	15.95 (5.84)	15.79 (3.24)	0.858[a]
GMFCS level[2]			
I-III	81 (38.0)	6 (11.5)	< 0.001[b]
IV-V	132 (62.0)	46 (88.5)	
CP type[2]			
Spastic quadriplegia	53 (24.9)	25 (48.1)	< 0.001[b]
Spastic diplegia	86 (40.4)	23 (44.2)	
Spastic hemiplegia	24 (11.3)	1 (1.9)	
Non-spastic	50 (23.5)	3 (5.8)	
Epilepsy[2]			
Yes	92 (43.2)	27 (51.9)	0.256[b]
No	121 (56.8)	25 (48.1)	
Baseline MP (%)[1]	21.3 (12.4)	29.9 (9.7)	< 0.001[a]
MP progression rate (%/year)	0.89	6.39	
Time to follow-up (year)[1]	2.18 (2.34)	2.44 (1.91)	0.459[a]

[1]Mean (SD), [2]Number (%); [a]Independent t-test, [b]X2-test, MP, migration percentage; ; BMI, body mass index; GMFCS, Gross Motor Function Classification System; CP, cerebral palsy

Table 2. Cumulative incidence of hip displacement at specific follow-up intervals

Time after first X-ray (years)	No. at risk	Cumulative incidence (95% CI)
0	265	-
2	120	17.8% (12.7, 24.7)
4	56	30.5% (23.3, 39.3)
6	19	41.0% (31.3, 52.5)
8	5	44.9% (33.6, 58.2)
10	0	-

The aHR of 0.76 (95% CI: 0.40, 1.45; $p = 0.407$) substantiates that seizure history does not confer additional risk when controlling for motor function.

Discussion

This 10-year retrospective cohort study evaluates the cumulative incidence and risk factors for hip displacement among children with CP enrolled in a surveillance program at a national tertiary referral center. To our knowledge, this is one of the first studies in Southeast Asia to report long-term hip surveillance outcomes using survival analysis. The principal finding is that the cumulative risk of significant hip displacement (MP > 40.0%) or the need for reconstructive surgery increases progressively, reaching 41.0% at 6 years of follow-up. Consistent with global literature, the severity of motor impairment (GMFCS levels IV-V) was identified as the most robust independent predictor. The lack of an independent association for epilepsy in our multivariable model is likely due to its strong correlation with higher GMFCS levels, which represent overall disease severity. This collinearity may explain why our findings differ from previous studies,[11] where epilepsy might have appeared significant in univariate analyses or in cohorts with different distributions of disease severity.

The cumulative incidence of hip displacement in this study (41.0% at 6 years of follow-up) is higher than figures reported from population-based surveillance programs in developed countries, such as Sweden (CPUP) and Australia.[2,14,15] However, it is important to note that our study defined the outcome as significant displacement (MP > 40.0%), capturing hips at risk rather than only those that had fully dislocated. Furthermore, unlike major population-based cohorts that report cumulative incidence by patient age[16], our study used 'follow-up duration' as the primary time axis. This approach was strategically selected to evaluate the surveillance program's operational effectiveness in the real world. Because children in our setting entered surveillance at highly variable ages due to delayed referrals, analyzing incidence by follow-up duration practically illustrates the progression risk after entering the system. While this methodology limits direct graphical comparisons with age-based incidence curves, a descriptive comparison reveals similar underlying trends. Consistent with established cohorts, we observed that MP gradually increased across all severity levels during the initial 2 to 4 years of follow-up. Subsequently, progression tended to stabilize in patients with milder CP, whereas those with GMFCS levels IV-V continued to experience MP progression, albeit at a shallower slope over time.

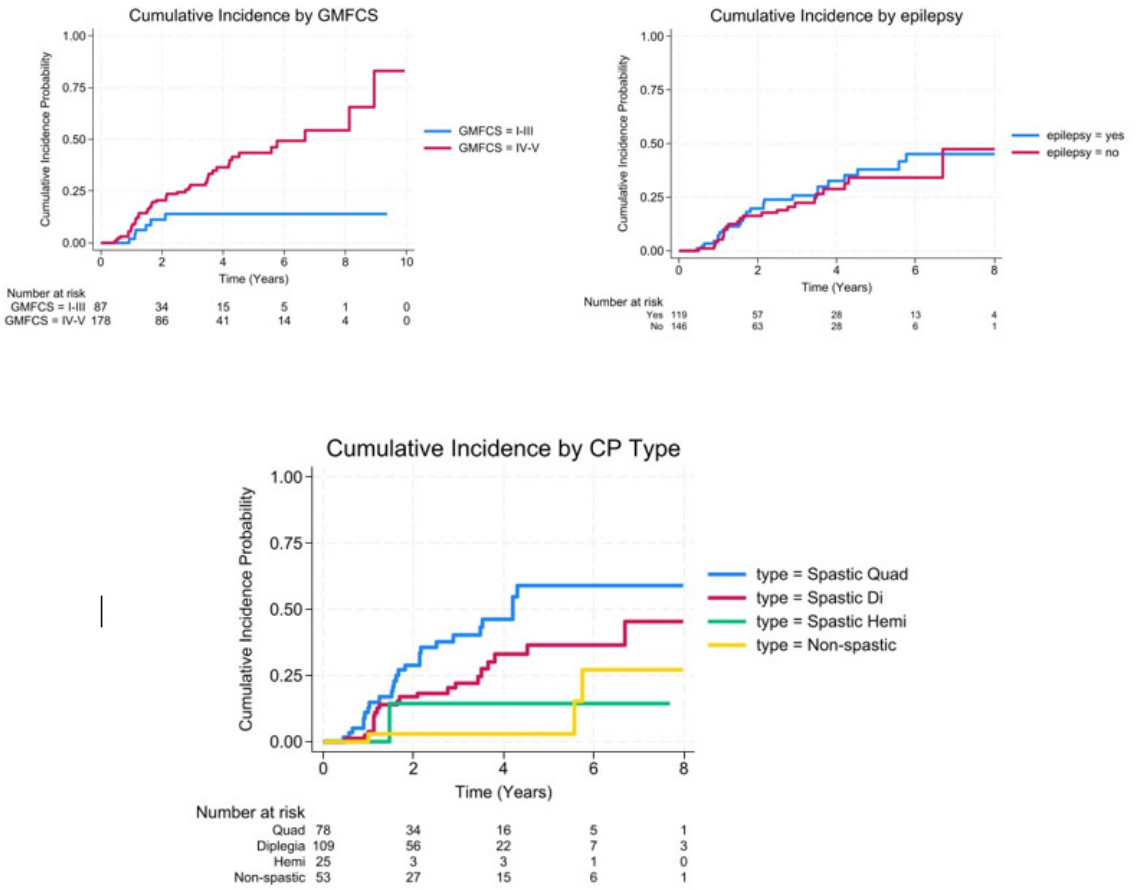

Figure 3. Kaplan-Meier cumulative incidence of significant hip displacement. (A) Stratification by GMFCS level showing rapid risk divergence, with significantly higher incidence in levels IV-V (red) compared to I-III (blue). (B) Stratification by epilepsy status shows overlapping curves, indicating no significant difference in risk. (C) Stratification by CP subtype: Spastic Quadriplegia (blue) and Diplegia (red) demonstrate the highest progression rates compared to Hemiplegia (green) and Non-spastic types (yellow).
GMFCS, Gross Motor Function Classification System; CP, cerebral palsy

Table 3. Multivariable Cox proportional hazards regression analysis of risk factors for significant hip displacement

Variables	Total N	Events (n)	Adjusted HR (95% CI)	*p*-value
GMFCS				
I-III	87	6	1.00 (Ref)	0.015*
IV-V	178	46	3.09 (1.24, 7.70)	
Epilepsy				0.407
Yes	119	27	0.76 (0.40, 1.45)	
No	146	25	1.00 (Ref)	
CP type				
Spastic quadriplegia	78	25	1.44 (0.72, 2.90)	0.306
Spastic diplegia	109	23	1.00 (Ref)	
Spastic hemiplegia	25	1	0.53 (0.07, 4.08)	0.544
Non-spastic	53	3	0.22 (0.07, 0.76)	0.017*

GMFCS, Gross Motor Function Classification System; CP, cerebral palsy

When compared to the natural history of the disease, which represents data collected before surveillance programs were common, our rates align with the 35.0% to 60.0% incidence typically seen in non-ambulatory populations.[17-19] It should be noted that while previous studies typically defined hip displacement at an MP threshold of approximately 30.0%, our study used a slightly higher institutional cut-point of MP > 40.0%.

Compared to our institution's preliminary study during the initial program implementation (from 2015 to 2019), which reported short-term success with 84.8% of patients maintaining hip stability (MP < 40.0%) over a mean follow-up of

1.89 years[5], the current 10-year analysis reveals a contrasting reality. We found that the cumulative risk of significant displacement progressively rose to 41.0% at 6 years of follow-up. This discrepancy highlights that short-term evaluation may lead to an underestimation of risk due to the silent, progressive nature of hip displacement. Consequently, these findings reinforce the necessity of strict, long-term surveillance until skeletal maturity, rather than relying solely on early-stage stability.

The higher incidence observed in our study compared to Scandinavian registries can be attributed to the nature of our institution. As a national tertiary referral center, we likely manage a population with greater disease complexity and comorbidity compared to community-based registries.[20] Furthermore, many patients in our setting may present with established contractures or delayed enrollment, which accelerates the progression of hip migration despite non-operative management.[19] Specifically, although our institutional guidelines recommend initiating baseline radiographic screening at 18 months of age, the mean age at the first screening radiograph in our cohort was more than 30 months. This reflects a substantial delay in real-world enrollment compared to established surveillance programs in developed countries, where baseline evaluations are typically initiated and consistently performed between 12 and 24 months of age.[19-21]

Another contributing factor to the high incidence observed in this study may be the inconsistency of follow-up visits. In our real-world practice, some patients are lost to follow-up for extended periods and only return when they become symptomatic or when the hip is already significantly displaced. This lack of continuous monitoring means that the opportunity for early, less invasive intervention is missed, leading to a higher rate of severe displacement upon return. Therefore, future research should aim to identify and collect data on the specific factors contributing to loss to follow-up such as socioeconomic barriers, geographic distance from healthcare facilities, and caregiver burden. Understanding these factors is crucial for developing targeted strategies to improve long-term adherence to the surveillance program.

This study confirms GMFCS level as the strongest predictor of hip displacement, consistent with global consensus.[2,17,22,23] Children with GMFCS levels IV-V face a three-fold increased risk (aHR 3.09), a relationship driven by delayed weight-bearing and muscle imbalance.[13] This analysis also indicates that non-spastic forms carry a significantly lower risk (78.0% reduction) compared to spastic diplegia, consistent with the Victorian Cerebral Palsy Register.[17] Notably, spastic quadriplegia was not an independent predictor in the multivariate model, suggesting that its high raw incidence is driven primarily by the associated GMFCS V status rather than topography.[22]

The strength of this study lies in its long-term follow-up (up to 10 years) and the use of survival analysis (Cox proportional hazards model), which accounts for variable follow-up times and censored data, providing a more accurate estimate of risk than simple cross-sectional prevalence used in many previous hospital-based studies. However, this study has limitations. First, the single-center design may limit generalizability to the broader community CP population, as our tertiary center likely manages more severe cases. Second, we did not evaluate the impact of pelvic obliquity or scoliosis, which are known to correlate with hip displacement.[24,25] Third, due to sample size constraints within specific subgroups, we dichotomized GMFCS levels into I-III and IV-V to ensure the statistical reliability of our multivariable model. We acknowledge that this broad categorization may mask subtle differences in hip displacement risk between adjacent GMFCS levels and reduce the granularity of our clinical risk estimates. Fourth, an important limitation concerns the interpretation of unadjusted baseline comparisons, like those presented in Table 1. Because follow-up duration varied substantially across participants, some patients classified as “successful” simply may not have been followed long enough to experience significant displacement. While our Cox regression appropriately accounts for this time-to-event data, there was still a substantial reduction in the number of patients at risk at later time points (e.g., years 6 to 8) due to right-censoring and loss to follow-up. This reduction inherently increases the uncertainty of our long-term cumulative incidence estimates.

To assess potential attrition bias, we compared baseline characteristics of patients who remained in the study with those of patients who were lost to follow-up (Appendix Table B1). Reassuringly, there were no significant differences in major clinical severity indicators, including GMFCS levels and epilepsy. However, patients who were retained in the program tended to be older at their initial X-ray and had slightly higher baseline MP, suggesting that those with more concerning initial clinical presentations were more likely to remain under long-term observation.

