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Content

Letter from the Editor

Dear Readers,

In this issue, we highlight several important studies that contribute significantly to our understanding of rehabilitation and assessment techniques in various clinical contexts.

Srisuthep et al. reported on the effectiveness of a custom-made compression garment for managing breast cancer-related lymphedema. Their preliminary data suggest a notable trend towards reduced arm volume with this new tailoring method compared to conventional techniques, highlighting the need for personalized approaches in lymphedema management.

In a prospective observational study, Suwanchai and Suksathien examined the functional outcomes of stroke patients undergoing a 3-month rehabilitation program within an intermediate care service plan. Remarkably, 79% of moderate severity stroke patients achieved good functional outcomes, underscoring the effectiveness of structured rehabilitation protocols.

Homrossukhon et al. evaluated the results of ultrasound training for Physical Medicine and Rehabilitation residents. Their study concluded that such training could enhance the skill set of PMR practitioners, although further research is needed to determine optimal training parameters and long-term retention of skills.

Jayubo et al. conducted a study from Philippines compared the reliability of universal goniometers (UG) and video goniometers (VG) in assessing the range of motion in patients with osteoarthritis. The findings indicate that while the UG provides better consistency among assessors, the VG offers more reliable assessments by individual assessors across multiple trials. This insight emphasizes the importance of selecting appropriate assessment tools in clinical practice.

Ekwatthannaku and Tantalanukul conducted a quasi-experimental study evaluating a newly developed comprehensive rehabilitation service model for subacute stroke patients in Northern Thailand. Their results demonstrate significant improvements in functional independence, quality of life, psychological well-being, and a reduction in caregiver burden, showcasing the potential of innovative rehabilitation approaches in enhancing patient outcomes.

Benjapornlert and colleagues presented a case study on the management of spastic trismus post-stroke through coronoidectomy. Their findings indicate that this surgical intervention may be a viable option for patients unresponsive to conventional therapies, offering new hope for effective management strategies.

These contributions reflect the ongoing efforts of researchers and clinicians to improve patient care and outcomes in rehabilitation and related fields. We encourage you to explore these studies and consider their implications in your practice.

Thank you for your continued support and engagement with our journal.

Sincerely,

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

Original Article

A Preliminary Study of the Effectiveness of a Custom-made Compression Garment with Simplified Tailoring for Breast Cancer-related Lymphedema: A Randomized Control Trial

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ABSTRACT

Objectives: To study the changes in arm volume and quality of life of breast cancer-related lymphedema patients after using a custom-made compression garment with simplified tailoring compared with a pressure garment tailoring by a standard method

Study design: A single-blinded randomized controlled trial

Setting: The Outpatient Physical Medicine and Rehabilitation Clinic in Siriraj Hospital, Bangkok, Thailand

Subjects: Females aged 18 years or older diagnosed with breast cancer-related lymphedema

Methods: Forty-three participants were randomly assigned to one of two groups. Both groups received complex decongestive therapy (CDT) over a period of three weeks. The control group was provided custom-made compression garments made using the conventional method, while the experimental group received custom-made compression garments made using a simplified technique of tailoring.

Results: Of the forty-three participants, 22 were in the intervention group and 21 were in the control group. In the control group, the mean arm volume decreased by 77.6 ml (SD = 201.8) after three weeks. The volume in the control group was not statistically significant different from baseline (p = 0.058). During the same period, the mean arm volume reduction in the intervention group was 172.7 ml (SD = 304.3), a statistically significant reduction in the affected arm volume from baseline (p = 0.015). However, no statistically significant difference was observed in other direct comparisons between the two groups, i.e., both groups statistically significantly improved their quality of life as measured by changes in the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL). However, there was no statistically significant difference between the two groups regarding quality-of-life improvement.

Conclusions: The data suggests a trend towards a more significant reduction in affected arm volume with the new custom-made tailoring method of making the compression garment over the conventional tailoring technique. These results suggest promising avenues for future larger-scale studies.

Keywords: compression garment, breast cancer-related lymphedema, quality of life, lymphedema, arm volume, functioning, disability and health questionnaire for upper limb lymphedema

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Introduction

Breast cancer was the most commonly diagnosed cancer worldwide in 2020, with 2.3 million women receiving a diagnosis and 685,000 individuals succumbing to breast cancer. Between 2015 and 2020, approximately 7.8 million people were diagnosed with breast cancer. This high prevalence makes breast cancer patients the top-ranked cancer survivors globally in the year 2020.[1]

Although the treatment for breast cancer has made significant progress, patients still have to face numerous side effects that occur after treatment. One of the most common side effects is lymphedema.[2] Lymph is a white milky fluid that all physical activities can influence. The contraction and relaxation of muscles transports lymph. The flow can be affected by the disturbance of lymphatic tissues. Observation of lymphedema subjects in an animal study showed that any method that can change the contour of extremities may increase the lymph flow.[3] Subjects who have lymphedema after mastectomy require special care because subjects with breast cancer usually have reduced physical activity, which may exacerbate the symptoms.[4] Reduced physical activity leads to reduced muscle activity, which secondarily leads to reduced lymph circulation, a cycle which continues repeatedly. Post-mastectomy lymphedema also reduces the subjects' regular physical activity, adversely affecting their quality of life.[5,6] Subjects with post-mastectomy lymphedema commonly complain about pain, discomfort, reduced hand grip strength and joint movements in the related extremities. The "tissue burst" sensation may occasionally lead to secondary edema and increase the limb circumference.[5-7] If left

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untreated, it can lead to various other side effects such as skin infections, infections in the lymphatic vessels, blockage of the blood vessels in the affected area, or severe swelling that compromises normal arm function. Consequences can include a loss of confidence in social situations.[2-8] All these issues contribute to a decreased quality of life for the patients.[9,10]

The standard treatment for lymphedema is complex decongestive therapy (CDT), which is comprised of manual lymphatic drainage, skincare, exercise, and compression garments. Each patient should continue the therapy at home.[11]

The principal objective of decongestive therapy is gradually decreasing the pressure gradient from the highest in the distal wrist area to the lowest toward the arm to facilitate the movement of lymphatic fluid upwards. This therapy helps relieve symptoms, prevents progression and reduces the risk of skin infection. It reduces edema by increasing the interstitial pressure, thus reducing capillary filtration, increasing the lymphatic reabsorption of interstitial fluid, increasing the lymphatic flow, shifting fluid to non-compressed areas, increasing the lympho-venous-muscular pump function, protecting the skin and breaking down fibrosclerotic tissue. In lymphedema, decompressive therapy has been considered the most effective therapeutic procedure.[12]

Compression garments require an appropriate pressure level for each patient; the hospital customizes the pressure for each individual. Pressure garments are tailored specifically for each patient, applying pressure ranging from 20-40 mmHg.[13]

Medical compression garments come in two primary types: circular knit and flat knit. Circular knit garments are seamless, highly elastic and are available as ready-to-wear options, making them suitable for mild lymphedema. In contrast, flat knit garments are made from flat fabric tailored to fit the patient's body measurements. These are constructed from stronger materials, resulting in less stretch, and are designed for moderate to severe lymphedema. Most research on custom-made compression garments has focused on PowerNet fabric,[14] a blend of synthetic fibers like nylon and elastane that provides strength and elasticity.

Studies have shown that compression garments effectively reduce volume and manage early-stage lymphedema.[15] Notably, about 80% of patients following breast cancer surgery were prescribed these garments, yet the guidelines for their use often varied significantly.[16] A randomized controlled trial in 2021 showed that incorporating nighttime compression therapy significantly improved arm lymphedema volume compared to using daytime therapy alone.[17] However, challenges remain: the production of custom-made garments is time-consuming, and some patients choose not to use them or to wear them for shorter periods than recommended, often due to discomfort, unease, and heat.

The research team aimed to develop a new tailoring method for making custom-made compression garments that would save time and reduce the production steps, making them more accessible and practical. The new technique involves measuring the fabric's compression pressure only once when the fabric is initially obtained, then setting the proportion between the width of the fabric and arm circumference, and measuring the pressure to ensure it falls within 25-30 mmHg, a moderate pressure range. Once the proportion of the width of fabrics and arm circumference is determined, sewing the garment must be adjusted to snugly fit the user's arm based on the individual's comfort, eliminating the need for repetitive pressure measurements, thus saving time and reducing complicated methods garment production time.

The key research question is whether this new method for making custom-made compression garments can reduce the volume of lymphedema and improve the quality of life of breast cancer-related lymphedema patients compared to the conventional method.

Material and Methods

Study design

A single-blinded, randomized controlled trial was conducted in a university hospital in Bangkok, Thailand. The study was approved by the Institutional Review Board, Faculty of Medicine, Siriraj Hospital (481/2565). It was registered in the Thai Clinical Trials Registry on September 21, 2022 (ID TCTR20221212005). This study was conducted in accordance with the CONSORT guideline.

Study participants

Inclusion criteria

1. Females age 18 years or older
2. Unilateral upper extremity lymphedema secondary to breast cancer
3. Lymphedema Stage 1 (an early accumulation of the condition which subsides with limb elevation. Pitting may occur) or stage 2 (limb elevation alone rarely reduces tissue swelling and pitting is manifest; the limb may or may not pit) upper extremity lymphedema secondary to breast cancer, as defined by the International Society of Lymphology[13]
4. Having not used a compression garment before

Exclusion criteria

1. Presence of infection in the affected arm
2. Recurrence of breast cancer
3. Unfinished treatment of breast cancer, either surgery, radiation, or chemotherapy
4. Previous treatment of lymphedema, such as surgery
5. Ongoing treatment of lymphedema, such as intermittent pneumatic compression and manual lymphatic drainage by a therapist
6. Bilateral leg edema due to a medical condition

Withdrawal or termination criteria

1. The participant's request to stop participating
2. Complications from using compression garments such as rash or affected arm infection

Sample size calculation

A research study by Vignes et al.[18] investigated the long-term treatment of patients with lymphedema associated with breast cancer using intensive decongestive physiotherapy. The study measured the volume of lymphedema before and after the therapy. The average volume of lymphedema before intensive decongestive physiotherapy was 1,054 ml, while after the therapy, it decreased to an average of 647 ml.

The sample size was calculated using the two independent means formulas, with a specified type I error of 0.05, β (beta) of 0.20, and standard deviations of 633 and 351 before and after therapy. The calculated sample size was 25 individuals per group. Assuming a 10% dropout rate, the sample size for this study was determined to be 28 individuals per group.

Randomization

After taking the patient's medical history, conducting a physical examination, and asking the participants for informed consent, patients with lymphedema were stratified into stages 1 or 2 based on the International Society of Lymphology criteria.[19] Each stage was then randomized using a computer-generated block of four method into 2 groups. The intervention group included 22 patients, and the control group included 21, as shown in Figure 1. The randomization results were placed in sealed envelopes by a third party who was not involved in the study.

Interventions

Both groups received a video teaching exercises to perform at home. The exercises included breathing exercises and neck and shoulder exercises for relaxation and range of motion. They were instructed to have manual lymphatic drainage massage and to use a moisturizer on the affected arm daily. The investigator provided the patient a single custom-made garment made from Powernet fabric.

The control group received a conventional tailoring method custom-made compression garment.19 Arm circumferences were measured at 13 fixed levels. After cutting and sewing to the measured size, adjustment was based on the interface pressure measured by an air-filled pneumatic pressure testing system (PicoPress®, Microlab Elettronica, Ponte San Nicolò, Italy). If the pressure was too high or too low, trained personnel had to remove the stitches before resewing the garment until the interface pressure was in the standard range of 25-30 mmHg. The total time for production was about 2 hours per piece.

The intervention group received garments made using a new tailored custom-made compression technique. Before the therapists began using each roll of fabric, a documented record was made by pulling pieces of the fabric of various widths to determine the percent they could be stretched beyond their original width to provide a pressure between 25-30 mmHg. Patient arm circumferences were measured using the standard method, and the investigator made the compression garment by stretching the fabric to the desired width as planned. There was no pressure measurement after the compression garment was completed; the patients were only asked to test the sensation of tightness to determine if they could tolerate wearing it. The total time for production was about 1.0-1.5 hours per piece.

After the participants received the garment, they were instructed to wear it continuously throughout the day and night, except during bathing (23 hours a day). To measure compliance, participants were asked to record the duration of wearing the compression garment, the frequency and duration of exercise and manual lymphatic drainage, and any adverse events each day for three weeks.

In evaluating the follow-up results at the third week, reference was made to the research conducted by Tantawy Sayed and colleagues[20] comparing the use of Kinesio taping with elastic compression garments in patients with post-mastectomy upper extremity lymphedema. In that study, significant statistical differences in the altered volume of lymphedematous arms were found after three weeks, so the same three-week timeframe was used to assess and monitor the outcomes in the present study.

Outcome measurements

Demographic data, including age, weight, height, body mass index (BMI), dominant hand side, type of breast surgery, duration after surgery, duration of lymphedema, history of chemotherapy, history of radiation therapy, stage of breast cancer and stage of lymphedema were collected at baseline.

Outcome measurements were made at baseline and after three weeks of participating in the rehabilitation program. A physiatrist who performed all measurements was blinded to participant grouping. The outcomes include the following:

1. Arm volume change was the primary outcome. The arm volume was measured using water displacement volumetry following the Archimedes principle. This validated method measures the volume of the whole arm, including the hand. It is an accepted gold standard for measuring limb volume change in a clinical environment.[21] Water displacement volumetry showed good concurrent validity with a high correlation to the cross-sectional area (measured by a computerized tomographic (CT) scan of the affected limb with a correlation coefficient of 0.904, (p < .001).[22] To measure volume while seated, the arm with lymphedema was gradually immersed in a prepared water container until it reached the specified mark. The arm's displaced water volume was then measured by raising the water level. To standardize immersion at the same depth in pre- and post-intervention, the distance from the lateral epicondyle in line with the lateral epicondyle-acromion was recorded in centimeters. This volume was used as the baseline. At the end of the third week, the volume was measured immediately after removing the compression garment. The volume at baseline and the end of the study were calculated to find the volume change.

2. Quality of life change was the secondary outcome. Quality of life was measured using the Thai version of the Lymphedema Functioning, Disability, and Health Questionnaire for Upper Limb Lymphedema (Lymph-ICF-UL).[23,24] The questionnaire consisted of 29 questions: seven questions on pain symptoms, emotions, immune system function, and mobility, four questions on mental well-being, four questions on household functionality, eight questions on mobility capability, and six questions on lifestyle and social participation. The maximum total score is 290 (10 points for each question); a higher score indicates a poorer quality of life. The scores at baseline and at the end of the third week were calculated to determine the change in quality of life.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 29.0 (IBM Corp, Armonk, NY, USA). Continuous data is shown as mean, standard deviation (SD), and median (IQR 25, 75). The categorical data are shown as numbers and percentages.

Differences between baseline characteristics and continuous outcomes of the two groups were analyzed by Independent T-test or Mann-Whitney U test. Categorical baselines were analyzed by Chi-squared test. A *p*-value less than 0.05 was considered statistically significant.

Results

Characteristics of the participants

Forty-five patients with grade 1-2 breast cancer-related lymphedema from December 2022 to May 2024 were assessed for eligibility. Two patients were excluded because they did not meet the inclusion criteria (Figure 1). The remaining 43 patients participated in this study.

Baseline demographic data

The baseline demographic and clinical characteristics of the participants are presented in Table 1. The mean age in the intervention group was 57.3 (SD = 12.6) years. The control group's mean age was 60 (SD = 11.7) years.