These findings highlight the urgent need to strengthen our national hip surveillance program. Although the institute’s 2016 protocol aligns with general screening principles, the high cumulative incidence observed in this study suggests that current surveillance intensity and intervention thresholds may be insufficient for high-risk populations (GMFCS IV-V). Specifically, reducing surveillance frequency to once a year after age 7 may miss rapid deterioration during the prepubertal growth spurt. Furthermore, the referral threshold of MP > 40.0% may preclude the opportunity for less invasive preventive surgery. Therefore, we recommend intensifying the protocol by maintaining 6-monthly surveillance for GMFCS IV-V until skeletal maturity and lowering the surgical referral threshold to allow for timely preventive interventions.

Crucially, the cumulative incidence and HR derived from this study serve as vital tools for prognostic counseling. Providing parents with evidence-based, time-specific risks facilitates informed and shared decision-making. Clear communication

of these figures, such as the 41.0% risk by 6 years or the three-fold increase in risk for GMFCS IV-V, can improve compliance with monitoring schedules and set realistic surgical expectations. Proactive communication and targeted monitoring of these vulnerable groups could help effectively prevent hip dislocation rather than merely documenting its progression.

Conclusion

The cumulative incidence of significant hip displacement was high in this study (41.0% at 6 years of follow-up). While higher GMFCS levels (IV-V) are the strongest independent predictors of hip displacement, having a non-spastic CP subtype acts as a significant independent protective factor. These findings highlight the critical need for structured, GMFCS-stratified surveillance. Furthermore, the results provide clinicians with robust evidence for prognostic counseling, facilitating more effective communication of time-specific risks to parents. This is essential for ensuring long-term adherence to monitoring protocols and preventing the progression to painful dislocations.

Conflicts of interest disclosure

The author confirms that there are no conflicts of interest related to the manuscript.

Generative AI declaration

During the preparation of this work, the author used Gemini to improve language and grammar. After using this tool, the author reviewed and edited the content as needed and takes full responsibility for the publication's content.

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Data availability

Research data are not shared.

Author declaration

The Principal Investigator is the sole author of this manuscript. The author was responsible for all aspects of the research, as defined by the CRediT taxonomy.

Supplementary materials

The following supporting information can be downloaded at: Supplementary file.

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Appendix A. The Clinical Practice Guideline for Hip Dysplasia in Cerebral Palsy, Queen Sirikit National Institute of Child Health, Thailand, 2016

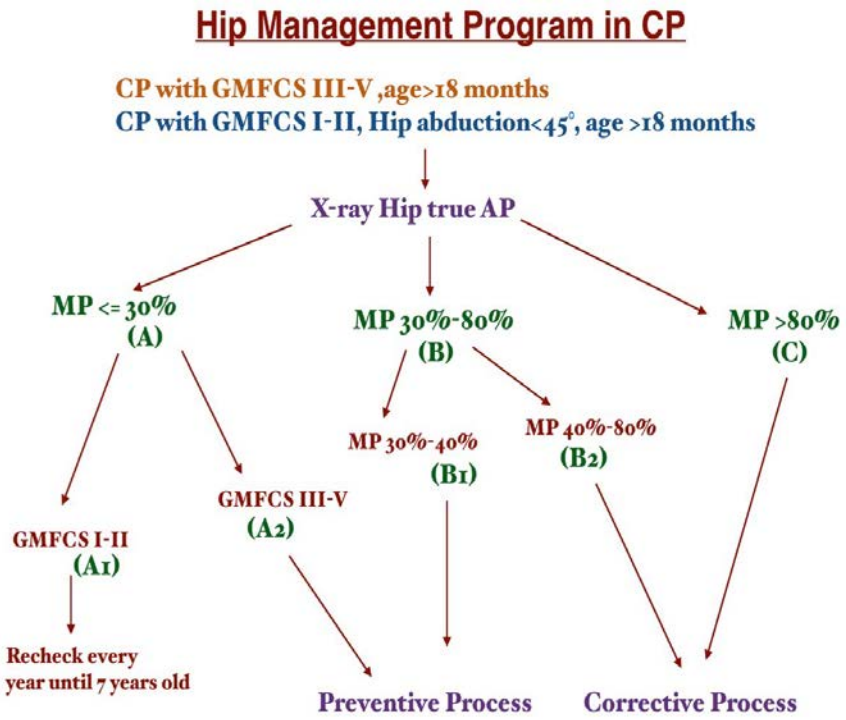

Figure A1. Algorithm for the screening and management of hip displacement in children with cerebral palsy, Queen Sirikit National Institute of Child Health, Thailand, 2016

Appendix B: Supplementary table

Table B1. Comparison of baseline characteristics between patients who completed follow-up and those lost to follow-up.

Variables	Completed follow-up (n = 126)	Loss to follow-up (n = 139)	*p*-value
Age at first X-ray (month)[1]	39.9 (28.4)	28.6 (11.8)	< 0.001[a]
Gender[2]			
Female	63 (50.0)	63 (45.3)	0.447[b]
Male	63 (50.0)	76 (54.7)	
BMI (kg/m^2)[1]	16.15 (7.19)	15.70 (3.06)	0.496[a]
GMFCS level[2]			
I-III	37 (29.4)	50 (36.0)	0.253[b]
IV-V	89 (70.6)	89 (64.0)	
CP type[2]			
Spastic quadriplegia	45 (35.7)	33 (23.7)	
Spastic diplegia	56 (44.4)	53 (38.1)	0.006[b]
Spastic hemiplegia	6 (4.8)	19 (13.7)	
Non-spastic	19 (15.1)	34 (24.5)	
Epilepsy[2]			
Yes	61 (48.4)	58 (41.7)	0.274[b]
No	65 (51.6)	81 (58.3)	
Baseline migration percentage (%)[1]	24.6 (12.3)	21.6 (12.3)	0.049[a]

[1]Mean (SD), [2]Number (%), [a]Independent t-test, [b]X^2-test

BMI; body mass index; GMFCS, Gross Motor Function Classification System; CP, cerebral palsy

Original Article

A Retrospective Analysis of Stroke Rehabilitation Outcomes in the Intermediate Care (IMC) Service Plan Comparing Home-based and Outpatient-Based Services Using Propensity Score Matching

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ABSTRACT

Objectives: To compare rehabilitation outcomes up to 24 weeks post-stroke, therapy exposure, and complication rates between home-based and outpatient-based IMC stroke rehabilitation programs, before and after propensity score matching in a hospital.

Study design: Retrospective observational cohort design with Propensity Score Matching

Setting: Department of Rehabilitation Medicine, Songkhla Hospital, a tertiary care hospital in southern Thailand

Participants: Intermediate care stroke patients who received rehabilitation services through either the home-based or outpatient-based model between October 2022 and September 2025.

Methods: This retrospective study analyzed stroke patients enrolled in the IMC program. Baseline characteristics, Barthel Index (BI) scores, dependency levels, complications, and therapy session counts were collected at baseline, 2 weeks, 12 weeks, and 24 weeks. Propensity score matching was conducted using initial BI, National Institutes of Health Stroke Scale (NIHSS), age, sex, and other key covariates to ensure baseline clinical balance.

Results: Before matching, the home-based group was older and predominantly female, while the outpatient-based group tended to present with more-severe strokes and lower initial BI scores. The outpatient-based group also received substantially more therapy (median PT: 10 vs. 3; OT: 8 vs. 1; both $p < 0.001$). After matching, therapy exposure remained higher in the outpatient-based group (PT: 1.6 [SD = 1.9] vs. 8.5 [SD = 6.6], SMD = –1.63; OT: 8.5 [SD = 6.2] vs. 9.2 [SD = 6.2], SMD = –1.43). Short- and intermediate-term BI gains were similar between the groups, with identical median gains during several intervals. Long-term BI gain (baseline–24 weeks) was greater in the outpatient-based group. The home-based group met non-inferiority criteria for BI gain at 24 weeks ($p = 0.035$), but not at 12 weeks. Trends toward higher pneumonia and pressure ulcer rates were observed in the home-based group, whereas recurrent stroke tended to be more common in the outpatient-based group, though neither reached statistical significance. At 6 months, 62.7% of the home-based and 63.7% of the outpatient-based group had achieved a level of mild or no disability.

Conclusions: Home-based and outpatient-based IMC rehabilitation yielded broadly comparable outcomes despite a substantially lower therapy dosage in the home-based group. Increasing therapy intensity and integrating advanced rehabilitation technologies could potentially further improve functional recovery within the IMC framework. The home-based group demonstrated statistically non-significant trends toward higher rates of preventable complications such as pneumonia and pressure ulcers.

Keywords: home-based, outpatient-based, functional outcome, intermediate care (IMC), propensity score

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Introduction

Stroke remains a leading cause of mortality and disability worldwide, including Thailand, with significant implications for functional independence and quality of life.[1-4] The subacute or intermediate care phase, defined as the first six months post-stroke, is recognized as a golden period for neuroplasticity and functional recovery. Neuroimaging studies have demonstrated enhanced cortical reorganization during this period,[5] and early rehabilitation interventions have been associated with improved activities of daily living (ADL) and reduced long-term dependency.[6,7]

In Thailand, the Ministry of Public Health has implemented an Intermediate care (IMC) service plan to address the growing burden of stroke-related disability and to provide a seamless service network to fill the gap left by insufficient transitional care between acute care to long-term care (LTC). This service system is composed of multidisciplinary teams that collaborate and link healthcare facilities at all levels. Depending on their needs and readiness, patients and families will be offered various rehabilitation services, including inpatient (minimum 15 hours per week), outpatient, and outreach services, with a mean of 1 to 3 sessions per week (minimum 30 sessions in 6 months).[8]

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Telerehabilitation (TR) technologies are increasingly being used in stroke rehabilitation. These technologies have the potential to increase therapy intensity, motivate users through engaging, interactive environments, and improve access to rehabilitation services in both clinical and home settings. Usability assessment is essential to ensure effective, engaging, and accessible interventions.[9]

Songkhla Hospital has implemented an IMC service tailored to stroke survivors since 2019, delivered through 2 intermediate beds, outpatient services, and outreach rehabilitation, including home-based and community-based rehabilitation. Due to infrastructure limitations, these services are limited to outpatient-based and home-based models, with no intensive inpatient rehabilitation available. This study aimed to evaluate the outcomes of these two service delivery models, focusing on functional outcomes as measured by the Barthel Index (BI), to identify current limitations and opportunities for improving stroke rehabilitation care in Songkhla Hospital.

The objectives of this study are twofold: (1) to compare patient characteristics (age, gender, comorbidities, stroke severity and type) and initial functional status between home-based and outpatient-based groups, and (2) to assess differences in functional outcomes (BI changes over time) between the two groups using standard t-tests and propensity score matching to account for potential biases. We hypothesized that home-based rehabilitation would be non-inferior to outpatient-based rehabilitation in BI gains, with a margin of 1.85 points.

Methods

Study design

This report is a retrospective observational cohort design using Propensity Score Matching. Chart review to analyze IMC rehabilitation stroke patients at Songkhla Hospital from October 2022 to September 2025. The Songkhla Hospital Institutional Review Board granted ethical approval (approval number SKH IRB 2026-Md-In3-1004, October 22, 2025). This study has been reported according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for observational studies.

Participants

Eligible cases included IMC stroke patients who had received rehabilitation services through either the outpatient-based or home-based model. Exclusion criteria were: (1) deceased patients (death occurring within 2 weeks after hospital discharge), n = 68, (2) incomplete medical records (BI scores at 2 weeks and 3 months), n = 38, and (3) patients achieving a BI score of 20 (indicating full functional independence) at 2 weeks post-stroke, n = 148. A total of 204 patients were included, with 102 in the home-based group and 102 in the outpatient-based group (Figure 1).

Data collection

Data were extracted from medical records, including:

- Demographics: age, gender.
- Premorbid health status: presence of dyslipidemia (DLP), hypertension (HT), diabetes mellitus (DM), heart disease, atrial fibrillation (AF), and previous stroke.
- Stroke characteristics: Type (ischemic or hemorrhagic), side (left or right), National Institutes of Health Stroke Scale (NIHSS) score at admission to acute care, and length of stay (LOS) in acute care.
- Rehabilitation outcomes: BI scores at admission (initial), 2 weeks, 3 months, and 6 months post-stroke plus BI gains between these time points.
- Care delivery: number of physical therapy (PT) and occupational therapy (OT) sessions.
- Home-based program: PT and/or OT delivered therapy, 45 minutes per session, 1 to 2 sessions per month.
- Outpatient-based program: PT and OT delivered therapy, 45 minutes per session, 1 to 2 sessions per week.
- Complications and impairments: Presence of complications (e.g., joint stiffness, pneumonia, recurrent stroke, urinary tract infection), speech impairments (aphasia, dysarthria), swallowing difficulties, and spasticity (Modified Ashworth Scale).