There were no significant differences in any of the baseline data, i.e., age, BMI, stage of breast cancer, stage of lymphedema, median duration after mastectomy, previous treatments, median duration after lymphedema, dominant side effects, baseline arm volume, and quality of life.

Primary and secondary outcomes

The mean arm volume at baseline for the control group was 1,696.2 (SD = 299.1) ml. After three weeks, the mean arm volume in that group had decreased to 1,618.6 (SD = 275.0) ml., a mean arm volume change of 77.6 (SD = 201.8) ml. The volume in the control group after three weeks was not statistically significantly different from the baseline (p = 0.058). In the intervention group, the mean arm volume at baseline was 1,892.7 (SD = 477.7) ml. After three weeks, the mean arm volume had decreased to 1,720.0 (SD = 311.9) ml, a reduction in the mean arm volume of 172.7 ml. (SD = 304.3). The volume in the intervention group after treatment was a statistically significantly lower than the baseline (p = 0.015). However, the between-group analysis did not show a statistically significant difference in arm volume reduction between the different methods of compression garment tailoring (p = 0.216). (Table 2)

Regarding quality of life as measured by the Lymph-ICF-UL, the median of the Lymph-ICF-UL score of the control group at baseline was 38.0 (interquartile range (IQR) = 17.0, 59.5). After three weeks, the median of the Lymph-ICF-UL score was reduced to 12.0 (IQR = 5.5, 37.0). For the intervention group, the median of the Lymph-ICF-UL score at baseline was 40.5 (IQR = 18.5, 69.8). After three weeks,

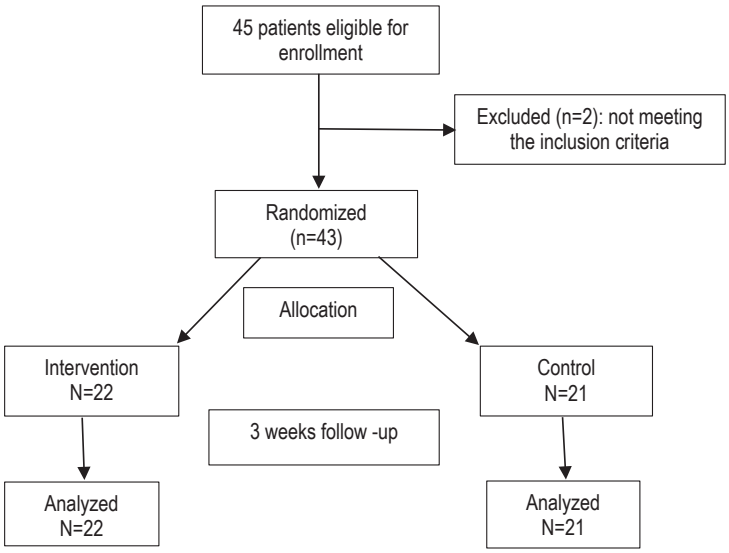

Figure 1. Study flow chart

Table 1. Baseline demographic data

Variables	Intervention	Control	*p*-value
Demographic data			
Age (years)[1]	57.3 (12.6)	60 (11.7)	0.474
BMI (kg/m^2)[1]	24.3 (6.8)	25.9 (4.2)	0.353
Duration after mastectomy (months)[2]	31 (15, 96)	27 (19.5, 72)	0.932
Duration after lymphedema (months)[2]	6 (2, 12)	3 (1, 10)	0.111
Stage of breast cancer[3]			
Stage I	1 (5.6)	1 (5.9)	0.838
Stage II	10 (55.6)	11 (64.7)	0.451
Stage III	7 (38.9)	5 (29.4)	
The dominant side affected[3]	9 (40.9)	11 (52.4)	0.184
Type of surgery[3]			
Total mastectomy	20 (95.2)	16 (76.2)	
Breast-conserving surgery	1 (4.8)	5 (23.8)	1.000
Adjunctive treatment[3]			0.457
Chemotherapy	20 (90.9)	20 (95.2)	
Radiotherapy	19 (86.4)	16 (76.2)	0.607
Lymphedema stage[3]			
Stage I	13 (59.1)	14 (66.7)	0.116
Stage II	9 (40.9)	7 (33.3)	0.644
Arm volume[1]	1692.2 (299.1)	1892.7 (477.7)	
Quality of life (Lymph-ICF-UL)[2]	40.5 (18.5, 69.75)	38 (17, 59.5)	

[1]Mean (SD), [2]median (Q1, Q3), [3]N (%), significant at $p < 0.05$
BMI, body mass index, Lymph-ICF-UL, lymphedema functioning, disability and health questionnaire for upper limb lymphedema;

Table 2. Comparison of arm volume change and quality of life change in the intervention and control groups

	Baseline		Week 3		Change		*p*-value
	Control	Intervention	Control	Intervention	Control	Intervention	
Arm volume mean (SD)	1696.2 (299.1)	1892.7 (477.6)	1618.6 (275.0)	1720.0 (311.9)	77.6 (201.8)	172.7 (304.3)	0.216
Lymph-ICF-UL median (IQR)	38.0 (17.0, 59.5)	40.5 (18.5, 69.8)	12.0 (5.5, 37.0)	13.5 (5.8, 43.0)	15.0 (9.0, 43.0)	16.5 (0.25, 41.8)	0.618

Lymph-ICF-UL, lymphedema functioning, disability and health questionnaire for upper limb lymphedema; SD, standard deviation; IQR, inter-quartile range

the median of the Lymph-ICF-UL score was reduced to 13.5 (IQR = 5.8, 43.0). The changes in both the control group and the intervention group were statistically significant with $p \leq 0.05$, indicating a better quality of life of the participants. Between-group analysis showed that the improvements of the two groups were not statistically significantly different ($p = 0.641$).

Compliance and co-interventions

From the logbook records, the median duration of wearing compression garments in the control group was 13.4 (IQR = 5.0, 20.0) hours per day. In contrast, the median duration in the intervention group was 11.7 hours per day (IQR = 4.7, 19.0). The difference was not statistically significant ($p = 0.641$).

The median duration of neck and arm exercise in the control group was 18.8 minutes per day (IQR = 9.5, 23.5), and in the control group was 14.2 minutes per day (IQR = 6.4, 22.4). There was no statistically significant difference between the two groups ($p = 0.900$). (Table 3)

Regarding decongestive massage, the median duration of massage in the control group's record was 11.7 minutes per day (IQR = 5.0-19.0). The median duration in the intervention group was 8.8 minutes per day (IQR = 4.8-18.3). There was no statistically significant difference between the two groups ($p = 0.641$). No other physical therapy intervention was reported. (Table 3)

Complications

36.4% of the control group reported minor adverse effects, such as discomfort, heat, sweating, and rash, while the percentage was 38.1% in the intervention group. There was no statistically significant difference in the occurrence of adverse effects between the two groups. No severe complications were reported by either group.

Table 3. Comparison of compliance and co-interventions in the intervention and control groups

Median duration (IQR)	Intervention	Control	*p*-value
Wearing compression garment (hours/day)	11.7 (4.7, 19.0)	13.4 (5.0, 20.0)	0.641
Neck and arm exercise (minutes/day)	14.2 (6.4, 22.4)	18.8 (9.5, 23.5)	0.900
Decongestive massage (minutes/day)	8.8 (4.8, 18.3)	11.7 (5.0, 19.0)	0.641

IQR, inter-quartile range

Discussion

The complex decongestive therapy (CDP) used in this study consisted of various techniques, including manual lymphatic drainage, compression garments, exercise, and skincare. This study's outcomes confirm previous studies' results that CDP can reduce arm volume and improve personal quality of life.[25-27]

The only difference in the type of therapy between the two groups was how the compression garment was tailored. Creating compression garments is intricate, involving multiple steps and often taking a significant amount of time. Insufficient pressure will not manage edema, and excessive pressure can be intolerable for the patient, cause pain on pressure points, or making the garment too difficult to wear. Consequently, the research team strived to introduce a new method for making compression garments that streamlines the process, making it efficient and practical.

The trial results indicate that, on average, the conventional technique reduced arm volume by 77.6 ml, while the new technique resulted in a greater reduction of 172.7 ml. However, statistical analysis revealed no significant difference between the two techniques. This lack of statistical significance may be attributed to the sample groups needing to reach the initially calculated statistical power.

However, looking at the tendency of arm volume reduction after three weeks of treatment, the new technique group showed a tendency for a more significant decrease compared to the conventional technique group. This trend might be explained by the longer duration of garment usage in the new technique group, with a median of 13.1 hours, while the conventional technique group had a median garment usage of 12.2 hours.

A review of the literature found that four studies directly evaluated the effectiveness of compression garments for breast cancer-related lymphedema.[17, 20, 28-29] Of the four studies analyzed, three compared Kinesio Taping to compression garments and one looked at nighttime compression. In addition, there was variability in garment pressure (20 to 60 mmHg), usage time (6.7 to 20 hours daily), and duration of the studies (3-24 weeks). McNeely, ML et al. demonstrated that increased wear time was correlated with improved lymphedema outcomes.[17] Due to the variations in pressure applied, usage time, and the duration of the studies, it is difficult to compare the results across these studies.

Regarding the adherence to the use of the compression garment, the lower-than-prescribed garment-wearing compliance may be due to the warm weather in Thailand, leading to sweating, minor skin issues, and discomfort among participants, which likely contributed to the reduced adherence to wearing the garments as recommended. Manufacturers of these garments have made great strides over the years in producing garments that are as lightweight and well-ventilated as possible. The rate of patients wearing compression garments as per recommendation in this study is consistent with a study from Turkey that found the rate of patients wearing compression garments as per recommendation was 51.7%.[30] The most common reasons for not wearing or discontinuing use included functional daily life difficulties (33.0%) and discomfort (28.8%). A Canadian study showed that only 31.0% reported adhering to wearing the garment for more than 12 hours each day because of user discomfort, negative emotions, interference with function, social situations, and visibility.[31]

Although standard information was provided to the patients, adherence to compression garment use was nonoptimal. Obstacles to adherence should be studied in detail to improve adherence to this method as it is the basis for maintaining treatment of lymphedema. A treatment program tailored to individual needs could be useful.

The results of this study demonstrate that the new simplified tailoring technique can reduce arm volume and enhance the quality of life for patients, with no statistically significant differences compared to the traditional technique. The new technique, however, does offer several advantages, including procedural simplicity, time savings for both healthcare providers and patients, and better suitability for implementation in busy hospital settings, making it a strong candidate for consideration. Thus, opting for the new technique for custom-made compression garments is a sensible choice.

However, from the patients' viewpoint, it is vital to account for additional expenses which may include travel costs and transit time to the hospital for measurements. Furthermore, since custom-made compression garments typically last around 4-6 months before requiring replacement, further exploration into the cost-effectiveness of this treatment method is warranted.

Study limitations

Due to time constraints, the number of participants recruited was slightly lower than planned, resulting in a smaller sample size. Therefore, it is important to interpret the results cautiously and to use larger sample sizes to confirm and strengthen the preliminary findings in future studies.

Another limitation of the study is the need for more control over the posture and daily activity of the participants. For posture, the recommendation to intermittently elevate the limbs has been a standard practice for lymphedema for an extended period[32] even though there is no evidence linking the severity of lymphedema to activities of daily living. One study showed that a controlled, short-duration arm exercise program can yield a small but significant increase in lymphoedema arm fluid immediately after exercise which returns to pre-exercise levels within 24 hours.[33] Thus, heavy arm activity similar to strengthening exercises should be considered a confounding factor.

Conclusions

Preliminary analysis showed no statistically significant difference between a custom-made compression garment and a standard garment in terms of arm volume reduction and quality of life improvement. Evaluation of the need for a less time-consuming tailoring method and patients' tendency to wear tailored garments for longer periods each day, suggests that the new simplified tailoring approach offers promising directions for a larger-scale study and in the future could be considered as a standard for producing compression garments.

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Conflicts of interest declaration

None

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Data availability

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

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Original Article

Functional Outcomes of A 3-month Stroke Rehabilitation Program Conducted Following the Intermediate Care (IMC) Service Plan

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ABSTRACT

Objectives: To study the functional outcomes of stroke patients receiving a 3-month rehabilitation program in an intermediate care (IMC) service plan and the association between recommended training sessions and good functional outcomes

Study design: Prospective observational study

Setting: The Stroke Unit and Outpatient Department of Rehabilitation Medicine, Maharat Nakhon Ratchasima Hospital (MNRH), Thailand

Subjects: Sixty-two patients with moderate stroke (NIHSS 5-15) who were admitted at MNRH between September 2022 and July 2023 and who were enrolled in IMC.

Methods: Patients' demographics, stroke information, rehabilitation program (physical therapy [PT] and occupational therapy [OT]), and locations of service were collected. Barthel index (BI) score on the day of IMC enrollment and at 2 weeks and 3 months were evaluated. In this study a BI ≥ 75 indicates a good functional outcome. Variables with statistically significant differences between the good and poor functional outcome groups were included in a multiple logistic regression analysis to examine the association between the number of training sessions and good functional outcomes.

Results: The mean age of the patients was 61 years (SD 9.3). 79.0% of the patients achieved good functional outcomes at 3 months after enrollment in IMC. There were 6 locations where patients received rehabilitation services following discharge from the hospital. The median total number of PT and OT sessions with interquartile ranges were 8 (4,13) and 1 (0,1). The mean and standard deviation of BI improvement was 45.6 (28.4) with a *p*-value < 0.01. 44.0% and 11.0% of patients received the PT program ≥ 10 sessions and the OT program ≥ 3 sessions as specified in the IMC guideline. In the multivariable analysis, the adjusted odds ratio of PT sessions ≥ 10 and OT sessions ≥ 3 and good functional outcomes were 4.58 (95%CI: 0.43, 48.70, $p = 0.207$) and 2.62 (95%CI: 0.09, 70.52, $p = 0.565$), respectively.

Conclusions: Stroke patients in the IMC service plan had significant BI improvement. A total of 44.0% and 11.0% of patients, respectively, received the recommended PT and OT training sessions following IMC guidelines. Although the number of PT and OT training sessions was not statistically significantly associated with the outcomes, the IMC service improved the clinical outcome of stroke patients and showed benefits in clinical practice.

Keywords: stroke, rehabilitation, functional outcome, intermediate care (IMC)

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Introduction

Stroke is the leading cause of mortality and disability worldwide, with long-term functional outcomes influenced by stroke severity, gender, age, comorbidities, and recurrence.[1,2] Most recovery occurs within the first 3 months due to spontaneous neurological recovery and rehabilitation efforts[3] and then gradually plateau at 3 to 6 months after onset.[4] Rehabilitation is crucial in stroke care globally. Several post-acute stroke rehabilitation models have proven effective internationally including post acute care (PAC), inpatient rehabilitation facilities (IRFs), early supported discharge (ESD), and home-based services.[5-8] ESD rehabilitation typically occurs at least 5 days per week, with the frequency gradually decreasing as the patient's condition improves.[7,8] In Thailand, many studies have shown that inpatient rehabilitation improve functional outcomes that and higher training intensity is associated with better outcomes.[9-11]

Research in Nakhon Ratchasima Province in 2012 found a significant barrier to stroke rehabilitation is accessibility, with only 18.37% of stroke patients having access to rehabilitation services.[12] To address this issue, the Ministry of Public Health developed an intermediate care (IMC) services plan to support patients transitioning from acute illness despite ongoing limitations in daily life activities, with the aim of optimizing functional outcomes based on individual potential. This care involves physiatrists and multidisciplinary teams over a period of 6 months, targeting stroke, spinal cord injury, and traumatic brain injury patients. IMC includes patients

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with a Barthel Index score (BI) of less than 75 and patients with multiple impairments such as dysphagia or aphasia. Rehabilitation options include intensive inpatient care (minimum 15 hours per week), outpatient visits which include a mean of 1-3 sessions per week of physical therapy (PT), occupational therapy (OT) at least 1 session per month, and home visits at least twice in 6 months, tailored to local contexts and made through shared decisions among patients, caregivers, and the medical team.[13] However, the IMC guideline does not specify which rehabilitation program suits specific patient characteristics, e.g., disease severity, transportation issues, and family and social support system.

Since introducing the IMC concept in 2015, many studies have assessed its outcomes. One study found that inpatient rehabilitation in community hospitals led to superior BI improvements compared to outpatient and home-based care, with better outcomes linked to more hours of physical therapy.[14,15] Maharat Nakhon Ratchasima Hospital (MNRH), a tertiary care center with 4,233 new strokes annually, implemented the IMC with a rehabilitation team comprising physiatrists, nurses, physical therapists, occupational therapists, and speech-language pathologists on the rehabilitation team. Only general practitioners, family medicine doctors, nurses, and physical therapists work in community hospitals and home-based care. Although the IMC following the published IMC guideline has been implemented for 5 years, no study has evaluated the functional outcomes of stroke patients or the actual rehabilitation services that the patients have received. This study aimed to investigate the functional outcomes of stroke patients under the IMC, focusing on the percentage of good functional outcomes and the rehabilitation services patients received. Additionally, the association between the number of training sessions according to the IMC guideline (at least 10 PT and 3 OT sessions within 3 months) and good functional outcomes was also studied.

Methods

Study design

This is a prospective observational study and was approved by the Ethics Committee of MNRH (No. 064/2022) on June 23, 2023.

Participants

Data were collected on acute stroke patients living in Nakhon Ratchasima Province who were admitted to MNRH between September 2022 and July 2023. The study included patients aged 18-75 with moderate stroke severity as indicated by a National Institute of Health Stroke Scale (NIHSS) score of 5-15, measured 24 hours after stroke onset.[16] Patients were also required to have been evaluated for IMC enrollment (BI less than 75). Exclusion criteria included patients who were in a dependent status before the stroke or who could not be contacted after discharge from the hospital. In cases where stroke patients had cognitive impairment or aphasia affecting their decision-making capacity, informed consent was obtained from family members. The sample size was calculated from a pilot study. The proportion of stroke patients with good functional outcomes in the IMC was 0.8. Using the sample size formula Z^2_1-α/2 *p(1-p)/d² with a statistical significance level of 0.05 and an error margin of 0.1, the required sample size is 62 patients.

Data collection

Stroke patients in acute stroke wards who consulted for rehabilitation were evaluated based on the inclusion and exclusion criteria. After the patient or their main caregivers gave informed consent, demographic data, stroke, and medical conditions were collected from the medical records. The data, including age, gender, diagnosis, underlying diseases, impairments, treatment, length of stay and complications, were recorded. The NIHSS and BI were evaluated by the author (KS) and Physical Medicine and Rehabilitation residents, all of whom had been trained to ensure consistent results. Medical and rehabilitation information, rehabilitation goals and management plans of all patients who enrolled in IMC, were referred to the community rehabilitation service of each patient. Telephone interviews were conducted at 2 weeks and at 1, 2 and 3 months to record the rehabilitation training patients had received (PT and OT), regular home-based rehabilitation by family members and other services, including acupuncture and Thai massage. To reduce recall bias, patients and caregivers were asked to record rehabilitation training received by patients in a logbook. The BI assessed the functional outcomes at 2 weeks and 3 months from the telephone interview[17] and medical records. At 3 months, patients were interviewed regarding satisfaction and suggestions for IMC improvement. The telephone interviews were performed by the author (KS) using a structured format.

Outcome measurements

The primary outcome was the BI which measures the ability to perform daily activities. The maximum score is 100 points; a higher score indicates greater ability. It assesses 10 areas of activities. This study classified BI of 75 or more as a good functional outcome.[18] BI is used to evaluate the patient at IMC enrollment (initial BI) and at 2 weeks and 3 months during the IMC period.

The secondary outcomes were the stroke rehabilitation program and other adjunctive modalities that patients received. The stroke rehabilitation program includes PT and OT, a number of training sessions, and health care services that provide the training (MNRH-OPD, intensive rehabilitation, community hospital, health-promoting hospital, private clinic, or home-based program). Other adjunctive modalities include acupuncture and Thai massage were collected. The number of training sessions of 10 PT and 3 OT within 3 months as in the IMC guideline was analyzed by multivariable analysis to address the association with good functional outcomes.

Statistical methods

STATA version 14.0 was used for data analysis. The demographic data were analyzed using descriptive statistics, presenting quantitative data as mean and standard deviation (SD). Differences in BI improvement at 2 weeks and 3 months were analyzed by repeated-measure analysis of variance (ANOVA) using Bonferroni correction for multiple comparisons. Comparisons between good and poor functional outcomes groups used Fisher's exact test for binary data and either the T-Test or Mann-Whitney U test for quantitative data. Variables with statistically significant levels and expected associations with good functional outcomes were included in a multiple logistic regression analysis to examine the relationship between the number of PT/OT sessions (following the 2019 IMC guideline: at least 10 PT and 3 OT sessions within 3 months) and good functional outcomes. A *p*-value < 0.05 indicates statistical significance.

Results

The study included 62 moderately severe stroke patients. Table 1 presents the patients' demographic data and bivariate analysis between variables and functional outcomes. The average time from stroke onset to enrollment in the IMC was 3.8 days (SD = 1.9). Among the 62 patients, 49 (79.0%) had good functional outcomes at the 3-month follow-up. Three patients died during follow-up from sepsis, renal failure and hypoglycemia. Gaining BI after IMC is shown in Table 2. Twenty of 62 patients (32.0%) who had an initial BI less than 75 had good BI (≥ 75) at 2 weeks. This score continued to improve at the 3 months follow-up.

Of the 62 patients receiving PT, 52 (84.0%) were from MNRH IPD as an acute stroke admission, 36 (58.0%) were from MNRH OPD, 36 (58.0%) were from community hospitals, and 33 (53.0%) received PT through home visits. Additionally, 6 patients (10.0%) attended a private clinic, 5 (8.0%) were from a health-promoting hospital, and 3 (4.8%) received intensive rehabilitation.

The median number of PT sessions was 8 (range 1-60), varying by service location, as shown in Table 3. 46 patients out of 62 (74.2%), received OT training with a median of 1 session (range 0-8). Of the 13 patients with poor functional outcomes, 3 (23.0%) received only community-based or primary care rehabilitation after entering the IMC. Three patients

Table 1. Demographic data of the patients and bivariate analysis between variables and functional outcomes

Factors	Total (n = 62)	Good outcome (n = 49)	Poor outcome (n = 13)	*p*-value
Male[1]	36 (58.0)	30 (61.2)	6 (46.2)	0.360
Age[2]	61.4 (9.3)	60.0 (9.7)	66.5 (5.3)	0.003*
Underlying disease[1]				
Hypertension	34 (54.8)	29 (59.2)	5 (38.5)	0.220
Diabetes mellitus	20 (32.3)	15 (30.6)	5 (38.5)	0.740
Dyslipidemia	17 (27.4)	14 (28.6)	3 (23.1)	1.000
Atrial fibrillation	4 (6.5)	1 (2.0)	3 (23.1)	0.026*
Ischemic stroke[1]	51 (82.3)	40 (81.6)	11 (84.6)	1.000
Dysphagia[1]	26 (41.9)	15 (30.6)	11 (84.6)	0.001*
Aphasia[1]	13 (21.0)	10 (20.4)	3 (23.1)	1.000
Treatment[1]				
Medication	51 (82.3)	39 (79.6)	12 (92.3)	0.742
rtPA	10 (16.1)	9 (18.4)	1 (7.7)	
Surgery	1 (1.6)	1 (2.0)	0 (0.0)	
Length of stay[2]	5.9 (3.0)	5.7 (3.1)	6.5 (2.7)	0.428
NIHSS after 24 hours[2]	9.4 (0.4)	8.7 (2.9)	12.2 (2.1)	0.0001*
Median initial BI score[3]	35 (25,50)	45 (30,55)	20 (5,25)	0.0002*

[1]Number (percentage), [2]mean (SD), [3]median (Q1, Q3), *statistically significant

SD, standard deviation; rtPA, recombinant tissue plasminogen activator; NIHSS, The National Institutes of Health Stroke Scale; BI, Barthel index

Table 2. Barthel index (BI) score of patients enrolled in intermediate care (IMC)

Group	Number (%)	Initial BI Mean (SD)	At 2-week Mean (SD)	At 3- month Mean (SD)	ΔBI Mean (SD)	*p*-value
Overall	62	35.9 (19.3)	56.0 (25.9)	81.5 (30.4)	45.6 (28.4)	<0.001*
Good functional outcome group	49 (79)	40.5 (18.1)	63.1(22.7)	95.4 (6.2)	54.9 (18.3)	<0.001*
Poor functional outcome group	13 (21)	18.5 (12.5)	29.2 (19.2)	28.8 (27.4)	10.4 (32.7)	0.278

p-value analyzed by repeated-measure analysis of variance (ANOVA) using Bonferroni correction for multiple comparisons, * statistically significant, ΔBI = different BI at 3 months and initial

undergoing intensive inpatient rehabilitation received both PT and OT training. Regular home-based rehabilitation by family members was present in 58 patients (93.6%). 18 patients (29.0%) received acupuncture and 14 patients (22.6%) received Thai massage. All of these patients also participated in PT. Following the IMC guideline, 27 patients (44.0%) received PT ≥ 10 sessions and 11 patients (18.0%) received OT ≥ 3 sessions.

Among the 39 rural patients, all received post-discharge PT: 19 (49.0%) through primary, secondary, or home visits alone; 3 (7.0%) from MNRH; and 17 (44.0%) via a combination of primary care, home visits, and hospital services. Conversely, of the 23 urban patients,16 (70.0%) received PT from MNRH, while 3 received home visits, and 4 did not undergo rehabilitation. Of the 59 patients scheduled for follow-up, 44 (75.0%) attended their outpatient rehabilitation appointments. Physiatrists recommended 7 patients for intensive inpatient rehabilitation, but 4 declined due to lack of caregiver support or to transportation issues. Of the 3 who accepted, 2 achieved good functional outcomes.

The bivariate analysis in Table 1 shows factors that differed between good and poor functional outcome groups were NIHSS, age, atrial fibrillation, dysphagia and initial BI. The bivariate analysis of rehabilitation intervention and adjunctive modalities (total PT and OT training sessions, IPD intensive rehabilitation, acupuncture and Thai massage sessions, and regular home-based rehabilitation by a family member) revealed that only regular home-based rehabilitation by a family member was statistically significantly different between good and poor functional outcomes, with a *p*-value of 0.026.

After controlling for factors that differed between good and poor functional outcomes, multivariable logistic regression was used to detect associations between the number of PT and OT training sessions and a good functional outcome as shown in Table 4. The adjusted odds ratio of PT sessions ≥ 10 and OT sessions ≥ 3 and good functional outcomes were 4.58 (95% CI 0.43, 48.70, $p = 0.207$) and 2.62 (95%CI 0.09, 70.52, $p = 0.565$).

Patients and relatives recorded rehabilitation data in logbooks in 17.7% of cases. The satisfaction score for the IMC service was 4.3 out of 5 (SD = 1.1). Suggestions for improvement included, “I want faster hospital services”, “I prefer receiving PT training rather than being taught for the home program”, “I want more outpatient sessions for those unable to recieve inpatient therapy”, “I want overtime PT”, “I want dietary advice”, “There was a fee for hospital-based PT”, and “I want hospital transportation for patients with impaired mobility”.

Discussion

The study showed that 79% of moderately severe stroke patients had good functional outcomes after undergoing rehabilitation in the IMC. A previous study in the same hospital by Intaratep et al. (2022)[19] reported that 82.9% of patients had BI ≥ 75 with data collected from stroke patients 3 months post-acute phase without stratifying by stroke severity or IMC involvement. The study may have included less-impaired patients, leading to better functional outcomes than the present study. This contrasts with a study by Namchundee (2021)[20] of stroke patients aged 18-80 in the IMC for 6 months which found that 66.7% had BI above 60. Despite setting a BI threshold of 60, older patients and varying stroke severities

Table 3. Number of physical therapy (PT) and occupational therapy (OT) training sessions in each rehabilitation services for each patient

Rehabilitation services	Number of training sessions median (Q1, Q3)	Min-max number of training sessions
All PT rehabilitation services	8 (4,13)	0-60
MNRH IPD – acute stroke	1 (1,1)	0-4
MNRH OPD	1 (0,2)	0-11
Community hospital	2 (0,6)	0-14
Health-promoting hospital	0 (0,0)	0-14
Home visit	1 (0,2)	0-22
Private clinic	0 (0,0)	0-57
IPD intensive rehabilitation	0 (0,0)	0-7
OT rehabilitation services	1 (0,2)	0-8

MNRH, Maharat Nakhon Ratchasima Hospital; IPD, inpatient department; OPD, outpatient department

Table 4. Association between the number of physical therapy (PT) and occupational therapy (OT) training sessions with good functional outcome

Number of training sessions	Crude odds ratio (95%CI)	Adjusted odds ratio (95%CI)	*p*-value*
PT ≥ 10 sessions	1.99 (0.54, 7.34)	4.58 (0.43, 48.70)	0.207
OT ≥ 3 sessions	1.24 (0.23, 6.58)	2.62 (0.09, 70.52)	0.565

*p-value of Adjusted odds ratio, Multivariable models were adjusted for the National Institutes of Health Stroke Scale (NIHSS), age, atrial fibrillation, dysphagia, initial BI and regular home-based rehabilitation by family member

were included, which may have led to fewer good outcomes compared to this study.

The present study found significant changes in BI among all stroke patients undergoing the IMC. BI changes averaged 54.9 in the good functional outcome group and 10.4 in the poor functional outcome group. Even in subgroup analysis, the poor functional group showed no statistically significant change in BI but did reach the minimal clinically important difference level of 9.3 points out of 100.[21]

After discharge from acute stroke care, patients received PT from 6 health care services. This corresponds with IMC policies of providing multiple service points for patients. More than half of the patients received PT from hospitals both MNRH (58.0%) and community hospitals (58.0%). This study shows that a high percentage of the patients (53.0%) received home visits PT. This may be influenced by the 2009 primary care unit and sub-district health promotion hospital policy, which included developing home visit teams. This policy was in place before the IMC implementation. Home visits PT can detect patients' environmental, family, and community problem contexts. However, we found that 20.0% of patients with poor functional outcomes were under primary care without referral to secondary or tertiary hospitals. The median number of home visit sessions was 1 in 3 months, which was insufficient for moderately severe stroke patients.

In this study, only 3 patients (4.8%) received inpatient rehabilitation, lower than the 10.7% reported by Chayaratanasin et al. (2022)[22] in medical school settings. Although it is known that inpatient stroke rehabilitation is effective, yielding better BI improvements than outpatient rehabilitation.[6,10,14,22] In rural areas, inpatient rehabilitation remains limited because of patient and caregiver issues. Evidence suggests that telerehabilitation can be as effective as face-to-face therapy, with evidence levels ranging from low to moderate.[23] Such systems would allow primary and secondary care providers to refer and consult on complex rehabilitation cases, ensuring patients receive appropriate care. Another model is ESD, which can also be a viable option for patients wishing to return home quickly, as it reduces hospital stays while achieving good functional outcomes and patient satisfaction.[7,24] However, patient selection is crucial. As Jeyaraj D. Pandian et al. (2015)[25] reported, there are poorer functional outcomes in stroke patients with caregiver-led home programs compared to hospital rehabilitation. However, this study did not aim to compare the efficacy of the IMC and inpatient rehabilitation but rather tried to relate the outcomes of routine IMC service in Nakhon Ratchasima province. All rehabilitation services, including OPD in secondary-tertiary hospitals, inpatient rehabilitation, and home visits, are important to provide rehabilitation for different severities and impairments.