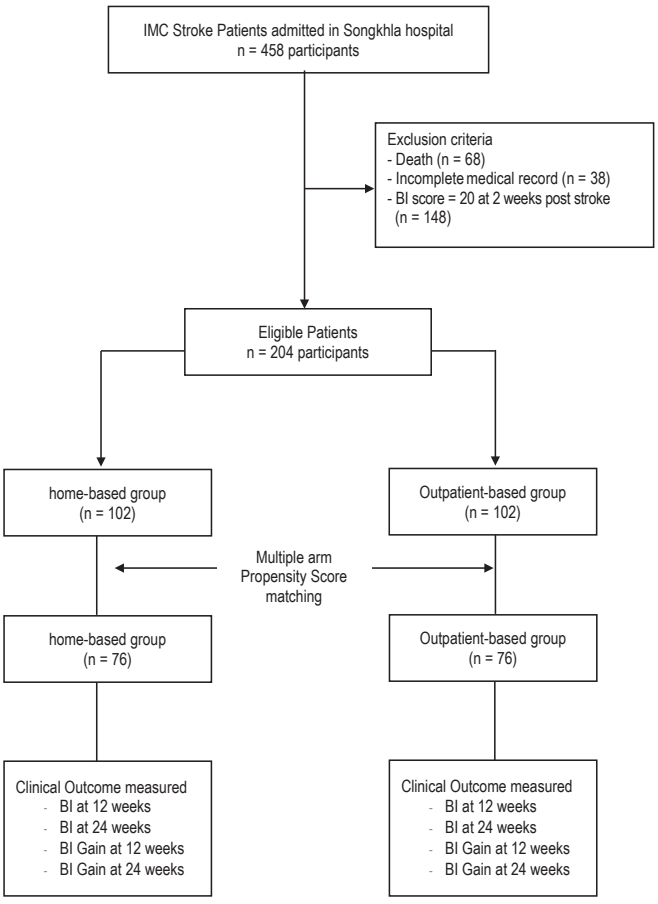

Figure 1. Flow of participants through the study
IMC, Intermediate care; BI, Barthel Index

- Dependency status: categorized at 2, 12 and 24 weeks post-stroke based on BI scores (no disability: 20; mild disability: 15 to 19; moderate disability: 10 to 14; severe disability: 5 to 9; very severe disability: 0 to 4).

Sample size

The sample size was calculated using the non-inferiority margin of 1.85, which represents the Minimal Clinically Important Difference (MCID) for the BI in stroke patients[10] with a standard deviation of 4.94 in clinical endpoint BI at 6 months after stroke, *p*-value = 0.05, power 0.80, and ratio sample size 1:1 (matching). The required sample size was 178 participants (89 per group).

Statistical analysis

Descriptive statistics were used to summarize patient characteristics and outcomes. Continuous variables (e.g., age, BI scores, number of therapy sessions) are reported as means (SD) or medians (interquartile ranges, IQR) for non-normally distributed data (confirmed by Shapiro-Wilk tests, $p < 0.001$ for most variables). Categorical variables (e.g., gender, complications) are reported as numbers and percentages. Group comparisons used:

- t-tests or Mann-Whitney tests for continuous variables, depending on normality.
- Chi-squared tests for categorical variables.
- Propensity score matching to adjust for potential confounding factors and to evaluate the unbiased effect of the service model on outcomes.
- Non-inferiority statistics to assess equivalence in dependency status at 3 and 6 months.

Statistical significance was set at $p < 0.05$. Analyses were conducted using appropriate statistical software.

Results

Patient characteristics

A total of 204 patients were included, with 112 (54.9%) males and 92 (45.1%) females. The home-based group (n = 102) had a higher proportion of females (52.0% vs. 38.2%, SMD = 0.27) and a higher mean age (68.1 (SD = 12.4) vs. 62.8 (SD = 12.9) years, SMD = 0.42) than the outpatient-based group (n = 102). No significant differences were found in comorbidities (DLP, HT, diabetes, heart disease, AF, previous stroke), stroke type (ischemic vs. hemorrhagic), stroke side, or LOS in acute care (Table 1).

Stroke severity and functional outcomes

There was a non-statistically significant trend suggesting that the outpatient-based group presented with higher median NIHSS scores (home-based: 6 [IQR: 4–11] vs. outpatient-based: 8 [IQR: 4–14], $p = 0.180$), a longer median LOS (home-based: 4 [IQR: 3–7] vs. outpatient-based: 5 [IQR: 3–7], $p = 0.327$), and lower median initial BI scores (home-based: 6 [IQR: 4–8] vs. outpatient-based: 5 [IQR: 2–7], $p = 0.036$) (Table 2). The outpatient-based group also demonstrated greater, longer-term BI gains from baseline to 24 weeks (home-based: 10 [IQR: 4–14] vs. outpatient-based: 12 [IQR: 7–14], $p = 0.202$), as well as from 2 weeks to 24 weeks (home-based: 4 [IQR: 2–8] vs. outpatient-based: 6 [IQR: 2–9], $p = 0.071$), although these differences did not reach statistical significance.

Interestingly, BI scores in the outpatient-based group tended to be lower than those in the home-based group at multiple time points: at 2 weeks (home-based: 12 [IQR: 6–15] vs. outpatient-based: 10 [IQR: 6–12], $p = 0.040$), at 12 weeks (home-based: 14 [IQR: 9–19] vs. outpatient-based: 12 [IQR: 9–17], $p = 0.055$), and at 24 weeks (home-based: 18 [IQR: 13–20] vs. outpatient-based: 17 [IQR: 12–20], $p = 0.655$). However, median BI gains over shorter time intervals—baseline to 2 weeks (home-based: 5 [IQR: 1–8] vs. outpatient-based: 5 [IQR: 2–7], $p = 0.936$) and 2 weeks to 12 weeks (home-based: 2 [IQR: 0–5] vs. outpatient-based: 2 [IQR: 0–5], $p = 0.950$)—were similar.

Care delivery and complications

The outpatient-based group received significantly more therapy sessions than the home-based group: median PT sessions were 10 (IQR: 7–17) vs. 3 (IQR: 2–4; $p < 0.001$), and median OT sessions were 8 (IQR: 3–14) vs. 1 (IQR: 0–2; $p < 0.001$). Complications were more frequent in the outpatient-based group (26.5% vs. 14.7%, $p = 0.038$), particularly joint stiffness (25.5% vs. 13.7%, $p = 0.034$). No statistically significant differences were observed in pneumonia (home-based: 6.9% vs. outpatient-based: 3.9%, $p = 0.352$), recurrent stroke (home-based: 6.9% vs. outpatient-based: 10.8%, $p = 0.324$), or urinary tract infections (home-based: 1.0% vs. outpatient-based: 2.0%, $p = 0.561$). Speech impairments, swallowing difficulties, and spasticity were also comparable between the groups (Table 3).

There were non-statistically significant trends indicating a higher occurrence of pressure ulcers in the home-based group (4.9% vs. 2.0%, $p = 0.249$) and recurrent stroke in the outpatient-based group (10.8% vs. 6.9%, $p = 0.324$), although neither of these trends reached statistical significance.

Dependency status

As shown in Table 4, both groups demonstrated a high proportion of very severe and severe disability at the initial time point (home-based: very severe 32.4%, severe 48.0%; outpatient-based: very severe 40.2%, severe 51.0%), with these proportions gradually decreasing over time in both cohorts. Interestingly, although the outpatient-based group showed a higher percentage of very severe and severe disability at baseline, at 3 months (home-based: very severe 6.9%, severe 18.6% vs. outpatient-based: very severe 3.9%, severe 23.5%) and 6 months (home-based: very severe 4.9%, severe 11.8% vs. outpatient-based: very severe 2.9%, severe 14.7%), the home-based group had a greater proportion of patients remaining in these more dependent categories;

Table 1. Patient demographics, clinical characteristics, and prognostic factors: a comparison between home-based and outpatient-based stroke rehabilitation programs

Characteristics	Original cohort			Propensity-matched cohort		
	Home-based	Outpatient-based	SMD	Home-based	Outpatient-based	SMD
n (%)	102 (50.0)	102 (50.0)		76 (50.0)	76 (50.0)	
Female[1]	53 (52.0)	39 (38.2)	0.27	43 (56.6)	44 (57.9)	0.02
Age[2]	68.1 (12.4)	62.8 (12.9)	0.42	65.8 (12.4)	65.2 (12.0)	0.04
Comorbidities[1]	91 (89.2)	86 (84.3)		66 (86.8)	66 (86.8)	0.00
Hypertension[1]	75 (73.5)	72 (70.6)	0.06	53 (69.7)	55 (72.4)	0.05
Diabetes[1]	32 (31.4)	26 (25.5)	0.13	22 (28.9)	23 (30.3)	0.02
Dyslipidemia[1]	47 (46.1)	39 (38.2)	0.15	32 (42.1)	32 (42.1)	0.00
Previous stroke[1]	31 (30.4)	24 (23.5)	0.15	20 (26.3)	20 (26.3)	0.00
Atrial fibrillation[1]	9 (8.8)	7 (6.9)	0.07	7 (9.2)	7 (9.2)	0.00
Heart disease[1]	14 (13.7)	10 (9.8)	0.12	9 (11.8)	10 (13.2)	0.03
Premorbidity[1]						
Independent free-hand	82 (80.4)	89 (87.3)		65 (85.5)	65 (85.5)	
Independent with gait aids	16 (15.7)	12 (11.8)		10 (13.2)	10 (13.2)	
Need assist or cannot walk	4 (3.9)	1 (1.0)	0.22	1 (1.3)	1 (1.3)	0.00
Type of stroke[1]						
Ischemia	74 (72.5)	74 (72.5)		53 (69.7)	58 (76.3)	
Hemorrhage	28 (27.5)	28 (27.5)	0.00	23 (30.3)	18 (23.7)	0.14
Side of stroke[1]						
Left	46 (45.1)	53 (52.0)		39 (51.3)	40 (52.6)	
Right	56 (54.9)	49 (48.0)	0.13	37 (48.7)	36 (47.4)	0.02
Dysphagia[1]	24 (23.5)	26 (25.5)	0.05	19 (25)	19 (25)	0.05
Aphasia[1]	9 (8.8)	15 (14.7)		8 (10.5)	8 (10.5)	
Dysarthria[1]	53 (52.0)	60 (58.8)	0.24	43 (56.6)	43 (56.6)	0.00
Cognitive impairment[1]	22 (21.6)	25 (24.5)	0.06	17 (22.4)	18 (23.7)	0.03
Spastic[1]						
MAS I	1 (1.0)	5 (4.9)		1 (1.3)	4 (5.3)	
MAS I +	1 (1.0)	1 (1.0)	0.23	1 (1.3)	1 (1.3)	0.22
NIHSS[2]	8.4 (6.2)	9.3 (6.2)	-0.09	8.5 (6.2)	9.2 (6.2)	-0.11
LOS[2]	6.6 (7.8)	7.3 (7.1)	-0.14	6.4 (6.2)	6.6 (6.6)	-0.02
BI Initial[2]	6.1 (4.1)	4.9 (3.5)	0.30	5.8.(3.8)	5.6 (3.5)	0.05
Treatment[1]				62 (81.6)	61 (80.3)	
Medication	79 (77.5)	78 (76.5)		8 (10.5)	8 (10.5)	
rtPA	10 (9.8)	13 (12.7)		2 (2.6)	2 (2.6)	
rtPA + thrombectomy	4 (3.9)	2 (2.0)		4 (5.3)	5 (6.6)	
Surgery	9 (8.8)	9 (8.8)	0.14	3.1 (1.7)	11.8 (7.3)	0.05
Number of PT session[2]	3.1 (1.5)	12.1 (6.8)	-1.82	1.6 (1.9)	8.5 (6.6)	-1.63
Number of OT session[2]	1.4 (1.7)	8.7 (6.3)	-1.57	8.5 (6.2)	9.2 (6.2)	-1.43

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

SMD, standardised mean difference; BI, Barthel Index; NIHSS, The National Institutes of Health Stroke Scale; LOS, Length of stay; rtPA, recombinant tissue plasminogen activator; OT, occupational therapy; PT, physical therapy; MAS, The Modified Ashworth Scale, BI initial, BI score at admission

however, these trends did not reach statistical significance.