MNRH is the only public health hospital in Nakhon Ratchasima province providing OT training. Approximately 74.0% of patients receive OT training tailored to individual impairments and needs. This study is the first to document the OT training program in the IMC.

The IMC guideline recommends at least 10 PT and 3 OT sessions within 3 months. However, this study found no statistically significant association between the recommended number of sessions and good functional outcomes. The adjusted odds ratio for PT sessions ≥ 10 was 4.58 (95%CI 0.43-48.70, p = 0.207), and for OT sessions ≥ 3, it was 2.62 (95%CI 0.09-70.52, p = 0.565). While the lack of statistical significance and wide confidence intervals indicate inconclusive results, the IMC service demonstrated benefits in improving patient functional outcomes.

Most patients received fewer than the recommended number of PT and OT training sessions, 56% and 89% respectively, which may have influenced the lack of association with functional outcomes. Despite selecting patients with moderate stroke severity and BI scores at IMC enrollment (mean 3.8 days post-stroke), acute phase BI scores at hospital discharge were low. Nonetheless, 32.0% achieved good functional outcomes at the 2-week follow-up, likely due to spontaneous neurological recovery and early BI evaluation. These findings suggest that not all patients require weekly rehabilitation. For some patients, an appropriate home program might be more suitable.[8, 24] Nakao et al. (2010)[26] found that BI scores at 3 weeks were reliable for predicting self-care disabilities. Thus, determining the optimal timing of BI assessments is crucial for IMC patient selection and for tailoring rehabilitation programs appropriate for the severity of impairments.

A limitation of this study is the use of participants' recall for the numbers and details of training that patients received. The use of logbooks was low (17.0%), potentially introducing recall bias. However, since most patients had infrequent rehabilitation sessions and bi-weekly and monthly follow-up interviews, patients and caregivers could recall session numbers. Collecting data from the IMC system would reduce recall bias, but the system is still not well developed. This is a single-province study; results may differ for other provinces which might have differences in the details of IMC services provided. Future research should collect more details on training, such as intensity and types of PT/OT, and should also include more data on stroke, such as muscle power, cognitive impairment, neglect and depression, which can affect functional outcomes.[27] The sample size was calculated based on the prevalence of good functional outcomes in stroke patients receiving IMC services, which may have been insufficient to detect significant associations between rehabilitation training and outcomes. Future studies should determine sample size based on this objective to identify the optimal number of training sessions for good functional outcomes. Lastly, this study evaluated the outcome at 3 months but the IMC service duration is 6 months. Extending data collection might increase the number of patients with good functional outcomes.

Conclusion

In summary, 79.0% of moderate-severity stroke patients who enrolled in the IMC service achieved good functional outcomes at 3 months. In the IMC service, stroke patients had significant BI improvement. Patients received rehabilitation training from various places including hospitals and community-based facilities. According to the IMC guideline, 44.0% and 11.0% of patients receive the recommended PT and OT training sessions, respectively. The IMC service improved the clinical outcome of stroke patients, but the recommended number of training sessions was not significantly associated with the outcome. Nevertheless, these findings did show benefits in clinical practice.

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Conflict of interest declaration

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Data availability

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

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Original Article

Accuracy in the Cross-Sectional Area of the Median Nerve at the Wrist Measured by Physical Medicine and Rehabilitation Residents

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ABSTRACT

Objectives: This study aimed to evaluate the accuracy of median nerve cross-sectional area (CSA) measurements at the wrist made by Physical Medicine and Rehabilitation (PMR) residents after a single training session.

Study design: Cross-sectional study

Setting: PMR Outpatient Unit, Phramongkutklao hospital, Bangkok, Thailand

Subjects: The study enrolled patients aged 20 years or over who had undergone median nerve conduction studies and were willing to sign the consent form.

Methods: A single-session ultrasound workshop on measuring the CSA of the median nerve at the wrist was provided to 17 PMR residents. Each resident was required to measure the median nerve CSA of five different wrists of patients who visited the electrodiagnostic laboratory in 2022-2023. The CSA was averaged from three separate measurements by each of the residents. Measurement of each wrist from a single expert physiatrist was considered as a reference standard. The intraclass correlation coefficient (ICC) was used to determine the accuracy of CSA measurement. Additionally, agreement on the determination of median nerve enlargement (≥12 cm^2) was made using Cohen's Kappa coefficient.

Results: Of 82 wrists, 64.0% were diagnosed with carpal tunnel syndrome (CTS) based on the electrodiagnosis study. The median nerve was correctly identified in 79 wrists (96.3%). The overall resident's ICC was 0.948 ($p < 0.001$) compared with an expert physiatrist. The Kappa coefficient was 0.849 ($p < 0.001$), with a 92.4% agreement percentage.

Conclusions: US training sessions may benefit PMR residency programs. Further research is needed to determine optimal training duration and frequency and to assess long-term skill retention.

Keywords: median nerve, cross-sectional area, ultrasound, accuracy, residency training

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Introduction

Median neuropathy at the wrist or carpal tunnel syndrome (CTS) is one of the most common issues among those who visit the outpatient unit of the rehabilitation department. It is also the most common focal neuropathy of the upper extremity. Globally, the prevalence of this condition is between 105 and 544 cases per 100,000 population.[1] Patients generally present with pain or numbness at hand, especially during nighttime. The thumb, index, and middle finger were commonly affected, which makes it necessary to differentiate diagnoses of conditions with similar symptoms such as brachial plexopathy and cervical radiculopathy.[2] CTS can be diagnosed by taking a history, performing a physical examination, and conducting a nerve conduction study (NCS). The latter has been recognized as a gold standard diagnostic tool, but patients undergoing NCS might feel discomfort/pain from electrical stimulation.

Diagnostic ultrasound (US) has been studied and developed over the past several decades to diagnose and manage musculoskeletal disorders. It can provide additional information on structural characteristics without causing pain and in less time.[3] Cost-effectiveness was also reported when using the US as a first-line test, confirmed by NCS if the US was negative.[4] Many studies have established the use of the cross-sectional area (CSA) of the median nerve at the wrist measured by the US in diagnosing CTS with sensitivity and specificity of 71.4-96.9 and 56.5-93.6, respectively.[5-7] These results support using US imaging as a routine diagnostic tool combined with the electrodiagnosis study.

The principal limitation of diagnostic US is its operator-dependency, with more examiner experience generally corresponding to more reliable diagnoses. However, several studies have been published recently about the learning process of musculoskeletal US from expert specialists to trainee residents or fellowship doctors. Those studies showed a significant effect of teaching even with a short study time.[8,9]

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In Thailand, residency training in rehabilitation medicine, or physical medicine and rehabilitation (PMR), includes attaining knowledge and skills in the diagnostic US. In PMR, US is generally used in the diagnosis of musculoskeletal disorders but is used less frequently in the diagnosis of focal compressive neuropathies. However, this study evaluated whether measuring median nerve CSA at the wrist to determine CTS should be included in Thailand's PMR residency curriculum, considering resident doctors are new to using the US to diagnose CTS. This research hypothesized that after a single training workshop, PMR residents could accurately measure median nerve CSA at the wrist, compared with an expert in electrodiagnosis and neuromuscular US.

Methods

Study design

A cross-sectional study was conducted between July 2022 and August 2023. The Royal Thai Army Medical Department Institutional Review Board approved this study protocol (R029h/65) on May 6, 2022.

Participants

The sample size was determined using a formula for agreement studies using an interclass correlation coefficient (ICC) with a minimal acceptable reliability of 0.5 and an expected reliability of 0.7.[10] Acceptable levels of type 1 and 2 errors were set up as 0.05 and 0.20, respectively. The calculation shows that the minimum number of wrists that should be included in this study is 79. Considering that 17 resident doctors were trained during the research period, each resident was required to investigate five wrists. Considering that 17 resident doctors were trained during the research period, each resident was required to investigate five wrists. During the study period, sample selection was made with convenience sampling in patients who visited the Electrodiagnostic Laboratory of the Department of Rehabilitation Medicine, Phramongkutklao Hospital. Patients aged 20 years or over who had undergone median nerve conduction studies and were willing to sign the consent form were enrolled to the study. Any patients with wrist deformity, bifid median nerve, a history of undergoing wrist surgery, or having received steroid injection at the investigating wrist were excluded.

Outcome measurement

Before the study, 17 residents (6 for year 1, 6 for year 2, and 5 for year 3) received a 1.5-hour training session for US measurement of median nerve CSA at the wrist by a physiatrist (X.X.) with eight years of experience in the neuromuscular US. The session included a lecture on anatomy and basic sonography. US section focused on distinguishing between the median nerve and surrounding tendons based on the nerve's marked "honeycomb" pattern. The US performed at the inlet level of the wrist was also demonstrated to the group. Then, individual hands-on training was given to each of the residents. Feedback was given individually after each resident attempted to repeat the diagnostic test.[11] All residents were informed of the study's purpose before making their decision about participation. They were assured that they would receive future study opportunities equally, regardless of whether they chose to participate in this study.

The US measurements were made using a SONIMAGE HS1 (Konica Minolta, Tokyo, Japan) with an L18-4 linear array transducer. The participant sat relaxed with forearms in full supination on the examination table. The device setup was as follows: frame rate of 40 frames-per-second, grain of 25. The US transducer was located at the carpal tunnel inlet,[12], with pisiform bone as a landmark of the examined plane.[13-15] The US picture was frozen When the median nerve was located. The CSA was measured in cm^2 using the user software application's 'trace area' menu. The tracing line was drawn at the margin of the hyperechoic line surrounding the median nerve (Figure 1).

An expert and an assigned resident measured the median nerve CSA at the wrist in a private space without knowing each other's value or NCS results. Each examiner performed a US examination three times for the median nerve, and an average value was used in statistical analysis.

For NCS, both Nicolet VikingQuest (Natus Medical, San Carlos, CA, USA) and Synergy On Nicolet EDX systems (Natus Medical) were used. The median nerve's sensory profile was measured at the third digit using a ring electrode 14 cm proximal to the active electrode. In contrast, using a disc electrode, the median nerve's motor conduction study was recorded at the motor point of the Abductor pollicis brevis muscle. Motor nerve stimulation was applied at the wrist (8 cm proximal to the active electrode) and at the elbow. CTS was diagnosed in those with an electrophysiology profile as follows: 1) mild degree if prolonged sensory distal latency (> 4 ms); 2) moderate degree if both abnormal sensory and motor distal latency (> 4.5 ms); 3) severe degree if both prolonged sensory and motor distal latency, with either absent sensory nerve action potentials or abnormal compound muscle action potentials (< 4.1 mV).[16,17]

Statistical methods

For descriptive statistical analysis, mean and standard deviation were used for continuous data, while number and percentage were used for categorical data. The accuracy of CSA measurement was determined using the ICC in a mixed-effects model 18. The agreement to determine the median nerve enlargement (≥ 0.12 cm^2) was determined using Cohen's Kappa coefficient. Additionally, comparing the area under the receiver operating characteristic ROC curve (AUC) was used to establish the equality of overall diagnostic values between residents and an expert.

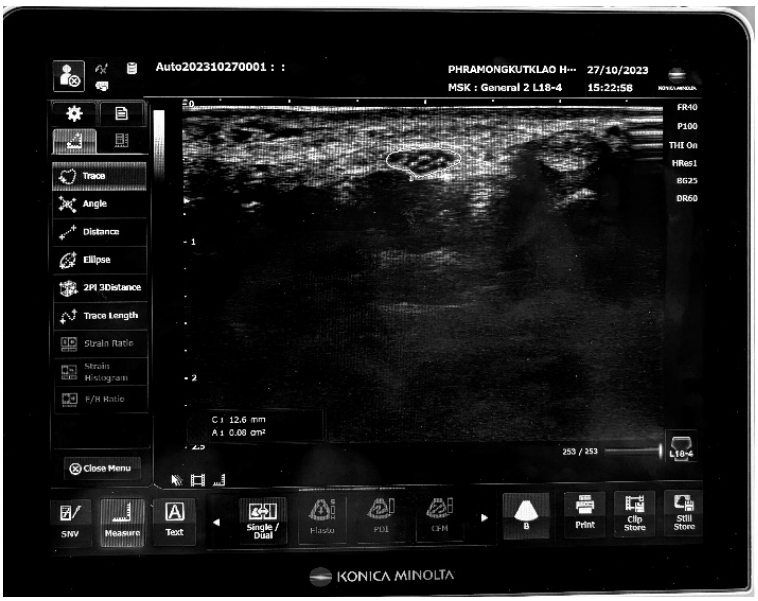

Figure 1. The CSA measurement of the median nerve using the 'trace area' menu.

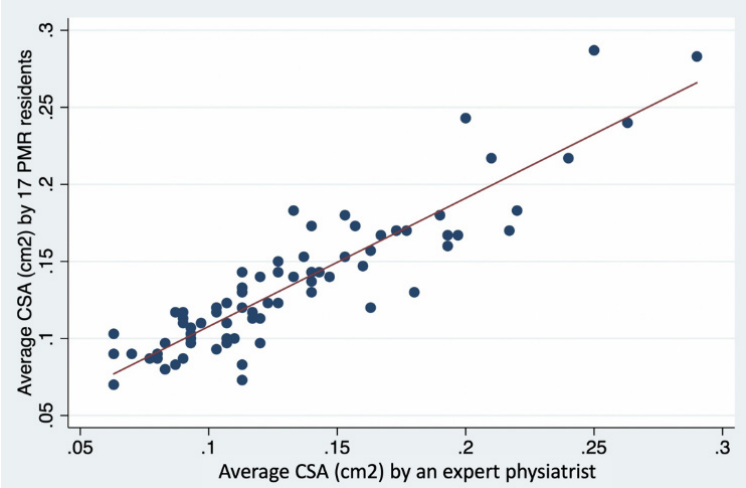

Figure 2. The scatter plot shows the accuracy of median nerve cross-sectional study (CSA) measured by 17 residents (an expert physiatrist as a standard reference).
[PMR, Physical medicine and rehabilitation; cm, centimeters.]

Results

A total of 98 wrists (49 patients) were enrolled in the study. However, 16 wrists were excluded due to the bifid median nerve (6 wrists) and a history of surgery at the wrist (10 wrists). Of the remaining 46 patients, most participants were female (68.0%), with a mean age of 59.8 (13.7). Of the 82 wrists examined, 53.0% were on the left side. Clinical symptoms of CTS were observed in 66 wrists (80.0%), although only 53 (65.0%) had electrophysiological findings of CTS.

Of the 82 wrists examined, residents correctly identified the median nerve in 79 wrists (96.3%). In three wrists, a structure other than the median nerve was misidentified as the median nerve. Thus, only those 79 were included in the statistical analysis. The accuracy of median nerve CSA measurement between residents and an expert physiatrist was represented as ICC, which was 0.948 (95% confidence interval [CI]: 0.919 to 0.967) with $p < 0.001$ (Figure 2).

Compared with the NCS result, the AUC of residents and an expert physiatrist was 0.782 (95%CI: 0.678 to 0.887) and 0.728 (95%CI: 0.613 to 0.844), respectively. However, this difference between AUCs was not statistically significant (chi2(1) = 2.82, $p = 0.093$). The measurement, defined as median nerve enlargement, had a cut-point value of 0.12 cm^2.[13,14] The agreement percentage between residents and an expert physiatrist was 92.4% (Table 1), with a Kappa coefficient of 0.849 ($p < 0.001$).[19]

Discussion

NCS has been known as the gold standard test for CTS. However, patient waiting time for NCS is usually long because this test is time-consuming and generally only available in tertiary care centers. Many studies have recommended using US measurement of median nerve CSA at the wrist to assist in CTS diagnosis. The American Association of Neuromuscular

Table 1. The inter-rater agreement of median nerve enlargement cross-sectional area ≥ 0.12 cm^2) at the wrist determined by residents and an expert physiatrist

US examiner	Expert physiatrist		Total
	≥ 0.12 cm^2	< 0.12 cm^2	
Residents			
≥ 0.12 cm^2	36 (97.3%)	5 (11.9%)	41 (51.9%)
< 0.12 cm^2	1 (2.7%)	37 (88.1%)	38 (48.1%)
Total	37 (100%)	42 (100%)	79 (100%)

CSA, cross-sectional area; US, ultrasound; cm, centimeters

and Electrodiagnostic Medicine stated that US imaging could provide an accurate test for diagnosing CTS.[20] Georgiev et al. also recommended using the US owing to several advantages, mainly the absence of unpleasant perception to patients and cost-effectiveness.[13]

Adequate US training for measuring median nerve CSA at the wrist is imperative for inexperienced operators such as PMR residents. This study found that after a single training session, measurements of median nerve CSA at the wrist by PMR residents were comparable to those by an expert physiatrist. The median nerve was misidentified in only 3 out of 82 (approximately 3.6%) wrists.

The findings of this study were similar to several previous studies. The study of Zumsteg JW et al. recruited six hand surgeon fellows for a 30-minute US training session and evaluated their competency in identifying wrist structures one month after the instruction. The evaluation was to examine several structures, including the CSA of median nerves. The results showed that all six fellows could provide the correct value of the median nerve CSA.[9] Another study focused on sonography imaging training of seven orthopedic residents and five hand fellows by Crasto et al. All participants attended a 5-minute teaching session on basic sonography and a hands-on demonstration on a single cadaver. Immediately after the instruction, all participants could identify and measure the median nerve CSA at the wrist and had increased confidence in performing US imaging.[8]

Although the overall percentage agreement between residents' and an expert physiatrist's determination of median nerve enlargement was strong, the false positive rate from residents' examinations was slightly elevated (11.0%), as shown in Table 1. This finding could reflect a tendency of the residents to overestimate the CSA. Moreover, this could be influenced by their relative inexperience in performing US imaging procedures, leading to errors; for example, US probe placement may not have been perpendicular to the median nerve, or CSA measurement may have included the nerve sheath.

Several strengths could be found in the present study. Firstly, the measurement of median nerve CSA in this study was conducted in clinical practice with 82 wrists examined and 17 inexperienced operators. Hence, the study results had good external validity. Moreover, the enrollment period of the participants was longer than in the previous studies. The accuracy of the CSA measuring was not a temporary proficiency.

Conclusion

• PMR residents' skill in measuring the CSA of the median nerve at the wrist for CTS diagnosis was good compared with an expert physiatrist after receiving a short training session.

• US training sessions would benefit PMR residency programs. Further research is needed to determine optimal training duration and frequency and to assess long-term skill retention.

Limitations

1. No control over residents' prior US experience and practice existed. Hence, year two and year three residents had some basic US skills before the study, and all residents possibly gained US experience from their practices throughout the study enrollment period.

2. Due to the exclusion criteria, residents had no experience identifying bifid median nerves. This exclusion criterion was included due to the lack of consensus on the size of the bifid median nerve that correlates with the diagnosis of CTS. However, several studies suggested that the bifid median nerve is related to CTS.[21,22]

3. The time gap between instruction time and each CSA measurement was not recorded. The difference in gap times could cause inconsistent accuracy in each resident doctor. In the future, monitoring the time since training and the reliability of US tests to schedule additional training sessions optimally would be worthwhile.

Conflict of interest declaration

There are no conflicts of interest or support from the medical equipment.

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Data availability

The data that support the findings of this study are available on request from the corresponding author, N. The data are not publicly available due to information that could compromise the privacy of research participants.

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Original Article

Reliability of Range of Motion Assessment Using Universal Goniometer and Video Goniometer Application: A Comparative Study

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ABSTRACT

Objectives: To compare the reliability of universal goniometer (UG) and video goniometer (VG) applications in assessing the range of motion of lower extremity involvement in patients with osteoarthritis during gait

Study design: A comparative study design

Setting: Department of Physical Therapy, Community-Based Rehabilitation of Doña Remedios Trinidad Romualdez Educational Foundation Inc., Tacloban City, Leyte, Philippines

Subjects: Forty-three participants with knee osteoarthritis

Methods: The research involved 43 participants aged 40 to 80 with persisting unilateral knee pain for at least 6 months and above who can perform independent walking activities recruited from Palo and Tacloban City, Leyte, Philippines, through a community-based program. Data collection included demographic information and range of motion (ROM) measurements during walking, which occurred over specific dates with a two-day gap between trials. Joint angles were measured using a universal goniometer and a video goniometer, with the universal goniometer attached to key joints like the knee, hip, and ankle during specific gait cycles. The video goniometer employed the Angles application to measure joint angles in the sagittal plane, using anatomical landmarks such as the greater trochanter, lateral epicondyle, and lateral malleolus. Measurements were adjusted to ensure consistency, with specific angles for hip flexion/extension, knee flexion/extension, and ankle dorsiflexion/plantarflexion recorded. To ensure impartiality, researchers randomized video sequences and restricted access to measurements. Reliability was assessed using the intraclass correlation coefficient (ICC) for inter and intra-rater assessments.

Results: The difference between the interrater reliability among UG and VG showed that UG (ICC = 0.536) is more reliable than VG (ICC = 0.318) in assessing hip, knee, and ankle range of motion (ROM). The difference between the intra-rater reliability among UG and VG, on the other hand, showed that VG (ICC = 0.714) is more reliable than UG (ICC = 0.611) in assessing hip, knee, and ankle ROM.

Conclusions: In conclusion, when assessing ROM in patients with arthritis with multiple assessors, the universal goniometer shows better consistency among assessors (interrater reliability), while the video goniometer demonstrates more consistent assessments by individual assessors across multiple trials (intra-rater reliability).

Keywords: universal goniometer, video goniometer, range of motion, knee osteoarthritis, reliability

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Introduction

Goniometers are crucial for measuring joint angles in various disciplines, but concerns exist regarding reliability and accessibility. Measuring range of motion (ROM) is vital for assessing joint function, diagnosing movement limitations, and tracking rehabilitation progress. Accurate ROM measurements help identify joint stiffness or asymmetry, guide treatment plans, and monitor recovery. In clinical and research contexts, reliable ROM data supports effective patient care and facilitates comparison across studies.

The traditional universal goniometer (UG) is a widely utilized instrument for measuring ROM. Research shows that a clinician's repeated use of the traditional goniometer on the same individual yields consistent measurements, indicating reliable ROM assessments with proper training and standardized protocols.[1] Key factors influencing reliability include clinician experience, as more experienced practitioners tend to demonstrate higher intra-rater reliability and adherence to standardized procedures for patient positioning and goniometer alignment.[2,3]

On the other hand, video goniometer (VG) applications have demonstrated high reliability, suggesting that consistent

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measurements can be obtained regardless of the assessor. This goniometer type offers several potential advantages, including increased objectivity, as the recorded movement can be reviewed multiple times, reducing the subjectivity inherent in manual measurements.[4] Additionally, it allows for a more detailed analysis of movement patterns, such as velocity, acceleration, and timing.[5] However, the reliability of video goniometry is influenced by several factors, including accurate camera calibration, the precision of the software used for analysis, and consistent camera angle and positioning, all of which are critical for ensuring reproducible and accurate results.[6]

Traditional UG remain popular despite drawbacks such as requiring two-handed operation. New technologies like the Angles Video-Goniometer app offer promising alternatives that are affordable and user-friendly alternatives for clinicians and researchers. The Angles Video-Goniometer application is both valid and reliable for assessing joint angles.[7] It can be used during static and dynamic activities for adults and children. While studies confirm the validity and reliability of the app, there is a lack of research comparing it to traditional goniometers, particularly in measuring functional activity among patient populations.

The Angles-Video Goniometer Application or the Angles App was developed to provide a modern, accessible tool for measuring joint angles using video technology. The development process involved designing a user-friendly interface allowing users to capture video recordings, mark anatomical landmarks and measure joint angles in static and dynamic positions.[8] The Angles App was meticulously designed to offer a cost-effective and efficient alternative to traditional goniometers. Its validation has been rigorously conducted, with research demonstrating that the App provides reliable and accurate measurements.[9] Studies comparing the application's measurements with those obtained from traditional goniometers have confirmed its accuracy.[10] Furthermore, the application's measurements have been tested against those of healthy subjects, showing consistency with established methods.[11] This validation supports the application's effectiveness and reliability for joint angle assessment in clinical and research settings.

Despite its promising capabilities, there is a notable gap in research comparing the Angles app to traditional goniometers, particularly in functional assessments for patients with knee osteoarthritis (OA). This gap highlights the need to evaluate whether the app can offer comparable or superior accuracy in measuring ROM during functional tasks such as gait, as this has already been used in assessing healthy individuals.[12] Furthermore, knee OA was chosen for this study due to its prevalence and the significant impact on gait and functional mobility. Precise measurement of ROM in this population is critical for assessing treatment efficacy and monitoring disease progression. However, limited research compares video goniometers to traditional methods, specifically in the context of knee OA. Focusing on knee OA patients, this study aims to determine the application's efficacy in a context where precise measurement is crucial for effective management and treatment planning. The findings will help address this gap and improve clinical practice for managing knee OA.

Methods

Research design

Approved by the Eastern Visayas Health Research and Development Consortium Committee on June 19, 2023 (protocol code 2023-010), this study was conducted at Palo and Tacloban City, Leyte, Philippines, through a community-based program under the facilitation of the Department of Physical Therapy, Community-Based Rehabilitation of Doña Remedios Trinidad Romualdez Educational Foundation Inc., Tacloban City, Leyte, Philippines. The research was designed as a comparative study to evaluate the range of motion (ROM) in the lower extremities—specifically the hip, knee, and ankle—in patients with knee osteoarthritis during gait. This evaluation utilized both a universal goniometer and a video goniometer.

Participants

The study included 43 patients from various communities in Palo and Tacloban City, Leyte, identified through the Remedios Trinidad Romualdez Community-Based Rehabilitation program. The sample size of 43 was calculated using a 95% confidence interval, a 5% margin of error, and a population proportion of 25%, with a total population size of 50. Eligible participants were males or females aged 40 to 80 with unilateral knee pain persisting for at least 6 months or diagnosed with knee osteoarthritis who could independently walk. Inclusion criteria were based on clinical signs and symptoms and classification criteria for knee osteoarthritis.[13] Participants with a medical history of joint arthroplasty in any lower extremity joint (hip, knee, or ankle) were excluded from the study.

Study procedure

Participants were recruited following protocols, ensuring confidentiality and obtaining informed consent through personal contact and signed consent forms. Initial contact was made with 50 potential participants, of whom 43 met the inclusion criteria and underwent assessment. The assessment process included administering a questionnaire gathering demographic information and ROM data.

Gait assessments were conducted in a controlled indoor environment with careful consideration for optimal camera positioning to capture the entire body during walking trials. An Apple iPhone 11 camera at high-definition video quality at 30 frames per second frame rate, mounted on a stabilizer, was used to record video footage by tracking the participant throughout their gait cycle. This approach ensured optimal distance from the participants while maintaining a full view of

the reference limb. The entire data collection process took an average time of 15 minutes. Researchers were also individually assigned different roles, including the one who prepares the markers for the participants, the cameraman, and the respective assessors with physical therapists throughout the process. Participants were instructed to walk along a 20-feet predetermined pathway at their preferred speed with their painful leg as reference faced towards the single camera, recording them at the lateral aspect. Markers (cotton and tape) were also affixed to the reference leg's hip, knee, and ankle joints to ensure precise identification of the fulcrum for accurate placement during measurement.

Joint angles were measured using two distinct methods: a universal goniometer and a video goniometer. The universal goniometer was utilized to measure specific gait cycles, with the small goniometer attached to joints of interest, such as the knee, hip, and ankle. This measurement was synchronized with video footage to document joint angles at various points in the gait cycle, as shown in Figure 2 and elaborated further in Table 1.

The video goniometer method employed anatomical landmarks marked with the Angles application (Figure 3). Joint angles in the sagittal plane were measured for the hip, knee, and ankle. Anatomical landmarks included the greater trochanter, lateral epicondyle of the femur, and lateral malleolus. Specific joint angle measurements included hip flexion (0° to 180° anteriorly), hip extension (0° to 180° posteriorly), knee flexion (0° to 180°), knee extension (180° to 0°), ankle dorsiflexion (0° to 90°), and ankle plantarflexion (90° to 180°). The reference point of 180° represented the initial or starting position, subsequently interpreted as 0°. To ensure consistency across all video goniometer assessments for the hip, knee, and ankle, the researcher adjusted the data by subtracting 180° where applicable. Ankle joint angles below 90° were classified as dorsiflexion, while angles above 90° were identified as plantarflexion.

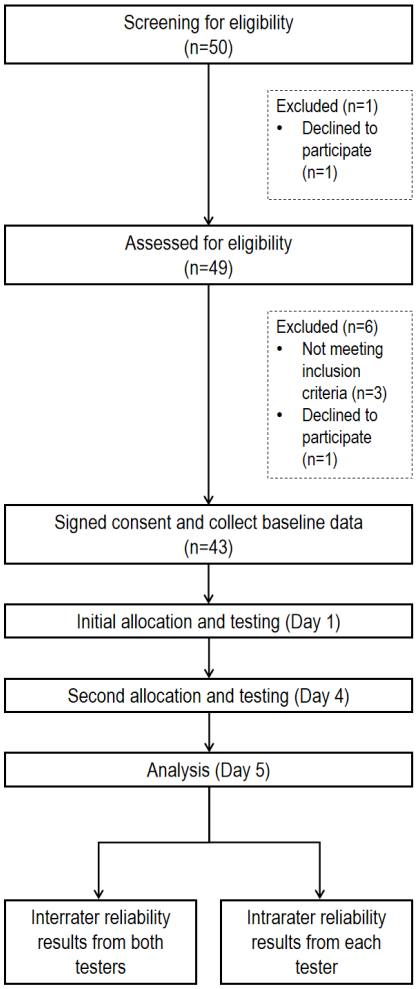

Figure 1. Data gathering procedure

Data collection occurred over specific dates with a two-day gap between trials to minimize fatigue and allow for recovery. All collected measurements were meticulously organized in a spreadsheet for subsequent statistical analysis, ensuring systematic data management and integrity throughout the study.