The only time point at which a statistically significant difference in disability level between groups was observed was at 3 months post-stroke (p = 0.047).

Propensity score matching

To mitigate potential confounding by indications arising from baseline differences between the home-based and outpatient-based groups, a propensity score (PS) was estimated using multivariable logistic regression. Covariates included gender, age, HT, DM, DLP, AF, premorbid functional status, treatment type, recurrent stroke, joint stiffness, initial BI, swallowing impairment, speech impairment, cognitive impairment, and NIHSS score (Table 5). The predicted probability of receiving home-based rehabilitation defined the PS for each patient.

Multiple-arm propensity score matching without replacement was performed within propensity score strata (deciles), seeded iteratively to minimize the standardised mean differences (SMD). The optimal seed (370) yielded the smallest mean pairwise SMD of 0.0428, indicating excellent covariate balance (Figure 2). After matching, 76 patients remained in each group (n = 152 total).

Table 2. Stroke severity and outcome of rehabilitation at different time points: comparison between home-based and outpatient-based stroke rehabilitation programs

Variables Median (IQR)	Home-based (n = 102)	Outpatient-based (n = 102)	Test Statistic	*p-value
NIHSS (at acute admission)	6 (4–11)	8 (4–14)	Z = -1.34	0.180[a]
LOS	4 (3–7)	5 (3–7)	Z = -0.98	0.327[a]
BI Initial	6 (4–8)	5 (2–7)	Z = -2.09	0.036[a]
BI at 2 weeks	12 (6–15)	10 (6–12)	Z = -2.05	0.040[a]
BI at 12 weeks	14 (9–19)	12 (9–17)	Z = -1.92	0.055[a]
BI at 24 weeks	18 (13–20)	17 (12–20)	Z = -0.45	0.655[a]
BI Gain initial to 2 weeks	5 (1–8)	5 (2–7)	Z = -0.08	0.936[a]
BI Gain 2 weeks to 12 weeks	2 (0–5)	2 (0–5)	Z = -0.06	0.950[a]
BI Gain 2 weeks to 24 weeks	4 (2–8)	6 (2–9)	Z = -1.80	0.071[a]
BI Gain Initial to 12 weeks	8 (3–12)	7 (4–11)	Z = -0.14	0.887[a]
BI Gain Initial to 24 weeks	10 (4–14)	12 (7–14)	Z = -1.27	0.202[a]

[a]Mann-Whitney test, *$p < 0.05$ indicate statistical significance; SMD, standardised mean difference
NIHSS, The National Institutes of Health Stroke Scale; LOS, Length of stay; BI, Barthel Index

Table 3. Rehabilitation care delivery, specific impairments due to stroke, and complications: comparison between home-based and outpatient-based stroke rehabilitation programs

Variables	Home-based (n = 102)	Outpatient-based (n = 102)	*p-value
Complications			
Joint Stiffness (Upper extremities)[1]	14 (13.7)	26 (25.5)	0.034[b]
Pressure sore[1]	5 (4.9)	2 (2.0)	0.249[b]
Pneumonia[1]	7 (6.9)	4 (3.9)	0.352[b]
Recurrent Stroke[1]	7 (6.9)	11 (10.8)	0.324[b]
UTI [1]	1 (1.0)	2 (2.0)	0.561[b]
Complex stroke impairments			
Aphasia[1]	9 (8.8)	15 (14.7)	0.107[b]
Dysarthria[1]	53 (52.0)	60 (58.8)	
Dysphagia[1]	24 (23.5)	26 (25.5)	0.933[b]
Spasticity[1]			
MAS I	1 (1.0)	5 (4.9)	
MAS I +	1 (1.0)	1 (1.0)	0.253[b]
Access to Care			
Number of OT sessions[3]	1 (0–2)	8 (3–14)	< 0.001[a]
Number of PT sessions[3]	3 (2–4)	10 (7–17)	< 0.001[a]

[1]Number (%), [3]median (IQR), [a]Mann-Whitney test, [b]Chi-squared test; UTI, urinary tract infection; MAS, The Modified Ashworth Scale; OT, occupational therapy; PT, physical therapy

Table 4. Comparison of Barthel index severity classes between home-based and outpatient-based stroke rehabilitation programs at 0, 2, 12 and 24 weeks after stroke

Time point	Program Number (%)	Severity class					*p-value
		Very severe disability (BI 0-4)	Severe disability (BI 5-9)	Moderate disability (BI 10-14)	Mild disability (BI 15-19)	No disability (BI 20)	
0 weeks	Home-based	33 (32.4)	49 (48)	16 (15.7)	4 (3.9)	0 (0.0)	0.143
	Outpatient	41 (40.2)	52 (51)	8 (7.8)	1 (1.0)	0 (0.0)	
2 weeks	Home-based	12 (11.8)	33 (32.4)	28 (27.5)	28 (27.5)	1 (1.0)	0.068
	Outpatient	11 (10.8)	40 (39.2)	38 (37.3)	13 (12.7)	0 (0.0)	
12 weeks	Home-based	7 (6.9)	19 (18.6)	26 (25.5)	32 (31.4)	8 (17.6)	0.047*
	Outpatient	4 (3.9)	24 (23.5)	42 (41.2)	23 (22.5)	9 (8.8)	
24 weeks	Home-based	5 (4.9)	12 (11.8)	21 (20.6)	25 (24.5)	39 (38.2)	0.852
	Outpatient	3 (2.9)	15 (14.7)	19 (18.6)	29 (28.4)	36 (35.3)	

*Statistically significant; BI, Barthel Index

Table 5. Derivation of propensity scores via multivariable logistic regression model

Equation parameters	Coefficient	Standard error	95% confidence interval	*p*-value
Female	-0.44	0.32	-1.07, 0.18	0.166
Age	-0.03	0.01	-0.06, -0.01	0.015
Hypertension	0.17	0.36	-0.53, 0.88	0.634
Diabetes mellitus	-0.28	0.37	-1.01, 0.44	0.440
Dyslipidemia	-0.29	0.34	-0.94, 0.37	0.396
Atrial fibrillation	-0.21	0.59	-1.37, 0.95	0.724
Recurrent stroke	0.80	0.58	-0.34, 1.94	0.168
Independent ambulation with gait aid	-0.39	0.48	-1.34, 0.55	0.416
Need assist or cannot walk	-0.82	1.23	-3.23, 1.59	0.506
Dysphagia-On NG	-0.56	0.57	-1.68, 0.56	0.329
Dysphagia-Oral feeding	-0.35	0.66	-1.64, 0.93	0.592
Aphasia	0.79	0.64	-0.46, 2.05	0.216
Dysarthria	0.42	0.35	-0.27, 1.12	0.234
Cognitive impairment	0.22	0.47	-0.70, 1.15	0.637
NIHSS	-0.01	0.04	-0.08, 0.06	0.737
Treatment with rtPA	-0.16	0.52	-1.17, 0.86	0.763
Treatment with surgery	-0.45	0.66	-1.75, 0.85	0.494
Joint stiffness	0.89	0.44	0.03, 1.76	0.042
BI initial	-0.07	0.05	-0.16, 0.02	0.128

On NG, nasogastric tube feeding; NIHSS, National Institutes of Health Stroke Scale; BI, Barthel Index

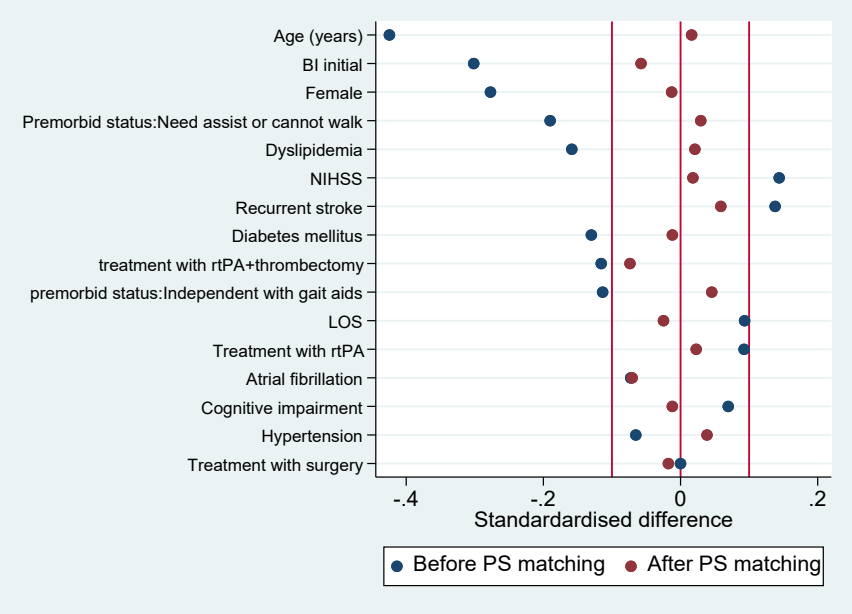

Figure 2. Standardised mean difference (SMD) before and after Propensity Score matching

BI, Barthel Index; NIHSS, The National Institutes of Health Stroke Scale; LOS, Length of stay; rtPA, recombinant tissue plasminogen activator; PS, Propensity Score

Regarding the characteristics of the propensity-matched cohort, all baseline variables achieved an SMD < 0.10 and non-significant *p*-values, confirming a successful balance between the groups. Notably, initial BI scores (home-based: 5.8 [SD = 3.8] vs. outpatient-based: 5.6 [SD = 3.5], $p = 0.739$) and NIHSS scores (home-based: 8.5 [SD = 6.2] vs. outpatient-based: 9.2 [SD = 6.2], $p = 0.497$) were equivalent (Table 1).

Table 6 displays the results of the two one-sided t-tests (TOST) for non-inferiority, using a pre-specified margin (Δ) of 1.85 BI points. In the matched cohort, home-based rehabili-

Table 6. Functional outcomes using non inferior test (two one side t-test, tostt)

Clinical endpoints Mean (SD)	Home-based (n = 76)	Outpatient-based (n = 76)	*p*-value
BI at 12 weeks	13.4 (5.4)	12.2 (5.1)	0.221
BI at 24 weeks	15.5 (5.3)	14.9 (5.5)	0.064
BI Gain initial to 12 weeks	7.6 (4.9)	6.6 (4.4)	0.129
BI Gain initial to 24 weeks	9.4 (5.1)	9.7 (5.2)	0.035*

*Statistically significant for non-inferiority; BI, Barthel Index

tation demonstrated non-inferiority for BI gain from baseline to 24 weeks (p = 0.035), but not at 12 weeks (p = 0.129). Furthermore, absolute BI scores at 12 weeks and 24 weeks did not meet the non-inferiority criteria (p = 0.221 and p = 0.064, respectively).

Discussion

Patients who entered the home-based and outpatient-based stroke rehabilitation programs differed clinically and demographically. The home-based group was significantly older and comprised a higher proportion of female patients. Non-statistically significant trends were observed in several clinical outcomes. The BI was used as the principal outcome measure due to its high validity and reliability for functional assessment in stroke populations.[11] BI scores correlate strongly with other established outcomes measures such as the Modified Rankin Scale (mRS) and the SF-36 physical function domain, supporting its appropriateness for comparative analysis and long-term follow-up in community rehabilitation settings.[12,13]

After propensity score matching, significant differences in therapy exposure persisted between groups.

The outpatient-based group continued to receive substantially more PT sessions than the home-based group (1.6 (SD = 1.9) vs. 8.5 (SD = 6.6); SMD = –1.63) and more OT sessions (8.5 (SD = 6.2) vs. 9.2 (SD = 6.2); SMD = –1.43), indicating that marked disparities in rehabilitation dosage remained even after adjustment for baseline characteristics. After propensity score matching, none of the differences in clinical outcomes between the two groups reached statistical significance, except that the home-based group is non-inferior to the outpatient-based group (p = 0.035).

Reconciling these findings requires consideration of the underlying differences between the two cohorts. In real-world practice, home-based patients tend to be older and more often female, whereas outpatient-based patients more frequently present with indicators of more severe stroke, including higher NIHSS scores, lower initial BI, and a non-statistically significant trend toward higher recurrent stroke rates. At the same time, the outpatient-based group received substantially more therapist contact. These baseline and service-delivery differences help explain the observed pattern of outcomes.

Despite receiving far fewer therapy sessions, the home-based group achieved short- and intermediate-term BI gains comparable to the outpatient-based group, with many time intervals showing identical median improvements. The finding is not that the outpatient-based group is superior, but rather that the home-based group is statistically non-inferior to the outpatient-based group at 24 weeks. The p-value of 0.035 confirms that the difference is within the equivalence margin, not that one group is “better” than the other.