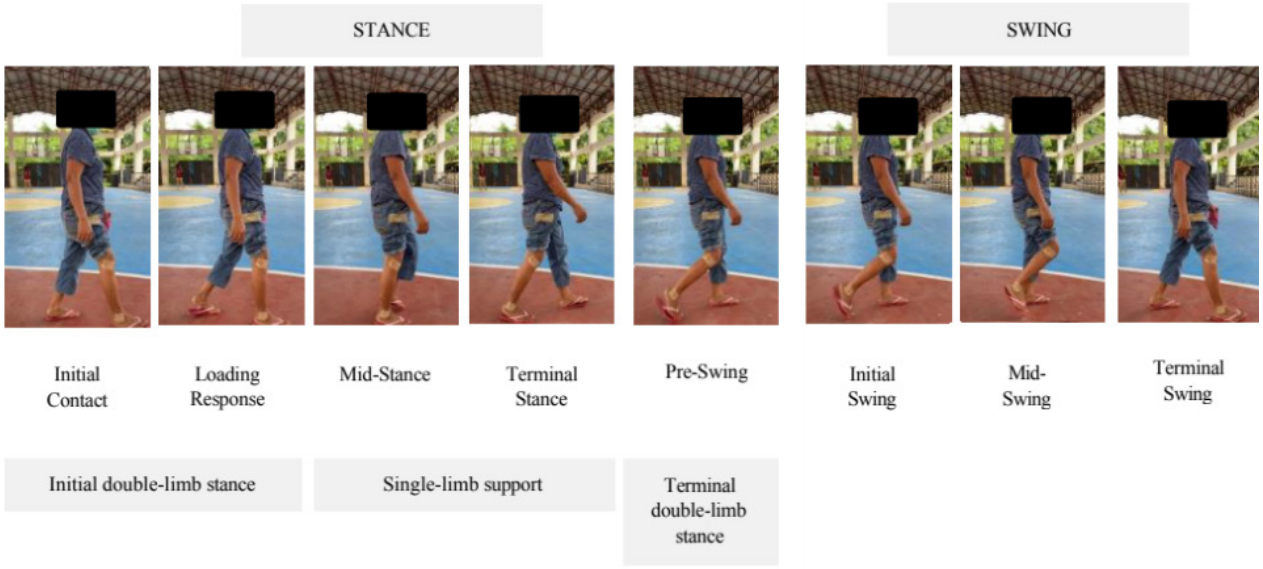

Figure 2. The phases and subphases of the gait cycle

Table 1.

The subphases of the Gait Cycle	Description
Initial contact	At the beginning of the stance, when the heel or some other portion of the foot contacts the ground.
Loading response	Body weight rapidly loads onto the lead limb from the trailing limb. The hip remains stable, the knee flexes to absorb shock, and the forefoot lowers to the ground. Immediately follows initial contact and ends when the opposite limb lifts from the ground for swing.
Mid-stance	The trunk progresses from behind to in front of the ankle over the single stable limb. It starts when the contralateral foot lifts from the ground for a swing.
Terminal stance	The trunk continues forward progression relative to the foot. The heel rises from the ground, and the limb achieves a trailing limb posture and ends with contralateral initial contact.
Pre-swing Initial swing	Body weight rapidly unloads from the reference limb, and the reference limb prepares for swing. It starts with contralateral initial contact and ends at the ipsilateral limb toe-off. It starts when the reference foot lifts from the ground. Hip, knee, and ankle rapidly flex for clearance and advancement.
Mid-swing	Thigh continues advancing, knee begins to extend, and ankle achieves neutral posture.
Terminal swing	The knee achieves maximal extension, and the ankle remains neutral in preparation for the heel's first initial contact. It ends when the foot contacts the ground.

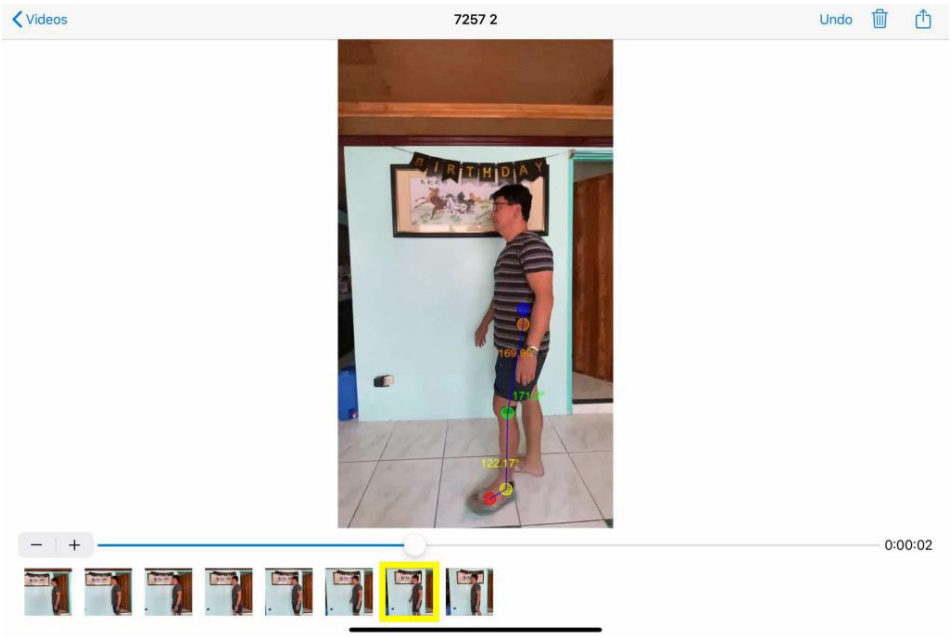

Figure 3. Data sample from the Angles-Video Goniometer Application

Statistical treatment of data

The intraclass correlation coefficient (ICC) formula was employed, utilizing SPSS statistical package version 26 to calculate ICC estimates and their 95% confidence intervals. For interrater reliability, a mean-rating (k = 2), consistency, and two-way mixed-effects model was applied, while for interrater reliability, an absolute-agreement, two-way mixed-effects model was used.

Results

General characteristics of the subjects

The demographic data of 43 participants (Table 2) revealed that the majority of participants were aged between 50-70 years (58.1%), with a smaller proportion under 50 years (30.2%) and over 70 years (11.7%). Females comprised 69.8% of the sample, while males accounted for 30.2%. Regarding disease onset, most participants (51.2%) reported onset between 1-4 years ago, with smaller percentages experiencing onset less than a year ago (25.6%), 5-8 years ago (13.9%), and over 8 years ago (9.3%).

Interrater reliability

The average interrater reliability measured by ICC for lower extremity motions during different subphases of gait using both UG and VG (Table 3) showed that the overall average reliability was higher for UG (ICC = 0.536, 95%CI [0.28, 0.72]) compared to VG (ICC = 0.318, 95%CI [0.02, 0.56]). Among the gait subphases, interrater reliability using UG was highest during the initial swing (Isw) with an ICC of 0.840 (95%CI [0.72, 0.91]). In contrast, VG reliability was consistently lower across all subphases, with the highest reliability also during the Isw at 0.547 (95%CI [0.30, 0.73]).

Table 2. Demographic data of 43 participants

Variables	Number (%)
Age	
< 50 years old	13 (30.2)
50-70 years old	25 (58.1)
> 70 years old	5 (11.7)
Gender	
Male	13 (30.2)
Female	30 (69.8)
Disease onset	
< 1 year ago	11 (25.6)
1-4 years ago	22 (51.2)
5-8 years ago	6 (13.9)
> 8 years ago	4 (9.3)

*Average ICC was obtained from the ICC values of hip, knee, and ankle joints

Table 3. The interrater reliability of the universal goniometer (UG) and video goniometer (VG) for measuring lower limb joint movements in gait cycle

Subphases of Gait Cycle	Average ICC of UG	Average ICC of VG
Initial contact	0.497	0.315
Loading response	0.506	0.415
Mid-stance	0.079	0.143
Terminal stance	0.501	0.249
Pre-swing	0.599	0.263
Initial swing	0.840	0.547
Mid-swing	0.725	0.398
Terminal swing	0.544	0.210
Average Reliability	0.536	0.318

*Average ICC was obtained from the ICC values of hip, knee, and ankle joints

Interrater reliability

The average interrater reliability (ICC) for lower extremity motions across different gait subphases using the UG and VG (Table 4) indicated that the overall average reliability was higher for VG (ICC = 0.714, 95%CI [0.53, 0.84]) compared to UG (ICC = 0.611, 95%CI [0.38, 0.77]). The highest reliability for UG was observed during terminal stance (Tst) with an ICC of 0.663 (95%CI [0.45, 0.80]). In comparison, VG showed its highest reliability during the Isw with an ICC of 0.814 (95%CI [0.68, 0.90]).

Discussion

Demographic data

This study provides valuable insights into the demographic and clinical characteristics of the participants, which are crucial for interpreting the findings and understanding their implications. The sample, consisting of 43 participants, showed that the majority were aged between 50 and 70 years (58.1%), reflecting the typical age range for knee OA, which is most prevalent among middle-aged and older adults.[15] A smaller proportion were under 50 (30.2%), and only 11.7% were over 70 years, consistent with epidemiological data.16 The gender distribution revealed a higher proportion of females (69.8%) compared to males (30.2%), aligning with

Table 4. The intrarater reliability of the universal goniometer (UG) and video goniometer (VG) for measuring lower limb joint movements in gait cycle

Subphases of Gait Cycle	Average ICC of UG	Average ICC of VG
Initial contact	0.547	0.777
Loading response	0.624	0.766
Mid-stance	0.529	0.699
Terminal stance	0.663	0.488
Pre-swing	0.640	0.602
Initial swing	0.697	0.814
Mid-swing	0.664	0.783
Terminal swing	0.523	0.781
Average Reliability	0.611	0.714

*Average ICC was obtained from the ICC values of hip, knee, and ankle joints

the known higher prevalence of knee OA in women due to hormonal changes and more significant knee joint stress.[17,18] Additionally, the majority of participants reported disease onset between 1 and 4 years ago (51.2%), with fewer experiencing onset within the past year (25.6%) or beyond 8 years ago (9.3%). This distribution indicates that the sample includes individuals at various stages of disease progression, offering insights into both early and more established OA.[19,20] Overall, the demographic characteristics of the study sample reflect the typical profile of individuals with knee OA and provide context for the findings on joint angle measurements and their implications for diagnosis and treatment. Future research should continue to explore these variables to refine and enhance management strategies for knee OA.

Interrater reliabilities

A UG showed moderate interrater reliability for osteoarthritic patients' lower extremity (LE) motions. These findings are consistent with several studies that noted UG's consistent performance in measuring joint ROM, particularly for the knee.[21,22] The research conducted in 2003 provides additional evidence reinforcing the notion of moderate interrater reliability associated with using UG in measuring ankle range of motion.[23] Overall, UG remains a reliable tool for clinical evaluations, providing accurate joint ROM measurements due to its standardized positions and precise landmarks.

The interrater reliability of VG showed poor interrater reliability. A study in 2023 emphasized the moderate reliability of knee joint angle measurements during walking in neurological patients,[24] while another study in 2001 stressed the importance of precise and consistent measurements,[25] advocating for standardized methodologies. These findings highlight the low interrater reliability of VG for assessing hip, knee, and ankle ROM in arthritis patients, underscoring the importance of standardized measurement approaches.

Interrater reliabilities

The interrater reliability of using UG showed moderate interrater reliability for LE motions in osteoarthritic patients. Compared to studies reporting high reliability with alternative

tools,[26,27] this review finds moderate interrater reliability with UG. Related studies also confirm the moderate reliability found here, stressing the importance of following specific protocols to ensure accuracy and dependability.[28,29]

The interrater reliability of using VG showed moderate interrater reliability. A similar study expressed good interrater reliability for hip, knee, and ankle joints, particularly at initial contact.[30] Emphasis should also be placed on the importance of design considerations in evaluating measurement changes applicable to VG reliability assessments.[31] These studies collectively validate VG as a reliable tool for clinical evaluations, emphasizing the need for consistent measurement practices.

Comparison of UG and VG reliabilities

As applied in this study, the universal goniometer is the traditional tool for measuring joint angles, typically requiring manual alignment of the device with anatomical landmarks at each subphase of gait. While familiar and commonly used, this method can introduce variability in measurements due to improper alignment with the necessary anatomical landmarks, leading to potential inconsistencies. On the other hand, the Angles video goniometer application streamlines the process by allowing clinicians to plot the joints directly within the specific gait subphase to obtain the joint angle. This process makes it more efficient, as the need to identify multiple landmarks is eliminated, with only the fulcrum of each joint needing attention. However, the VG can be somewhat confusing due to its use of a coordinate grid, which necessitates subtracting degree angles to calculate the correct joint angle, adding a layer of complexity to its interpretation.

In assessing hip ROM, UG demonstrated higher interrater reliability than VG, in contrast to previous findings that reported equal reliability between the two methods.[32] Discrepancies in this study may be attributed to human errors.[33] UG also demonstrated higher reliability in assessing knee ROM, echoing previous research findings that showed greater interrater reliability with UG than a smartphone goniometer application in dancers with knee osteoarthritis.[34] In evaluating ankle ROM, UG demonstrated more excellent reliability, which aligns with previous findings suggesting higher interrater consistency using a traditional universal goniometer over other measurement instruments.[35] In contrast, VG showed higher interrater reliability than UG in assessing hip, knee, and ankle ROM. In a study conducted by researchers in 2017, findings indicated that a goniometer app displayed high levels of intra- and interrater reliability, with minor differences noted between measurements taken by students and experienced physicians when compared to UG.[36]

Furthermore, the VG offers several distinct advantages over the UG, contributing to its increased reliability and utility. Firstly, the VG eliminates the need for physical contact and manual alignment, which can introduce variability and measurement errors with the UG. The UG relies on precise manual positioning and alignment by the examiner, which can be influenced by factors such as examiner experience and consistency.[37] In contrast, the VG uses video recordings to capture joint angles, allowing for more consistent and repeatable measurements by minimizing human error.[38] Secondly, the VG provides a more comprehensive analysis of joint motion. Analyzing video recordings enables detailed assessments of dynamic movements and multiple gait cycles, which is challenging with the UG due to its one-time measurement approach.[39] This capability allows for better capture of complex gait patterns and provides a more complete picture of joint kinematics during functional activities.[40] Additionally, the VG is more accessible and user-friendly. Traditional UG measurements often require two-handed operation and direct physical contact, which can be cumbersome and less practical in clinical settings.[41] The VG, however, simplifies the measurement process through an intuitive interface and does not require physical interaction, making it more suitable for both clinical and research applications.[42] Finally, the VG's digital format allows easy data storage, retrieval, and analysis. This digital advantage streamlines documentation and facilitates using advanced analytical tools and software for in-depth evaluation and comparison of joint angles.[43] In contrast, UG data is typically recorded manually, which can be time-consuming and prone to inaccuracies.[44] As for the limitations of this study, a small sample size may affect the generalizability of the findings to a broader population. Addi-tionally, the study focused on a specific group of osteoarthritic patients, was conducted in a controlled environment, and assessed short-term reliability, limiting the applicability of the results to other patient populations, real-world settings, and long-term measurements.

Conclusion

In conclusion, the universal and video goniometer are reliable tools for measuring joint ROM. However, the universal goniometer shows high interrater reliability, meaning assessments by different evaluators were highly consistent. Conversely, the video goniometer exhibits higher interrater reliability, indicating more consistent assessments by the same evaluator across different trials.

Future studies should assess the reliability of both goniometers in larger, more diverse populations. Additionally, the impact of training and standardized protocols on measurement consistency, especially with the video goniometer, should be explored. Lastly, future studies should ask participants for consent to wear fitted clothes or undergarments to ensure accurate landmark marking.

Conflict of interest declaration

The authors declare no conflicts of interest with any financial organizations about the materials presented in this manuscript.

Data availability

The authors confirm that the major data supporting the findings of this study are available within the article. However, other supporting data of this study are available from the corresponding author, DTJ, upon reasonable request.