These findings are broadly consistent with reports from other regions of Thailand. Data from Korat Province showed that 79.0% of stroke survivors in 2017 and 82.0% in 2022 achieved either mild disability or no disability at follow-up (BI 15–20) under a similar IMC-style, low-dose outpatient rehabilitation model.[14] In comparison, our outcomes at 6 months were fairly close: 62.7% in the home-based cohort (24.5% mild + 38.2% no disability) and 63.7% in the outpatient-based cohort (28.4% mild + 35.3% no disability). The slight difference may be partly attributable to selection bias, as our analysis excluded patients who had died, those with missing data, and those who had already achieved full independence (BI = 20) at 2 weeks—factors that may shift the overall distribution toward more functionally impaired cases at follow-up.

The equivalent outcomes observed in our home-based and outpatient-based groups—despite substantial disparities in therapy dosage—may reflect a common ceiling of recovery determined primarily by stroke lesion severity and initial impairment (mean NIHSS ~8.5–9.2 in both groups after matching). However, it is also possible that more intensive, neuroscience-guided rehabilitation could elevate this ceiling by enhancing neuroplasticity and accelerating functional gains beyond what is achievable with low-dose therapy alone.

In contrast, intensive inpatient rehabilitation programs demonstrate substantially greater gain.[15-17] At Ramathibodi Hospital,[18] a structured 28.9-day inpatient rehabilitation program achieved a discharge BI of 17.4—similar to the BI level our patients reached only approximately 12 weeks post-stroke. This highlights the influence of rehabilitation intensity and structured multidisciplinary care on accelerating functional recovery.

Overall, these findings imply that both IMC models provide meaningful recovery, but neither fully realizes the potential gains achievable with higher-intensity, neuroscience-guided rehabilitation. The modest improvements observed across both groups align with expectations for low-dose, community-based rehabilitation and contrast with the more robust gains in high-intensity inpatient programs.

The outpatient-based group showed a higher percentage of recurrent stroke events, whereas the home-based group demonstrated higher rates of pneumonia and pressure ulcers, despite exhibiting a trend toward milder disability at baseline.

These patterns may reflect real-world clinical decision-making in which patients perceived as having more severe, medically complex conditions or being at higher risk for deterioration are preferentially directed toward outpatient-based care, while those with comparatively milder presentations are managed at home—unless socioeconomic, logistical, or caregiver-related constraints dictate otherwise.

The only complication that appeared more common in the outpatient-based group was joint stiffness. This difference may be attributable to increased frequency of in-person encounters with healthcare staff, leading to heightened detection of stiffness or spasticity during hands-on assessments, rather than representing a true increase in severity. This interpretation is supported by the absence of a corresponding trend toward higher Modified Ashworth Scale ratings, suggesting

that the observed difference may reflect detection bias rather than a genuine difference in spasticity burden. Interestingly, the home-based group demonstrated non-significant trends toward higher rates of preventable complications such as pneumonia and pressure ulcers, despite initially presenting with milder disability. This may reflect reduced direct supervision, less frequent reassessment, and variation in caregiver skill in the home environment.

The reliability of these findings is strengthened by the hospital's integrated health information system, which automatically registers all acute stroke cases linked to national payment programs. This ensured near-complete case capture during the study period. However, the number of deceased patients and those with incomplete data could not be verified, as these cases were excluded during extraction. The final matched sample size (n = 152) was lower than the calculated sample size (n = 178), which may have reduced statistical power. This limitation may have introduced selection bias and should be considered as an overestimation when interpreting the overall representativeness of the results.

It is important to avoid drawing the incorrect conclusion that home-based rehabilitation is inherently as effective as outpatient-based therapy, or that home-based care should replace outpatient services entirely. The apparent similarity in outcomes between the two groups is likely influenced by the overall low rehabilitation dose delivered in both models, which allows the effects of natural neurological recovery to dominate the trajectory of functional improvement. When therapy intensity is low in both settings, the differences attributable to treatment dose become less visible, making the two models appear more similar than they may truly be under higher-intensity conditions. Therefore, the near-equivalent outcomes observed in this study should not be interpreted as evidence that home-based rehabilitation alone is sufficient, nor that outpatient-based therapy offers no additional benefit.

Future studies should explore strategies to enhance therapy dose, specificity, and accessibility within the IMC framework. Potential avenues include integrating advanced rehabilitation technologies (e.g., robotic-assisted gait training, telerehabilitation platforms, neuromodulation), revising reimbursement policies that limit therapy intensity, and considering broader financial reforms such as expanded insurance coverage or government-supported rehabilitation benefits.

Evaluations should include not only clinical outcomes but also health economic analyses, which may help demonstrate the long-term value of enhanced rehabilitation services through reduced disability, lower downstream medical costs, and improved quality-adjusted life years (QALYs).

Conclusions

Stroke survivors in this general hospital are accessing outpatient-based versus home-based rehabilitation. Home-based rehabilitation can achieve non-inferior outcomes despite a substantially lower therapy dosage. Therefore, the near-equivalent outcomes observed in this study should not be interpreted as evidence that home-based rehabilitation alone is sufficient, nor that outpatient-based therapy offers no additional benefit. Increasing therapy intensity and integrating advanced rehabilitation technologies may further improve functional recovery within the IMC framework. These results highlight opportunities for improving access to and the quality of rehabilitation care.

Conflict of interest declaration

The authors declare no conflicts of interest.

Generative AI declaration

The authors confirm that all core intellectual contributions to this manuscript, including conceptualization, data analysis planning and execution, drafting of the narrative flow, conclusion, and discussion, were performed entirely through human reasoning and effort. A large language model (Grok) was used solely for grammar checking and minor improvements to sentence structure in the final drafts, without generating any original content, ideas, or analyses.

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Data availability

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

Author contributions

Phuangphet Siriloetthananon: conceptualization, methodology, data curation, formal analysis, writing-original draft, writing – review and editing,

Nataporn Nakkaew: data curation, visualization, writing, review and editing.

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Appendix

Table 7. Functional outcomes using non inferior test (two one side *t*-test, tostt), original cohort

Clinical endpoints	Home-based (n = 102)	Outpatient-based (n = 102)	*p*-value
BI at 12 weeks[2]	13.7 (5.5)	12.4 (4.9)	0.227
BI at 24 weeks[2]	15.5 (5.4)	15.3 (5.2)	0.013*
BI Gain initial to 12 weeks[2]	7.6 (5.0)	7.4 (4.5)	0.005*
BI Gain initial to 24 weeks[2]	9.4 (5.5)	10.3 (5.1)	0.120

[2]mean(SD), *statistically significant

Table 8. Outcome of rehabilitation at different point of time: comparison between home-based and outpatient-based stroke rehabilitation programs, propensity-matched cohort

Variable	Home-based (n = 76)	Outpatient-based (n = 76)	Test Statistic	*p*-value
BI Initial[3]	6 (4–8)	6 (4–7)	Z = 0.47	0.635[a]
BI at 2 weeks[3]	6 (4–11)	11 (6–12)	Z = 1.02	0.307 [a]
BI at 12 weeks[3]	14 (9–18)	12 (8–17)	Z = 1.42	0.157 [a]
BI at 24 weeks[3]	18 (13–20)	17 (12–20)	Z = 0.53	0.593 [a]
BI Gain Initial to 12 weeks[3]	8 (4–11)	7 (2–10)	Z = 1.31	0.191 [a]
BI Gain Initial to 24 weeks[3]	10 (6–14)	11 (6–13)	Z = 0.41	0.683 [a]

[3]median(IQR) , [a]Mann-Whitney test

Original Article

Ambulation Outcomes After Robotic Gait Rehabilitation in a Regional Hospital: A 2-Year Retrospective Observational Study

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ABSTRACT

Objectives: To evaluate changes in the level of walking ability as measured by the Functional Ambulation Category (FAC) following 10 sessions of robotic gait rehabilitation

Study design: A retrospective observational study

Settings: Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital, a public regional hospital in Thailand

Participants: A total of 162 patients diagnosed with stroke, traumatic brain injury (TBI), or incomplete spinal cord injury (SCI), who presented with ambulation impairments and who received robotic gait rehabilitation at a regional hospital between November 2022 and November 2024.

Methods: Medical records of patients with ambulation impairments who received robotic gait rehabilitation at a regional hospital between November 2022 and November 2024, completed 10 training sessions, and had available pre- and post-training ambulation outcome data were included in the analysis. General demographic characteristics, diagnoses and ambulation outcomes, including the FAC, were collected. FAC scores before training and after 10 training sessions were compared. Associations between clinical variables and improvements in FAC were analyzed.

Result: Among the 162 patients who received robotic gait rehabilitation at a regional hospital, 48 were excluded due to incomplete training or missing data, leaving 114 patients for analysis. More than half of the patients (54%) demonstrated improvement in FAC scores after 10 training sessions. No patients experienced a reduction in FAC following training. Factors significantly associated with FAC improvement included the interval from the neurological event and the patients' baseline FAC. Minor complications were reported, including muscle strain in eight patients and dizziness in one patient.

Conclusion: This retrospective analysis of 2 years of robotic gait rehabilitation services at a regional hospital demonstrated that more than half of the patients achieved at least a one level improvement in the FAC following training. Factors associated with FAC improvement included the interval from the neurological event and the patients' baseline FAC.

Keywords: Gait disorders, neurologic, robotics, rehabilitation, stroke, spinal cord injuries

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Introduction

Robotic gait rehabilitation has been shown to be an effective intervention for improving ambulation in patients with stroke, spinal cord injury (SCI), and other neurological disorders. However, a major limitation of this approach is its high cost.[1] Previous studies have demonstrated that the robot-assisted gait training (RAGT) facilitates gait recovery after stroke.[2-4] Among RAGT devices, end-effector and exoskeleton systems are the most commonly reported modalities.[5-9] Some evidence suggests that end-effector systems may be more effective in improving walking ability in patients with subacute stroke.[10,11] In addition to stroke, robotic gait devices have also been used to improve gait patterns in patients with SCI.[12,13] Nevertheless, achieving optimal outcomes requires well-trained physical therapists with a thorough understanding of the principles underlying robotic gait training devices.

At Maharat Nakhon Ratchasima Hospital, a tertiary regional referral center in northeastern Thailand, a commercial end-effector-type RAGT device (Figure 1) was introduced in November 2022. Patients with stroke, traumatic brain injury (TBI), or SCI who presented with gait impairment were prescribed robotic gait rehabilitation by physiatrists, typically at a weekly frequency. Training sessions were conducted by specialized, experienced physiotherapists, with session durations ranging from 10 to 40 minutes, depending on patient endurance. Functional Ambulation Category (FAC) scores were assessed at baseline by physiatrists and physiotherapists and were reassessed after completion of 10 robotic gait training sessions.

This robotic gait rehabilitation service represents a pioneering model in an Asian country. To date, no studies have evaluated changes in pre- and post-training FAC scores over

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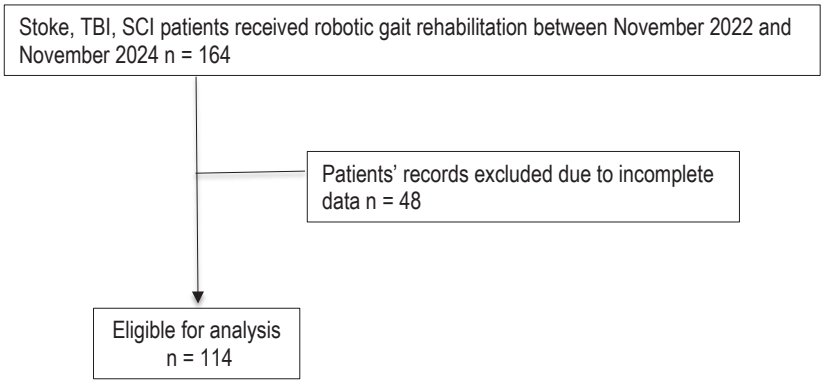

Figure 1. Participants

a 24-month period of robotic gait rehabilitation in real-world clinical practice in this setting. Therefore, the aim of this study was to evaluate ambulation outcomes following robotic gait rehabilitation, with a primary focus on changes in FAC scores before and after training.

Methods

This study retrospective observational study was conducted at the Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital. Electronic medical records and robotic gait training data of all patients who received robotic gait rehabilitation between November 2022 and November 2024 were reviewed. The patients who completed 10 training sessions were included. Patients with incomplete ambulation outcome data were excluded.

General demographic data collected included age, sex, diagnosis (stroke, TBI , or spinal cord injury), interval from the neurological event, and health coverage. Ambulation outcomes were measured using the FAC before and after training, assessed by both physiatrists and physiotherapists, and recorded by the attending physiotherapists. The frequency of robotic gait rehabilitation and concurrent treatments—such as conventional physical therapy, traditional massage, and transcranial magnetic stimulation—was also documented. Complications related to robotic gait training were recorded. For patients who received more than one course of robotic gait rehabilitation, only the first course was included in the analysis.

Statistical analyses were performed using descriptive statistics for general demographic data such as age, gender, diagnosis, interval from the neurological events, health coverage, etc. Pre and post-training FAC are presented as descriptive statistics. The factors associated with FAC improvement were calculated by Fisher's exact test. Variables identified as potential confounders and those with a *p*-value < 0.10 in the univariable analysis were included in the multivariable logistic regression model. Age was categorized as < 60 years and ≥ 60 years prior to inclusion in the model. As this was a retrospective review of all eligible patients over a 24-month period, no formal sample size calculation was performed.

The present study was approved by the Ethics Committee of Maharat Nakhon Ratchasima Hospital (No.162/2024, approve on December 18, 2024) and was conducted in accordance with the STROBE guidelines.

Results

Over the 24-month study period, 162 patient records were initially identified. Of these, 48 cases were excluded due to incomplete ambulation outcome data, leaving 114 for comprehensive analysis. Patient demographic characteristics are summarized in Table 1. The patients' ages ranged from 17 to 87 years, with a predominance of male patients (72.8%). Stroke was the most common diagnosis. The interval from the neurological event and the robotic gait rehabilitation varied widely, ranging from 1 to 228 months. Hypertension was the most common comorbidity, affecting 36 patients (31.6%).

Table 2 shows the distribution of patients' pre- and post-training FAC. Initially, 20 patients (17.5%) had an FAC of 0, while 9 patients (7.9%) had the highest FAC score of 5. After

Table 1. Clinical characteristics of the patients (n = 114)

Characteristics	Number (%)
Mean age (years) (min-max)	54.48 (17-87)
Gender	
Male	83 (72.8)
Female	31 (27.2)
Diagnosis	
Stroke	80 (70.2)
TBI	23 (20.2)
SCI	11 (9.6)
Mean Interval after neurological events (months) (min-max)	13.95 (1-228)
Comorbidity	
Hypertension	36 (31.6)
Diabetes mellitus	18 (15.8)
Dyslipidemia	1 (0.9)
Health coverage	
UC	60 (52.6)
Government officer welfare	35 (30.7)
Social security	19 (16.7)

TBI, traumatic brain injury; SCI, spinal cord injury; UC, universal coverage

Table 2. Cross-tabulation of pre-training and post-training Functional Ambulation Categories (FAC)

Pre-training FAC (n)	Post-training FAC 0	Post-training FAC 1	Post-training FAC 2	Post-training FAC 3	Post-training FAC 4	Post-training FAC 5	Total
0	11	3	5	0	1	0	20 (17.5)
1	0	2	5	3	0	0	10 (8.8)
2	0	0	9	19	3	0	31 (27.2)
3	0	0	0	11	10	4	25 (21.1)
4	0	0	0	0	12	7	19 (16.7)
5	0	0	0	0	0	9	9 (7.9)
Total, n (%)	11 (9.6)	5 (4.4)	19 (16.7)	33 (28.9)	26 (22.8)	20 (17.5)	114 (100.0)

Table 3. Pre-treatment and post-treatment Functional Ambulation Classification (FAC) status and category transitions

Pre-treatment	Post- treatment: Dependent (FAC 0–3)	Post treatment: Independent (FAC 4–5)	Total, n (%)
Pre: Dependent (FAC 0–3)	67 (78.8%) (Remained dependent)	18 (21.2) (Gained independence)	85 (100%)
Pre: Independent (FAC 4–5)	0 (0.0%) (Lost independence)	29 (100.0%) (Remained independent)	29 (100%)
Total, n (%)	67 (58.8%)	47 (41.2%)	114

Table 4. Multivariate analysis of factors associated with Improved and unimproved Functional Ambulation Categories (FAC)

Factors	FAC improvement (n = 60)	FAC no improvement (n = 54)	*p*-value
Diagnosis			
Stroke	39 (65)	41 (75.93)	0.2
TBI	5 (8.33)	6 (11.11)	
SCI	16 (26.67)	7 (12.96)	
Interval from neurological events			
< 3 months	28 (46.67)	9 (16.67)	0.001
3-6 months	15 (25)	15 (27.78)	
> 6 months	17 (28.33)	30 (55.56)	
Training frequency/week			
< 3	15 (25)	19 (35.19)	0.306
> 3	45 (75)	35 (64.81)	
Received concomitant PT			
Yes	32 (53.33)	27 (50)	0.851
No	28 (46.67)	27 (50)	

TBI, traumatic brain injury; SCI, spinal cord injury; PT, physical therapy

training, the proportion of patients with an FAC of 0 decreased to 11 persons (9.6%), while those with an FAC of 5 increased to 20 (17.5%). This shift towards higher FAC indicates an improvement in functional ambulation levels. Of 114 patients, 54 (47.4%) showed no change in FAC, 44 (38.6%) improved by 1 level, 15 (13.2%) improved by 2 levels, and 1 (0.9%) improved by 4 levels. No patient experienced a reduction in FAC.

Pre- and post-training FAC levels stratified by gait independence are presented in Table 3. FAC scores of 0–3 were classified as dependent ambulation, whereas scores of 4–5 were classified as independent ambulation. Prior to training, 85 patients (74.6%) were classified as dependent ambulators, and 29 (25.4%) as independent ambulators. Following training, the proportion of dependent ambulators decreased to 67 patients (58.8%), and the proportion of independent ambulators increased to 47 patients (41.2%). Notably, 18 of the 85 patients (21.1%) who were initially gait-dependent achieved independent ambulation after training.

Univariable associations between factors and FAC improvement are shown in Table 4. The interval from the neurological event and pre-training FAC showed a significant association

Table 5. Multivariable logistic regression analyses of factors associated with improvement in Functional Ambulation Categories (FAC)

Factors	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)	*p*-value
Age < 60 years	1.08 (0.50, 2.35)	1.08 (.44, 2.58)	0.868
Interval from neurological events			
< 3 months	5.44 (2.15, 13.8)	4.46 (1.69, 11.68)	0.002
3-6 months	2.1 (0.77, 5.72)	2.01 (0.69, 5.87)	0.002
> 6 months	Ref.	Ref.	0.202
Pre-training FAC 0 -3	4.81 (1.85, 12.57)	3.69 (1.33, 10.26)	0.012
Training frequency			
> 3 times/week	1.63 (0.72, 3.65)	1.22 (0.49, 3.03)	0.667
Received concomitant PT	1.31 (0.62, 2.74)	1.07 (0.46, 2.48)	0.879

PT, physical therapy

with FAC improvement. Diagnosis, robot gait training frequency, and concomitant physical therapy did not show a statistically significantly association with FAC improvement. Multivariate analysis was performed and found that 2 variables were statistically significantly correlated with improvement in FAC were an interval from neurological event of less than 3 months and pre-training FAC 0-3, with adjusted odds ratios of 4.46 (95% CI: 1.70, 11.69) and 3.7 (95% CI: 1.33, 10.27), respectively. Multivariable logistic regression analysis was performed to identify factors associated with improvement in FAC (Table 5). After adjustment for potential confounders, patients with an onset of < 3 months had significantly higher odds of improvement compared with those with an onset of > 6 months (adjusted OR = 4.46, 95% CI: 1.70-11.87; p = 0.002). Patients with pre-training FAC scores of 0-3 also had significantly higher odds of improvement (adjusted OR = 3.70, 95% CI: 1.33-10.27; p = 0.012). However, age < 60 years, training frequency > 3 times per week, and receipt of concomitant physical therapy were not significantly associated with FAC improvement in the adjusted model.

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Concurrent treatments included conventional physical therapy, traditional massage, and transcranial magnetic stimulation. Of the 114 patients, 59 (51.8%) receiving conventional physical therapy, 1 (0.9%) received massage, and 1 (0.9%) received transcranial magnetic stimulation. There were reports of complications during robotics gait rehabilitation. The complications were 8 (7.0%) cases of muscle pain and 1 (0.9%) case of dizziness. These complications were mild and did not require additional medical treatment.

Discussion

Over 2 years of robotic gait rehabilitation, FAC improved in more than half (54.4%) of patients. Changes in FAC from pre-training to post-training show that most patients improved by 1 or 2 FAC levels. No patient experienced a decline in FAC either during or after the training program. These numbers represent real cases at a rural hospital who had received robotics-assisted gait rehabilitation as prescribed by physicians. The statistical numbers for selected cases and controlled environments may differ. Nevertheless, the outcomes of this study are consistent with previous studies.[1, 5] Compared with conventional physical therapy, robotic gait rehabilitation offers the advantages of providing intensive, repetitive, and task-specific training.[2-4] Previous studies have also suggested that robotic gait rehabilitation may enhance motor recovery.[5,10,11]

The factors associated with FAC improvement were the interval from the neurological event and pre-training FAC. Patients with an interval of less than 3 months from the neurological event had greater FAC improvement than those in the other groups. This may be associated with robotic gait rehabilitation, which promotes motor recovery.[5,10,11] The other factor, pre-training FAC, was found to be one of the factors associated with FAC improvement in a previous study.[5] The present study also found that initial FAC was associated with FAC improvement. Patients with FAC of 0 and 1 were included in more studies than those with FAC of 2 to 5.5, because patients with lower FAC are more likely to improve their FAC after training. This is not the case in this study, which included all patients regardless of their initial FAC.

The complications found in this study were few (7.9%) and minor. These findings suggest that robotic gait rehabilitation is a relatively safe rehabilitation procedure. However, further observation is still required to ensure that there are no major or life-threatening complications in robotic gait training. One problem of robot gait rehabilitation is the loss of follow-up patients. Of the initial 162 patients, only 114 completed 10 sessions of robotic gait rehabilitation. The reasons for loss of follow-up varied among the patients, such as the long duration of the 10 sessions (at least 10 days), caregivers being

unable to transport the patients to the treatment facility, etc. This problem had been partially solved by admitting the patients for inpatient robotic gait rehabilitation.

This study had some limitations. Firstly, this study was retrospective, so the authors could not provide data beyond what was recorded in medical records. Secondly, this study included heterogeneous neurological diagnoses (stroke, TBI, and SCI), each with different pathophysiological mechanisms and recovery trajectories. Therefore, the results may not be generalized to any specific diagnostic group. The results may not represent the specific group or disease. Thirdly, the absence of a control group prevented causal inference regarding the effectiveness of robotic gait rehabilitation. Improvement in FAC may have been influenced by spontaneous neurological recovery, concurrent rehabilitation therapies, or other uncontrolled confounders. Fourthly, variability in training intensity and session duration (ranging from 10 to 40 minutes) may have introduced additional heterogeneity in treatment exposure. Lastly, this study included all available data, even though some of that data would not have been included in other studies, which may have affected association analyses, such as the initial FAC[5], which would decrease overall FAC improvement due to the ceiling effect.

However, this study represents a real-life scenario in a rural hospital with limited opportunities for advanced therapies such as robotic gait training. This data may provide more insight into robotic gait rehabilitation in a certain region of an Asian country. Another advantage of this study is that it included more diseases than stroke, which were not included in previous studies. This study represents a large retrospective case series of more than 100 cases conducted over 24 months. Although it is not a prospective randomized controlled trial (RCT), the large sample size and longitudinal design enhance the reliability of the findings.

Conclusion

In conclusion, this retrospective analysis of 2 years of robotic gait rehabilitation services at a regional hospital demonstrated that more than half of the patients achieved at least a 1-level improvement in the FAC following training. Improvements in FAC were statistically significantly associated with the interval from the neurological event and the patients' baseline FAC.

Conflicts of interest declaration

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

Generative AI declaration

The authors confirm that the following large language models (LLMs) or artificial intelligence (AI) tools were used in the preparation of this manuscript: ChatGPT for language editing and improving readability. All generated content was critically reviewed and edited by the authors.

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Data availability

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

Author contributions

Napatt Phusiripinyo: conceptualization, data curation, investigation, methodology, Visualization, writing - original draft

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

Paveenrath Charussuriyong: formal analysis, validation.