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Original Article

Effectiveness of A Newly Developed Comprehensive Rehabilitation Service Model for Subacute Stroke Patients: A Quasi-Experimental Study at A Tertiary Care Hospital in Northern Thailand

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ABSTRACT

Objectives: To evaluate the effectiveness of a newly developed comprehensive rehabilitation service model for patients with subacute stroke at a tertiary care hospital in Northern Thailand

Study design: A quasi-experimental study with pretest-posttest control group design

Setting: Department of Rehabilitation Medicine, Uttaradit Hospital, a 680-bed tertiary care hospital serving as a regional referral center in Northern Thailand

Subjects: One hundred and fifty-four patients (77 per group) with first-ever stroke, aged 18-80 years, admitted 2-6 weeks post-onset between January and December 2021, with Modified Rankin Scale scores 2-4

Methods: The intervention group received a 12-week comprehensive rehabilitation program including (1) intensive, multidisciplinary rehabilitation (3 hours/day, 5 days/week), (2) structured caregiver education and training, (3) technology-assisted home-based rehabilitation with telemedicine support, (4) regular multidisciplinary team review and care plan adjustment. The control group received standard rehabilitation care. The primary outcome measure was Barthel Index (BI) score. Secondary outcome measures included the Stroke Impact Scale (SIS), Hospital Anxiety and Depression Scale (HADS), EuroQol 5-Dimension (EQ-5D) quality of life assessment, and Modified Caregiver Strain Index (MCSI).

Results: At 12 weeks, the intervention group showed statistically significantly greater improvement in BI scores (mean difference 11.4, 95%CI: 6.8-16.0, $p < 0.001$), SIS scores (mean difference 15.6, 95%CI: 10.2-21.0, $p < 0.001$), HADS scores (mean difference -3.2, 95%CI: -4.8 to -1.6, $p = 0.003$), EQ-5D index (mean difference 0.15, 95%CI: 0.08-0.22, $p < 0.001$), MCSI scores (mean difference -6.4, 95%CI: -9.1 to -3.7, $p < 0.001$). These participants maintained their improvement at a 6-month follow-up.

Conclusions: The newly developed comprehensive rehabilitation service model significantly improved functional independence, quality of life, psychological well-being, and reduced caregiver burden in patients with subacute stroke compared to standard care. This model demonstrates the clinical and cost-effectiveness in a Thai healthcare setting, supporting its potential for broader implementation in similar settings.

Keywords: stroke rehabilitation, subacute care, multidisciplinary care, telemedicine, caregiver training

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Introduction

Stroke remains a leading cause of disability and mortality worldwide, significantly impacting patients' quality of life and placing substantial burdens on healthcare systems and families.[1] In Thailand, the age-standardized prevalence of stroke is 1.88% (95%CI: 1.83-1.92), with approximately 250,000 new cases annually. The estimated economic burden exceeds 50 billion THB (approximately US$1.4 billion) annually, highlighting the urgent need for effective rehabilitation strategies.[2] The subacute phase, typically spanning from 2 to 6 weeks post-stroke onset, represents a critical window for rehabilitation interventions due to heightened neuroplasticity and potential for recovery.[3]

The existing stroke rehabilitation system in Thai public hospitals faces several significant challenges. A critical issue is the limited availability of rehabilitation personnel, with an average ratio of one physiotherapist per 50-100 stroke patients.[4] Care delivery is often fragmented, characterized by poor coordination between departments and insufficient rehabilitation intensity, typically consisting of only 30-45 minutes per session, 2-3 times per week.[5] Furthermore, inadequate caregiver training and limited follow-up care after discharge contribute to suboptimal functional recovery and high readmission rates, approximately 25.0% within 30 days.[6] These systemic limitations result in increased caregiver burden, poor community reintegration, and escalating long-term healthcare costs.[7]

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To address these challenges, a multidisciplinary team at Uttaradit Hospital, a 680-bed tertiary care facility, conducted a comprehensive review of existing practices and developed an innovative rehabilitation model.[8] The development process of the new model involved multiple stakeholders, including rehabilitation physicians, nurses, therapists, social workers, and hospital administrators. Through systematic analysis of service gaps and stakeholder interviews,[9] the team integrated international best practices with locally appropriate solutions, including technology-assisted care coordination[10] and standardized protocols for seamless care transitions between hospital and community settings.[11]

The primary objective of this study is to evaluate the effectiveness of this newly developed comprehensive rehabilitation service model for patients with subacute stroke at a tertiary care hospital in Northern Thailand. Secondary objectives include assessing the impact on caregiver burden, evaluating cost-effectiveness, measuring the sustainability of functional improvements, and analyzing the effectiveness of technology-assisted components.

We hypothesize that the new service model will significantly improve patients' ability to perform daily living activities as measured by the Barthel Index. Additional hypotheses propose that the model will enhance quality of life (measured by EuroQol 5-Dimension), reduce caregiver burden (measured by Modified Caregiver Strain Index), demonstrate cost-effectiveness from a healthcare system perspective, and maintain functional improvements through the 6-month follow-up period.

This study represents the first comprehensive attempt in Thailand to integrate technology-assisted rehabilitation monitoring[12] with structured caregiver training programs and standardized multidisciplinary care protocols. This innovative approach includes seamless care transitions between hospital and community, and developing evidence-based, culturally appropriate rehabilitation guidelines.[13] The findings could significantly inform policy decisions and improve long-term outcomes for stroke patients in Thailand and similar healthcare contexts. The model's design carefully considers resource limitations and cultural factors specific to the Thai healthcare system, making it potentially scalable to other regional hospitals.[14]

Methods

Study design

This study was quasi-experimental, comparing a prospective intervention cohort (January-December 2021) with retrospectively collected historical controls (January-December 2020). For the historical control group, data were obtained from medical records, rehabilitation documents, and hospital database systems. All outcome measures were routinely collected as part of standard care documentation at the rehabilitation department. Two trained research assistants independently extracted and verified the historical data using a standardized data extraction form. Cases with incomplete outcome measures were excluded from the study. The study was approved by the Ethics Committee of Uttaradit Hospital on August 27, 2021 (Approval No. 46/2021). The Thai Clinical Trials Registry Number was TCTR20250402003.

The study was conducted at the Department of Rehabilitation Medicine, Uttaradit Hospital, a 680-bed tertiary care hospital in Northern Thailand. The rehabilitation service includes inpatient and outpatient care, a dedicated stroke unit, and a rehabilitation ward.

Participants

Patients were recruited from both the inpatient and outpatient departments. Neurologists confirmed stroke diagnoses based on clinical presentation and neuroimaging (CT/MRI). The National Institutes of Health Stroke Scale (NIHSS) was used to assess stroke severity at baseline as part of the standard stroke protocol.

Inclusion criteria were:

1. Age 18-80 years
2. First-ever stroke diagnosis
3. Modified Rankin Scale (mRS) score of 2-4
4. Basic communication ability in the Thai language (ability to follow simple commands and express basic needs, allowing for mild-moderate dysarthria or aphasia)

Exclusion criteria were expanded to include:

1. Severe cognitive impairment (Montreal Cognitive Assessment Thai version score < 10)
2. Severe communication disorders preventing meaningful participation
3. Unstable medical conditions (e.g., uncontrolled hypertension, unstable cardiac conditions)
4. Severe psychiatric disorders
5. Active participation in other rehabilitation research studies

Sample size was calculated using GPower, with effect size = 0.5, $\alpha = 0.05$, and power = 0.8. This resulted in 64 participants per group. Accounting for a 20.0% dropout rate, the total sample size was 154 participants.

Intervention

The standard care group (historical controls) received:

1. Initial rehabilitation assessment by a physiatrist within 48 hours of hospital admission
2. Physical therapy sessions:
   - Duration: 30-45 minutes per session
   - Frequency: 2-3 times per week
   - Total program duration: 12 weeks
   - Total planned sessions: 24-36 sessions
3. Basic activities of daily living training integrated into each session
4. A simple home exercise program with weekly updates
5. Regular follow-up appointments every 4-6 weeks
6. Referral to other specialists as needed

The actual number of completed sessions and reasons for missed sessions were documented. Patients who completed less than 75.0% of planned sessions were noted in the analysis.

The intervention group received a comprehensive rehabilitation program including:

1. Multidisciplinary assessment and planning
   • Comprehensive assessment within 24 hours of enrollment by:
     - Rehabilitation physician
     - Rehabilitation nurses
     - Physical therapists
     - Occupational therapists
     - Speech therapists (when indicated)
     - Social workers
     - Nutritionists
2. Individualized rehabilitation planning
   • Structured goal-setting using the Canadian Occupational Performance Measure (COPM)[11]
   • Weekly multidisciplinary team meetings to review and adjust goals
   • Regular assessment of goal achievement using standardized outcome measures
3. Intensive rehabilitation program
   • 3-hour daily sessions, 5 days/week, including:
     - Task-specific training
     - Functional electrical stimulation
     - Virtual reality-based therapy
     - Group exercise sessions
     - Cognitive training when indicated
4. Caregiver education and support
   • Structured training program (2 hours/week)
   • Hands-on practice with supervision
   • Educational materials and videos
   • Peer support group sessions
5. Technology-enhanced home program
   Implementation timeline:
   - Initial setup: Week 1 of enrollment
   - Training period: Weeks 1-2 (2 sessions, 1 hour each)
   - Active usage period: Weeks 2-12
   Components:
   a) Custom smartphone application:
     - Exercise tracking with daily reminders
     - Progress monitoring through automated weekly reports
     - Direct messaging system with healthcare team (response within 24 hours)
     - Video-based educational resources
     - Automated appointment reminders
   b) Home-program structure:
     - Daily exercise modules (30-45 minutes)
     - Weekly progress uploads (photos/videos)
     - Bi-weekly virtual check-ins with a therapist
     - Monthly virtual group sessions

   Technical support:
   - Initial face-to-face training for patients and caregivers
   - Backup paper-based materials for technical difficulties

   Monitoring and compliance:
   - Weekly review of usage data
   - Follow-up calls for inactive users (>3 days)
   - Monthly satisfaction surveys
   - Technical issue logs and resolution times

   Prerequisites:
   - Smartphone ownership or provided tablet
   - Internet connectivity at home
   - Caregiver technical capability assessment

For patients without access to technology (n=X), modified paper-based home programs were provided with a telephone at the outset of follow-up.

All assessments were conducted by trained evaluators who were blinded to group allocation. Primary and secondary outcomes were measured at baseline, 12 weeks, and 6 months by different assessors than those providing treatment.

Measurement

Primary outcome: Barthel Index (BI) for functional independence

Secondary outcomes:

- Modified Rankin Scale (mRS)
- Stroke Impact Scale (SIS)
- Hospital Anxiety and Depression Scale (HADS)
- EuroQol 5-Dimension (EQ-5D)
- Modified Caregiver Strain Index (MCSI)
- Healthcare utilization and costs

Statistical analysis

Data analysis was performed using a software package. Between-group comparisons used independent t-tests for continuous data and chi-square tests for categorical data. Changes in outcomes over time were analyzed using linear mixed models to account for missing data and repeated measurements. Cost-effectiveness analysis was conducted from a healthcare system perspective.

Results

Between January 2020 and December 2021, 320 patients with subacute stroke were screened for eligibility. After applying selection criteria, 154 patients were included: 77 in the intervention group (2021 cohort) and 77 in the control group (2020 historical controls). The completion rates were 91.0% (70/77) for the intervention group and 88.0% (68/77) for the control group at 6-month follow-up. The most common reasons for dropout were relocation (n = 8) and medical complications unrelated to the intervention (n = 5). Analysis followed intention-to-treat (ITT) principles, with the last observation carried forward for missing data. (Figure 1)

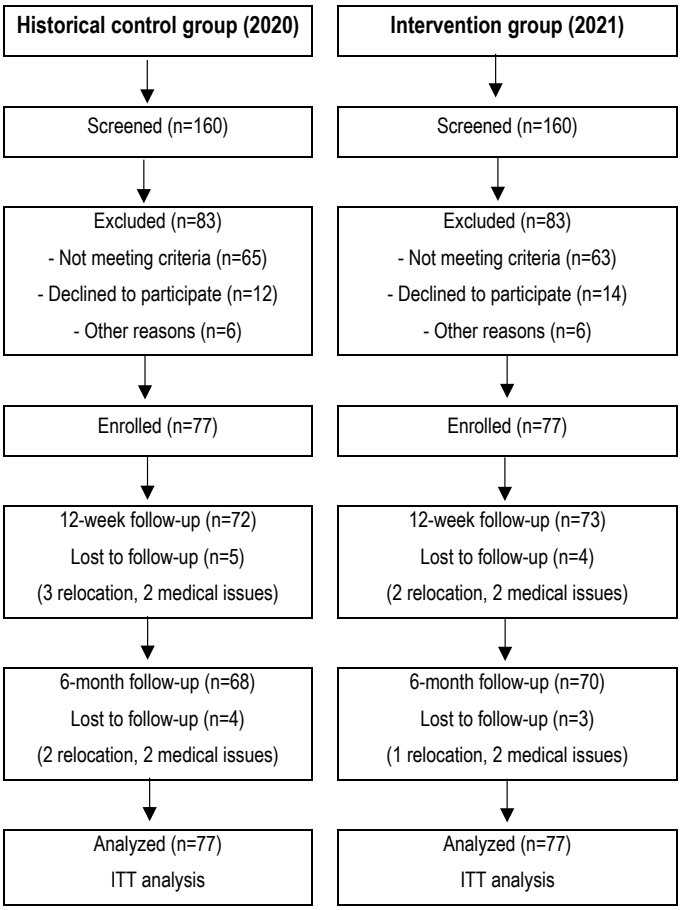

Figure 1. Study flow diagram

Table 1. Baseline demographic and clinical characteristics of study participants

Characteristic	Intervention group (n = 77)	Control group (n = 77)	*p*-value
Age (years)[1]	65.3 (10.2)	66.1 (9.8)	0.621[4]
Male gender[2]	42 (54.5)	40 (51.9)	0.743[5]
Days since stroke onset[1]	28.4 (5.6)	27.9 (5.8)	0.582[4]
Education level[2]			0.892[5]
Primary or lower	45 (58.4)	43 (55.8)	
Secondary	20 (26.0)	22 (28.6)	
Tertiary	12 (15.6)	12 (15.6)	
Stroke type[2]			0.865[5]
Ischemic	61 (79.2)	62 (80.5)	
Hemorrhagic	16 (20.8)	15 (19.5)	
Initial NIHSS score[3]	8 (5-12)	7 (5-11)	0.723[6]
Initial mRS score[3]	3 (2-4)	3 (2-4)	0.891[6]
Baseline BI score[1]	45.6 (15.3)	46.2 (14.9)	0.798[4]
Living situation[2]			0.815[5]
With family	68 (88.3)	67 (87.0)	
Alone	9 (11.7)	10 (13.0)	

[1]Mean (SD), [2]number (percentage), [3]median (IQR), [4]Independent t-test, [5]Chi-square test, [6]Mann-Whitney U test.

NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; BI, Barthel Index; IQR, interquartile range; SD, standard deviation.

Table 1 presents the baseline demographic and clinical characteristics. At baseline, there were no significant differences between groups in age, gender, stroke type, stroke severity, or functional status.