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Original Article

Cross-Cultural Adaptation and Psychometric Properties of the Thai Version of the Short-Form Urinary Quality of Life Questionnaire (SF-Qualiveen) in Individuals with Neurogenic Lower Urinary Tract Dysfunction Following Spinal Cord Injury

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ABSTRACT

Objectives: To develop the Thai version of the short form of the Urinary Quality of Life Questionnaire (SF-Qualiveen) and evaluate its validity and reliability in patients with neurogenic lower urinary tract dysfunction following spinal cord injury

Study design: Cross-cultural adaptation and psychometric validation study

Setting: Department of Rehabilitation Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand, a tertiary care university hospital

Participants: Patients with spinal cord injury and neurogenic lower urinary tract dysfunction who visited Siriraj Hospital between July and December 2024.

Methods: Following the translation of the SF-Qualiveen into Thai and its evaluation for content validity, 56 patients with spinal cord injury (SCI) (34 males, 22 females) were assessed using the Thai SF-Qualiveen to determine construct validity. This was done using Pearson's correlation coefficient to analyze its positive correlation with the Urinary Distress Inventory-6 (UDI-6) and negative correlation with the WHOQOL-BREF-THAI. Reliability was evaluated through internal consistency and test-retest reliability with patients reassessed after one week.

Results: The Thai SF-Qualiveen demonstrated excellent content validity, with a Content Validity Index (CVI) of 1.00 after linguistic adjustment. Regarding construct validity, it showed a significant moderate positive correlation with the UDI-6 ($r = 0.52$, $p < 0.001$) and a low negative correlation with the WHOQOL-BREF-THAI ($r = -0.46$, $p < 0.001$). Internal consistency was very good with a Cronbach's alpha of 0.86 (95% CI: 0.79, 0.91). Test-retest reliability was excellent, with an Intraclass Correlation Coefficient of 0.93 (95% CI: 0.89, 0.96).

Conclusions: The Thai SF-Qualiveen questionnaire is a valid and reliable instrument for assessing quality of life in Thai patients with neurogenic lower urinary tract dysfunction following spinal cord injury.

Keywords: neurogenic lower urinary tract dysfunction, spinal cord injury, quality of life, SF-Qualiveen

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Introduction

Patients with spinal cord injuries (SCI) experience neurogenic lower urinary tract dysfunction (NLUTD) in approximately 70%-80% of cases.[1] The type and severity of bladder and sphincter dysfunction depend on the location of the lesion and the area of spinal cord injury. Symptoms in these patients can vary, ranging from urinary incontinence to incomplete bladder emptying.[2] These issues significantly reduce quality of life[3] by adversely affecting physical health, emotional well-being, social interactions, and increasing dependence on others.

Although generic instruments such as the SF-36[4] and the EQ-5D-5L[5] are commonly used, they lack the specificity needed to capture the unique impact of NLUTD. The International Continence Society (ICS) therefore recommends using condition-specific tools,[6] as standard measures often fail to account for specific stressors such as the burden of bladder management or the psychological distress associated with potential leakage. Tools like the King's Health Questionnaire,[7] the Incontinence QOL Instrument,[8] and the Overactive Bladder Questionnaire[9] focus primarily on storage symptoms, such as urinary incontinence, while neglecting voiding symptoms. This limitation is particularly relevant in patients with SCI, who frequently experience both storage and voiding dysfunction.

The Qualiveen questionnaire was originally developed as a comprehensive instrument to evaluate the impact of urinary disorders on the quality of life (QoL) of patients with neurological conditions.[10,11] This tool has been translated into multiple languages, tested for validity, and is recognized for its

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effectiveness in evaluating patients.[12,13] Although recognized for its effectiveness, its length (30 items) can be impractical for routine outpatient clinical settings. To enhance feasibility while maintaining psychometric rigor, the Short Form Qualiveen (SF-Qualiveen) was developed.[14] This 8-item version is specifically designed to capture four key domains: bother with limitations, fears, daily frequency of urinary reflections, and feelings related to urinary problems. These components address unique disease-specific factors that generic tools often overlook. Since QoL is inherently a subjective experience, the SF-Qualiveen is designed for self-administration to directly reflect the patient's perspective. Consequently, meticulous translation and cross-cultural adaptation are essential to ensure conceptual equivalence when applied across different populations.

Despite the global utility of the SF-Qualiveen and its recommendation in recent clinical guideline (2026),[15] a validated Thai version is currently unavailable. Therefore, this study aims to translate the SF-Qualiveen into Thai and evaluate its psychometric properties—specifically validity and reliability—among Thai patients with NLUTD following SCI. The availability of this validated tool will provide a precise and practical instrument for both clinical practice and future research in Thailand.

Methods

Study design

This study involved the cross-cultural adaptation and psychometric validation of the SF-Qualiveen from English to Thai, following the guidelines established by Beaton et al.[16] The protocol was approved by the Siriraj Institutional Review Board (COA No. Si 054/2024) on January 22, 2024. The Thai Clinical Trials Registry number is TCTR20240609006. Formal authorization for the translation and adaptation process was granted by the Mapi Research Trust, the copyright holder of the instrument.

Participants

Fifty-six patients with spinal cord injury and NLUTD were recruited from the outpatient and inpatient departments of Urology, Orthopedic Surgery, and Rehabilitation Medicine at Siriraj Hospital. Eligible patients were aged 18 and above who used Thai as their primary language of communication. Exclusion criteria included cognitive impairments, difficulty understanding language or reading problems due to limited proficiency in Thai (not caused by visual impairment), unstable medical conditions, and symptoms suggestive of urinary tract infection during the study, including fever, chills, a burning sensation during urination, cloudy or bloody urine, or abdominal/back pain. Participants who could not attend two questionnaire sessions or who did not complete all questions in the questionnaire were also excluded.

After providing written informed consent, participants completed the Thai SF-Qualiveen, the Urinary Distress Inventory-6 (UDI-6),[17] and the WHOQOL-BREF-THAI,[18] either at the outpatient clinic or the inpatient department (test session). One week later, participants completed the Thai SF-Qualiveen questionnaire again (re-test session). The participants' clinical characteristics were obtained from their medical records.

Translation and cross-cultural adaptation

Prior to initiating the translation process, formal permission was obtained from the MAPI Research Trust to translate and culturally adapt the copyrighted SF-Qualiveen into Thai. The cross-cultural adaptation was conducted according to the guidelines proposed by Beaton et al.,[16] comprising five stages.

First, two bilingual Thai translators independently performed initial translations without consultation; one was a clinical expert, and the other was a linguistic expert with no medical background. This was done to provide two distinct perspectives on the translated items. Second, the two independent versions were synthesized into a single Thai version after resolving any discrepancies. Third, two native English speakers, working independently and blinded to the original version, performed back-translations to ensure conceptual equivalence. Fourth, an expert committee comprising one clinician-translator, one clinical methodologist, two physicians, and one nurse reviewed all translations to ensure semantic, idiomatic, experiential, and conceptual equivalence. Finally, a pre-testing phase was conducted with 10 patients with SCI using cognitive debriefing for every item. After participants completed the Thai SF-Qualiveen they were then asked the following questions: "Are the questions easy to understand? Do you find them relevant for your condition? Do you have any suggestions?" The threshold for item revision during pre-testing was set at a 15.0–20.0% frequency of uncertain responses.

Validity

In this study, both content and construct validity were evaluated, with construct validity including assessments of convergent and discriminant validity.

Content validity

The Thai version of the SF-Qualiveen was reviewed by five bilingual experts: two urologists, two rehabilitation physicians, and one nurse. All experts had at least five years of experience in managing patients with neurogenic bladder and were well-versed in instrument translation and validation. These experts evaluated the relevance and comparability of each of the eight questions to the original version using a 4-point scale (1 = not relevant to 4 = highly relevant). Any question rated as irrelevant (scores of 1 or 2) by more than 20% of the experts was revised. The Content Validity Index (CVI) was then calculated as the proportion of items rated 3 or 4. Following the recommendations of Polit et al., the interpretation criteria for an acceptable CVI with five experts required an item-level CVI (I-CVI) of 1.00. For the overall

instrument, a scale-level CVI based on the average method (S-CVI/Ave) of 0.90 or higher was considered to indicate excellent content validity.[19]

Construct validity

Construct validity was assessed through convergent and discriminant validity analyses. To evaluate convergent validity, the correlation between the Thai SF-Qualiveen and the UDI-6 was analyzed using Pearson's correlation coefficient (r). It was hypothesized that the Thai SF-Qualiveen would show a moderate to high positive correlation with the UDI-6 based on previous findings.[20] Discriminant validity was assessed by comparing the Thai SF-Qualiveen with the WHOQOL-BREF-THAI, under the premise that the former focuses on urinary-related quality of life (UrQoL) while the latter measures overall subjective well-being across broader life contexts, thereby expecting a low negative correlation. The magnitude of the correlation coefficients was interpreted based on the criteria of Hinkle et al. (2003): 0.90 to 1.00 as very high, 0.70 to 0.90 as high, 0.50 to 0.70 as moderate, 0.30 to 0.50 as low, and 0.00 to 0.30 as little or no correlation.[21]

The SF-Qualiveen is a validated 8-item questionnaire that assesses the impact of NLUTD on QoL in patients with SCI or multiple sclerosis (MS). The 8 items cover four domains (two items each): Bother with limitations, Fears, Feelings, and Frequency of limitations. Items are rated on a Likert scale from 0 to 4, with 0 meaning "no impact/bother" and 4 meaning "high impact/bother". A higher score indicates a greater negative impact on QoL.[14]

The UDI-6 questionnaire is used to assess the impact of urinary incontinence on QoL and consists of six items, each scored on a 4-point scale from 0 to 3, with higher scores indicating poorer quality of life, and lower scores indicating a better QoL.[17]

The WHOQOL-BREF-THAI is a QoL assessment tool developed by the World Health Organization. It consists of 26 items and evaluates four domains: physical health, psychological health, social relationships, and the environment. Each item is rated on a 5-point Likert scale, with higher scores indicating a better QoL, and lower scores indicating a poorer QoL.[18]

Reliability

Reliability was assessed using internal consistency and test-retest reliability. Internal consistency was determined by measuring the coherence of each question using Cronbach's alpha. The internal consistency was interpreted based on the criteria suggested by DeVellis et al.[22]: a Cronbach's alpha between 0.80 and 0.95 was considered very good, 0.70 to 0.80 as respectable, 0.65 to 0.70 as undesirable, and below 0.60 as unacceptable.

Test-retest reliability was evaluated by administering the Thai SF-Qualiveen to all 56 patients one week after the initial assessment. The Intraclass Correlation Coefficient (ICC) was interpreted according to the guidelines by Koo et al. ICC values were interpreted as follows: below 0.50 as poor, 0.50 to 0.75 as moderate, 0.75 to 0.90 as good, and above 0.90 as excellent reliability.[23] This one-week interval is commonly used to balance recall bias and clinical stability. To minimize carryover effects, the same questionnaire items were used during the retest, but in a different order.

Sample size calculation

The sample size was determined based on both validity and reliability requirements. For construct validity, the primary expected outcome was the correlation coefficient (r) between the SF-Qualiveen and the UDI-6. Based on a previous study by Reuvers et al.[20] which reported a correlation of $r = 0.66$ ($p < 0.001$), we utilized this coefficient as our primary parameter. Although the reference study did not provide the standard deviation (SD) for the total scores, the r value served as a robust basis for power analysis. We hypothesized a conservative expected correlation coefficient of 0.50 (representing a large effect size according to Cohen[24]) against a null hypothesis of 0.10 (small effect size). With a type I error of 0.05 and a type II error of 0.10 (90% power), a minimum of 56 participants was required.

Reliability was assessed using the Intraclass Correlation Coefficient (ICC). To ensure at least good reliability, an expected ICC of 0.75 was used at the 95% confidence level, with a precision (margin of error) of 0.25, requiring 48 participants. To account for a potential 15% dropout rate, the final sample size was set at 56 participants, which met the requirements for both validity and reliability testing.

Statistical analysis

The CVI was calculated to assess content validity. All statistical analyses were performed using IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA). Pearson's correlation coefficient was used to evaluate convergent and discriminant construct validity. Internal consistency was assessed using Cronbach's alpha, and test-retest reliability was evaluated using the ICC.

Results

A total of 56 patients with SCI were enrolled in this study. The study population was comprised of 60.7% males and 39.3% females. The distribution of SCI levels was as follows: cervical level, 34.0%; thoracic, 44.6%; and lumbar, 21.4%. The methods of ambulation were categorized into three groups: (1) wheelchair ambulation, including both self-propulsion and attendant propulsion (60.7% in household and 78.6% in the community settings); (2) ambulation with gait aids and/or assistance (30.4% in the household and 16.1% in the community settings); and (3) independent ambulation without gait aids or assistance (8.9% in the household and 5.4% in the community settings). Bladder-emptying methods were categorized according to the predominant technique

used by participants. These included indwelling catheterization (42.9%), voluntary voiding (35.7%), and clean intermittent catheterization (CIC) (21.4%). Detailed demographic and clinical characteristics of the participants are summarized in Table 1.

Table 1. Demographic characteristics of the 56 participants

Variable	n = 56
Age, years[1]	53 (16.2)
Sex[2]	
Male	34 (60.7)
Female	22 (39.3)
Onset of SCI[2]	
≤ 6 months	13 (23.2)
> 6 months - 1 year	6 (10.7)
> 1 year - 5 years	15 (26.8)
> 5 years	22 (39.3)
Level of SCI[2]	
Cervical	19 (34)
Thoracic	25 (44.6)
Lumbar	12 (21.4)
ASIA Impairment Scale[2]	
A	13 (23.2)
B	4 (7.1)
C	18 (32.13)
D	20 (35.7)
E	1 (1.8)
Ambulation (household)[2]	
Wheelchair (self-propulsion/attendant propulsion)	34 (60.7)
Walk with gait aid and/or assistance	17 (30.4)
Independent walking	5 (8.9)
Ambulation (community)[2]	
Wheelchair (self-propulsion/attendant propulsion)	44 (78.6)
Walk with gait aid and/or assistance	9 (16.1)
Independent walking	3 (5.4)
Manner of bladder emptying[2]	
Indwelling catheterization	24 (42.9)
Clean intermittent catheterization	12 (21.4)
Voluntary voiding	20 (35.7)

[1]Mean (SD), [2]Number (percentage)
SCI, spinal cord injury; ASIA, American Spinal Injury Association

Validity

Content validity and cultural adaptation

During the expert committee review, Item 2 received an initial I-CVI score of 0.6, resulting in an overall Scale-level Content Validity Index (S-CVI/Ave) of 0.88. This necessitated a targeted revision. The committee identified a cultural-linguistic discrepancy: the phrase 'disturbing daily life' in the initial Thai translation was too broad and failed to capture the specific 'subjective bother' intended by the SF-Qualiveen. Consequently, the committee refined the phrasing from the initial version: 'Are you disturbed by the amount of time required for urination or catheterization?' (Thai original: 'เวลาที่ใช้ไปกับการปัสสาวะหรือสวนปัสสาวะรบกวนการดำเนินชีวิตของคุณหรือไม่'; Romanization: Wela thi chai pai kap kan patsawa rue suan patsawa ropkuan kan damnoen chiwit khong khun ruemai?)" to 'คุณถูกรบกวนเพราะเวลาที่ใช้ในการปัสสาวะหรือสวนปัสสาวะหรือไม่' (Romanization: Khun thuk ropkuan phro wela thi chai nai kan patsawa rue suan patsawa ruemai?). This adjustment emphasizes the participant's direct perception of being bothered by the time consumed. This adjustment ensured superior idiomatic and conceptual equivalence. Following this revision, the final evaluation demonstrated perfect consensus, with the I-CVI for Item 2 and the overall S-CVI/Ave both reaching 1.0, indicating excellent content validity.

To complement the expert-based evaluation, a pre-test was conducted with 10 patients with SCI. Cognitive debriefing confirmed that the revised phrasing was not only clear but also culturally relevant. All 10 participants (100.0%) reported a clear understanding of the items, and the frequency of uncertain responses was 0%, which is well below the 15.0–20.0% threshold for further adjustment. These results demonstrate that the items accurately reflect personal experiences with NLUTD, providing robust target-population evidence for the cultural and content validity of the Thai SF-Qualiveen.

Construct validity

In terms of convergent validity, Pearson's correlation coefficient between the Thai SF-Qualiveen and the UDI-6 was 0.52 ($p < 0.001$), indicating a significant moderate positive correlation between the two instruments (Table 2).

To assess discriminant validity, the correlation between the Thai SF-Qualiveen and the WHOQOL-BREF-THAI was analyzed. The Pearson correlation coefficient for these two instruments was -0.46 ($p < 0.001$), indicating a significantly low negative correlation between the Thai SF-Qualiveen and the WHOQOL-BREF-THAI (Table 2). The correlation between the Thai SF-Qualiveen and the WHOQOL-BREF-THAI domains were also analyzed, revealing negligible to low correlations across all domains (Table 3).

Reliability

Internal consistency

The Thai SF-Qualiveen demonstrated satisfactory internal consistency, with a Cronbach's alpha coefficient of 0.86 (95% CI: 0.79, 0.91). Item-level analysis showed that removing individual items generally maintained acceptable internal consistency; however, deleting Item 8 increased Cronbach's alpha to 0.91. Detailed internal consistency results are shown in Table 4.

Test-retest reliability

To evaluate test-retest reliability, the Thai SF-Qualiveen was re-administered to 56 patients one week after the initial assessment. The order of the questionnaire items was altered for the re-test to minimize carry-over effects. An ICC of 0.93 indicated excellent test-retest reliability for the Thai SF-Qualiveen (Table 5).

Table 2. Construct validity of the Thai SF-Qualiveen compared to the UDI-6 and WHOQOL-BREF-THAI

Variables		SF-Qualiveen	UDI-6	WHOQOL-BREF-THAI
Pearson's correlation coefficient	Pearson's correlation coefficient	1.00	0.52	- 0.46
p-value	*p*-value	-	< 0.001	< 0.001

SF-Qualiveen, Short form-Qualiveen; UDI-6, Urinary Distress Inventory-6; WHOQOL-BREF-THAI, World Health Organization Quality of Life Brief Version - Thai Version

Table 3. Correlation between the Thai SF-Qualiveen and the four domains of the WHOQOL-BREF-THAI

		SF-Qualiveen	Physical domain	Psychological domain	Social domain	Environment domain	Overall
Pearson's correlation coefficient	Pearson's correlation coefficient	1.00	- 0.35	- 0.40	- 0.26	- 0.44	- 0.46
p-value	*p*-value	-	0.008	0.002	0.051	0.001	< 0.001

SF-Qualiveen, Short form-Qualiveen; WHOQOL-BREF-THAI , World Health Organization Quality of Life Brief Version - Thai Version

Table 4. Internal consistency of the Thai SF-Qualiveen assessed using Cronbach's alpha coefficients

		Scale mean if item deleted	Scale variance if item deleted	Corrected item total correlation	Cronbach's Alpha if item deleted
1.	In general, do your bladder problems complicate your life?	10.12	43.38	0.65	0.84
2.	Are you bothered by the time spent passing urine or realizing catheterization?	10.70	43.45	0.71	0.83
3.	Do you worry about your bladder problems worsening?	10.25	40.56	0.77	0.82
4.	Do you worry about smelling of urine?	10.70	42.40	0.74	0.83
5.	Do you feel worried because of your bladder problems?	10.32	39.97	0.86	0.81
6.	Do you feel embarrassed because of your bladder problems?	10.71	43.37	0.71	0.83
7.	Is your life regulated by your bladder problems?	10.21	44.57	0.57	0.84
8.	Can you go out without planning anything in advance?	9.61	52.83	0.03	0.91

SF-Qualiveen, Short form-Qualiveen; WHOQOL-BREF-THAI , World Health Organization Quality of Life Brief Version - Thai Version

Table 5. Test-retest reliability of the Thai SF-Qualiveen assessed using intraclass correlation coefficients

		95% confidence interval	95% confidence interval	F Test with true value	F Test with true value	F Test with true value	F Test with true value
	Intraclass Correlation	Lower bound	Upper bound	Value	df1	df2	Sig
Average	0.93	0.89	0.96	15.16	55	55	< 0.001

SF-Qualiveen, Short form-Qualiveen; WHOQOL-BREF-THAI, World Health Organization Quality of Life Brief Version - Thai Version

Discussion

The Thai SF-Qualiveen was developed to address the absence of a disease-specific instrument for assessing UrQoL in Thai patients with SCI. This study demonstrates that the Thai version demonstrated excellent content validity and test-retest reliability, along with good convergent validity and internal consistency.

Regarding construct validity, the moderate positive correlation with the UDI-6 (r = 0.52) aligns with findings from the Dutch and Russian versions,[20,25] confirming its ability to capture distress related to neurogenic bladder. In contrast, the low correlation with the WHOQOL-BREF-THAI (r = - 0.46) highlights a fundamental difference in the nature of these instruments. As a disease-specific tool, the Thai SF-Qualiveen detects subtle psychosocial impacts of urinary dysfunction, whereas the WHOQOL-BREF-THAI is a generic instrument for assessing global domains. In the SCI population, global QoL is often dominated by factors like mobility and social accessibility, which may outweigh specific urinary concerns. Despite this weak statistical discrimination against a generic proxy, the tool's high clinical sensitivity and strong content validity justify its suitability for specialized assessments where generic tools lack sufficient detail.

The Cronbach's alpha of the Thai SF-Qualiveen was 0.86, demonstrating good internal consistency (0.8–0.9).[22] This result is comparable to those reported for the Dutch and Greek versions[20,26] but slightly lower than that of the Russian version, which was validated in patients with MS.[25] The observed increase in alpha to 0.91 upon excluding Item 8

suggests a conceptual shift from emotional distress to functional behavior. Item 8 is unique in its "positive" framing and broad "planning" requirement, which in the Thai context often involves accessibility issues beyond urinary management. To enhance future consistency, we propose: (1) rephrasing Item 8 to focus on the distress caused by planning, aligning its directionality with other items; and (2) explicitly linking "planning" to urinary issues to minimize cultural-linguistic ambiguity.

The ICC for test-retest reliability of the Thai SF-Qualiveen was 0.93, which is excellent (> 0.90).[23] Compared to other studies, this reliability is consistent with the Dutch version[20] but higher than that of the Russian version.[25]

Limitations

A primary limitation is the lack of a Thai gold-standard UrQoL measure for SCI, necessitating the use of the UDI-6 and WHOQOL-BREF-THAI as suboptimal proxies. While the UDI-6 focuses on symptom distress, it does not fully encompass the UrQoL construct, and the WHOQOL-BREF evaluates broader life domains. Furthermore, the generalizability of our findings may be constrained by the single-center design, a relatively modest sample size (n = 56), and the clinical heterogeneity in bladder management among participants. These sample size constraints also precluded a formal factor analysis to identify key determinants of neurogenic bladder-related QoL. Regarding reliability, the one-week retest interval was selected to balance the need for clinical stability with the risk of recall bias; however, we recognize that minor fluctuations in urinary symptoms or participants' recall of previous responses could still affect stability scores. Finally, the exclusion of patients with cognitive or language impairments—though necessary for data integrity in self-administered tools—may have introduced a selection bias, limiting the applicability of these results to a broader SCI population with concurrent cognitive challenges. Future multicenter studies with larger, more diverse cohorts are warranted to further validate these findings and to explore multifaceted determinants of UrQoL in individuals with SCI.

Conclusion

This study demonstrated that the Thai SF-Qualiveen is a reliable and valid instrument for assessing UrQoL in individuals with spinal cord injury. Its simplicity and conciseness make it a practical tool for routine clinical assessment, enabling a more precise evaluation of UrQoL than generic measures. While future studies might benefit from using more closely aligned reference instruments to further strengthen comparative validation, the current Thai SF-Qualiveen is suitable for clinical and research applications to enhance the management of patients with NLUTD.

Conflict of interest declaration

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

Generative AI declaration

The authors confirm that no large language models (LLMs) or artificial intelligence (AI) tools were used in the creation of this manuscript, including the writing, editing, or preparation of figures and tables, except for using Grammarly for basic grammar and spell-checking.

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Data Availability

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

Author contributions

Pasinee Theerapap: conceptualization, methodology, data curation, funding acquisition, investigation, formal analysis, writing-original draft preparation,

Chayaporn Chotiyarnwong: conceptualization, methodology, investigation, validation, writing-review & editing,

Thanitta Thanakiatpinyo: conceptualization, methodology, funding acquisition, supervision, validation, writing-review & editing.

Supplementary materials

The following supporting information can be downloaded at: Supplementary file

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Supplementary material

Table S1. Synthesis of linguistic and conceptual adjustments for the Thai SF-Qualiveen.

Stage	Item No.	Original Issue	Resolution / Adjustment	Rationale
Stage IV (Synthesis of Translations)	Item 2	Cultural-linguistic discrepancy: The phrase "disturbing daily life" was too broad	Refined phrasing	To capture the specific "subjective bother" intended by the original tool, emphasizing the participant's direct perception rather than general lifestyle impact
Stage V (Pre-testing)	All items	No issues reported	Maintained pre-final version	High clarity (100%) among target users