Table 2 demonstrates significant improvements across all secondary measures in the intervention group compared to controls. The Stroke Impact Scale showed substantial gains at 12 weeks (mean difference: 26 points, $p < 0.001$) and 6

Table 2. Barthel Index scores across evaluation time points

Time point	Intervention group (n = 77)	Control group (n = 77)	Mean difference (95%CI)	*p*-value
Baseline	45.6 (15.3)	46.2 (14.9)	-0.6 (-5.2 to 4.0)	0.798
12 weeks	72.8 (18.6)	61.4 (17.2)	11.4 (6.8 to 16.0)	<0.001
6 months	78.5 (19.2)	65.7 (18.1)	12.8 (7.9 to 17.7)	<0.001

All values are presented as mean (SD). CI, confidence interval

Table 3. Secondary outcome measures across different time points

Outcome measure	Time point	Intervention group	Control group	Mean/median difference	*p*-value
SIS score[1]	Baseline	112 (95-130)	114 (97-132)	-2 (-8 to 4)	0.823
	12 weeks	168 (145-189)	142 (122-162)	26 (18 to 34)	<0.001
	6 months	182 (158-201)	151 (130-172)	31 (22 to 40)	<0.001
HADS score[1]	Baseline	16 (12-20)	15 (11-19)	1 (-2 to 4)	0.652
	12 weeks	10 (6-14)	13 (9-17)	-3 (-5 to -1)	0.003
	6 months	8 (4-12)	12 (8-16)	-4 (-6 to -2)	<0.001
EQ-5D index[2]	Baseline	0.45 (0.15)	0.46 (0.14)	-0.01 (-0.05 to 0.03)	0.624
	12 weeks	0.72 (0.18)	0.57 (0.16)	0.15 (0.08 to 0.22)	<0.001
	6 months	0.78 (0.19)	0.61 (0.17)	0.17 (0.10 to 0.24)	<0.001
MCSI score[2]	Baseline	13.5 (4.2)	13.2 (4.1)	0.3 (-1.0 to 1.6)	0.658
	12 weeks	7.1 (3.8)	11.4 (4.0)	-4.3 (-5.6 to -3.0)	<0.001
	6 months	6.4 (3.6)	10.8 (3.9)	-4.4 (-5.7 to -3.1)	<0.001

[1]Median, [2]mean

SIS, Stroke Impact Scale; HADS, Hospital Anxiety and Depression Scale; EQ-5D, EuroQol 5-Dimension; MCSI, Modified Caregiver Strain Index. SIS and HADS values are presented as median (IQR); EQ-5D and MCSI values are presented as mean (SD)

Table 4. Patient and caregiver satisfaction scores at 12 weeks

Domain	Intervention group Mean (SD)	Control group Mean (SD)	Mean difference (95%CI)	*p*-value
Overall satisfaction	4.2 (0.6)	3.5 (0.7)	0.7 (0.5 to 0.9)	<0.001
Treatment process	4.1 (0.6)	3.4 (0.7)	0.7 (0.5 to 0.9)	<0.001
Staff communication	4.3 (0.5)	3.6 (0.6)	0.7 (0.5 to 0.9)	<0.001
Facility and equipment	4.0 (0.7)	3.7 (0.6)	0.3 (0.1 to 0.5)	0.003
Home program support	4.4 (0.5)	3.3 (0.8)	1.1 (0.9 to 1.3)	<0.001
Caregiver support	4.3 (0.6)	3.2 (0.7)	1.1 (0.9 to 1.3)	<0.001

SD, standard deviation; CI, confidence interval

months (mean difference: 31 points, $p < 0.001$). Similarly, the intervention group exhibited more significant reductions in anxiety and depression on the HADS, with significant differences at both time points ($p = 0.003$ and $p < 0.001$, respectively). Quality of life measured by EQ-5D improved markedly in the intervention group (0.45 to 0.78) compared to controls (0.46 to 0.61), with a significant between-group difference ($p < 0.001$). Caregiver burden decreased more substantially in the intervention group, with MCSI scores dropping from 13.5 to 6.4 compared to 13.2 to 10.8 in controls ($p < 0.001$).

Table 3 presents our primary outcome measure results. While baseline scores were comparable between groups (mean (SD) of BI score of intervention and control groups were 45.6 (15.3) and 46.2 (14.9), respectively with $p = 0.798$), the intervention group showed significantly greater improvement at 12 weeks (mean (SD) of the improvement in intervention and control groups were 72.8 (18.6) and 61.4 (17.2) with mean difference = 11.4, 95%CI: 6.8-16.0, $p < 0.001$). This improvement was maintained and slightly increased at 6 months (mean (SD) of the improvement in intervention and control groups were 78.5 (19.2) and 65.7 (18.1) with mean difference = 12.8, 95%CI: 7.9-17.7, $p < 0.001$), demonstrating clinically meaningful and sustained functional independence gains

All outcome measures used validated Thai versions and were administered by trained research assistants. Due to stroke-related communication impairments (mild-moderate dysarthria or mild expressive aphasia) that developed during the study period, 15 participants (8 in the intervention group, 7 in the control group) required assistance from their primary caregivers to clarify their responses. This assistance was limited to clarifying the patient's intended responses without

answering on their behalf. The need for caregiver assistance was documented and analyzed to ensure it did not significantly impact the outcome measures.

Discussion

This study aimed to evaluate the effectiveness of a comprehensive rehabilitation service model for patients with subacute stroke. The prospective cohort design with historical controls was chosen to address scientific rigor and ethical concerns regarding access to potentially beneficial interventions.[11] This design ensured that all patients admitted after the implementation received the enhanced intervention, aligning with emerging evidence that supported intensive rehabilitation during the subacute phase.[2]

The intervention group demonstrated significantly improved functional independence, with mean Barthel Index increases exceeding the minimal clinically significant difference of 10 points.[12] However, these improvements must be interpreted within natural recovery and neuroplasticity. The subacute phase (2-6 weeks post-stroke) represents a period of enhanced endogenous plasticity, characterized by increased expression of growth-promoting factors and heightened neural reorganization.[2] The intensive rehabilitation program may have optimized this natural recovery window through activity-dependent plasticity enhancement, environmental enrichment, and synchronized timing of interventions with spontaneous recovery processes.[11]

The improvements in quality of life and psychological well-being align with recent evidence supporting holistic rehabilitation approaches.[8] The significant reduction in caregiver burden (MCSI score difference -6.4) suggests that structured caregiver education and support systems are crucial components of effective rehabilitation models.[6] Integrating technology-assisted monitoring and communication platforms further enhanced care coordination and treatment adherence.[10]

Our study demonstrated significant improvements in functional outcomes in the intervention group compared to the control group. However, we must note some limitations in our study design and analysis. We did not perform subgroup analyses to identify factors that might have influenced treatment outcomes, such as initial stroke severity, socioeconomic status, and level of caregiver support. Future studies should consider investigating these factors to help identify which patient populations might benefit most from this comprehensive rehabilitation program. Additionally, research examining the effectiveness of this program in patients with more severe impairments (NIHSS >15) would be valuable, as our inclusion criteria limited our study to those with moderate impairment levels.[13]

The community support component proved particularly important for sustaining improvements. Mobile rehabilitation units, telemedicine follow-up, community health worker training, and enhanced social service coordination may help address barriers to care access, especially in rural areas.[14] Integrating these services with existing healthcare infrastructure appears crucial for program sustainability.

Preliminary cost analysis suggests potential long-term economic benefits through reduced readmission rates and lower long-term care expenses.[15] However, the initial implementation costs, including staff training and technology infrastructure, require careful consideration. Future research should include comprehensive cost-effectiveness analysis and budget impact studies to inform scaling decisions.[5]

Several limitations warrant consideration. Historical controls such as differences in environmental factors, potential variations in standard care practices over time, and possible documentation inconsistencies may have introduced temporal bias, although baseline characteristics were similar between groups.[16] The resource-intensive nature of the intervention may challenge scalability, particularly in settings with limited rehabilitation personnel. Additionally, the 6-month follow-up period may not capture the entire trajectory of recovery.[17]

Future research should focus on three key areas. First, long-term follow-up studies (12-24 months) are needed to evaluate sustained benefits. Second, implementation research should examine adaptation strategies for resource-limited settings.[18] Finally, technology development should enhance telemedicine platforms and automated progress tracking systems.[10]

In conclusion, this comprehensive rehabilitation model significantly improves stroke outcomes. The findings suggest that intensive, technology-enhanced rehabilitation, combined with structured caregiver support, can significantly improve functional independence and quality of life.[19] Future efforts should focus on optimizing care for challenging cases and ensuring sustainable implementation across diverse healthcare settings.[20]

Conclusions

This study demonstrates that a comprehensive rehabilitation service model improved outcomes in patients with subacute stroke. The intervention, combining intensive, multidisciplinary rehabilitation, structured caregiver training, and technology-assisted monitoring, resulted in clinically significant improvements in functional independence (mean Barthel Index difference 11.4, 95%CI: 6.8-16.0) compared to historical controls. Secondary benefits included enhanced quality of life, reduced caregiver burden, and decreased depressive symptoms, with improvements sustained at the 6-month follow-up.

While implementation requires considerable resources and organizational change, the potential benefits of improved patient outcomes and reduced long-term care needs suggest this model could be cost-effective in tertiary care settings. Future research should focus on adaptation strategies for

resource-limited environments and long-term cost-effectiveness analysis.

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Conflict of interest declaration

The authors confirm that there are no known conflicts of interest associated with this publication, and no significant financial support has been received that could have influenced the results or conclusions of this work.

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Data availability

The data that support the findings of this study are available on request from the corresponding author, Dr. Seubtrakul Tantalanukul. The data are not publicly available due to privacy and ethical restrictions, as they contain personal health information obtained from hospital medical records and patient-reported outcome measures. Access to anonymous data may be granted upon reasonable request and subject to approval by the institutional ethics committee.

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Potential Role of Coronoidectomy for Stroke-Induced Spastic Trismus Patients with Botulinum Toxin Insensitivity: A Case Report

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ABSTRACT

Background: Trismus is a consequence of muscle spasticity, often secondary to stroke, leading to compromised oral functions and increased aspiration pneumonia risk. However, in some cases, the patient does not respond to conservative treatment such as rehabilitation procedures, medication, and botulinum toxin injection.

Objective: To evaluate the efficacy of coronoidectomy in managing spastic trismus unresponsive to conventional and botulinum toxin treatments post-stroke.

Case description: A 40-year-old man, with post right middle cerebral artery (MCA) infarction presented with spastic trismus, exhibiting an incisor gap of 1 cm. The patient remained non-responsive after receiving 25 units of botulinum toxin serotype A in the bilateral masseter muscles and consequently suffered an aspiration pneumonia episode. Computerized tomography (CT) imaging identified left temporomandibular joint (TMJ) ankylosis. A bilateral coronoidectomy and interposition gap arthroplasty on the left condyle expanded the mouth opening to 5 cm. Post-surgical management included intensive swallowing rehabilitation and a dental splint to preserve the achieved incisor gap.

Conclusion: Coronoidectomy can be a potential therapeutic intervention for stroke-induced trismus, particularly when non-responsive to conservative therapies.

Keywords: trismus, dysphagia, stroke, coronoidectomy, botulinum toxin

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Introduction

Spastic trismus, a condition marked by reduced mouth opening due to muscle spasticity, can result from various underlying conditions, including head and neck cancers, temporomandibular joint (TMJ) disorders, trauma, and neurological events such as stroke. Among stroke patients, trismus prevalence ranges from 2-8%, highlighting it as a notable sequela that can severely impact post-stroke recovery and quality of life. Despite standard rehabilitation efforts, including jaw exercises, hot packs, ultrasound diathermy, and muscle relaxant medications, some studies indicate that approximately 20-30% of patients may experience limited or no improvement with conservative treatment alone.[1] This lack of response underscores the need for alternative therapeutic strategies.

The consequences of trismus in stroke patients extend beyond oral difficulties. Restricted jaw movement impairs speech, reduces the efficiency of oral feeding, and leads to inadequate nutrition and dehydration. Furthermore, trismus significantly increases the risk of aspiration pneumonia, as compromised oral hygiene can lead to bacterial accumulation, which, when aspirated, causes respiratory complications.[1]

While conventional treatments such as perioral massages, muscle stretches, and other physical modalities such as hot packs and ultrasound diathermy primarily focus on reducing muscle spasticity and improving mouth opening, botulinum toxin injections have shown promise for patients unresponsive to initial interventions. Botulinum toxin treatment is typically reserved for patients with severe muscle spasticity who fail to respond to conservative therapies.[2,3] In these cases, persistent, high-intensity muscle contraction in the jaw and limited progress in traditional treatment approaches often justify botulinum toxin as a supplementary intervention. Further diagnostic imaging, such as computerized tomography (CT) scans, may be essential for non-responders to conventional and botulinum treatments to assess TMJ pathologies like ankylosis or osteoarthritis, which contribute to limited jaw movement.[4] In cases of structural abnormalities or when all other options fail, surgical interventions, such as coronoidectomy, are considered to restore oral function and enhance the patient's quality of life.[5]

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This case report aims to raise awareness of spastic trismus as a common yet often overlooked complication in stroke patients, to review current literature and conservative treatment failure rates, and to propose a management pathway that includes both conventional and advanced interventions. This report seeks to contribute to the understanding of trismus management and to support the development of improved treatment protocols for affected patients. The case report was conducted in accordance to the CARE guideline.

Patient information

A 40-year-old male suffered a middle cerebral artery (MCA) infarction in 2017, which led to left spastic hemiparesis. Treatment included a right craniotomy, cranioplasty, and a ventriculoperitoneal (VP) shunt. Medical history revealed chronic atrial fibrillation (AF) with left atrial (LA) thrombosis, prompting left atrial appendage (LAA) occlusion in 2019. Concurrently, he had Graves' disease and hypertension, both diagnosed at the stroke's onset and managed with medication. Total dependency on activities of daily living (ADL) and wheelchair sitting were noted. The summarized timeline is shown in Table 1.

The first admission to rehabilitation was in 2020.

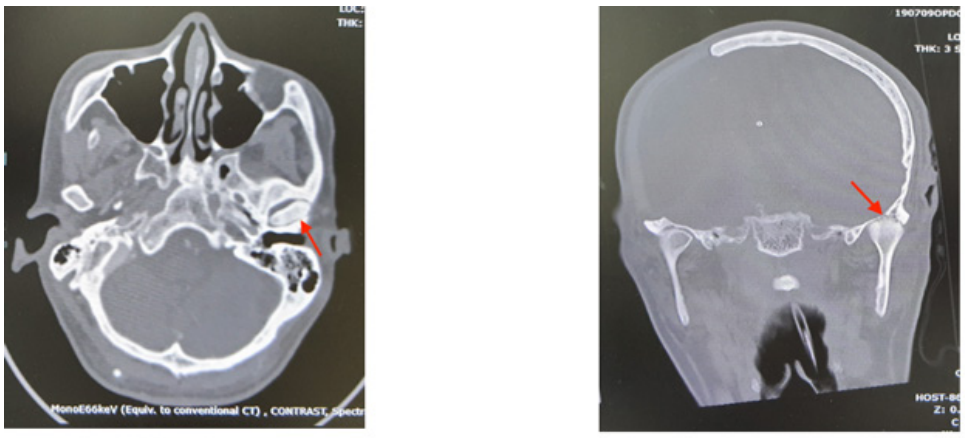
The patient was admitted for intensive stroke rehabilitation 2.5 years post-stroke onset. The focus was enhancing ADL and removing the nasogastric (NG) tube. The swallowing assessment revealed a restricted mouth opening (1 cm incisor gap), an inability to evaluate tongue range of motion, a delayed swallowing triggering response, favorable laryngeal excursion, and successful performance during 5-ml and 10-ml water swallowing tests without the presence of a wet voice or cough. This restriction in mouth opening was linked to an irregular left TMJ and muscle atrophy on the right side, as identified by a CT scan in 2019 (Figure 1). The mouth opening remained limited despite undergoing muscle relaxation procedures in 2019. During this admission, treatments included perioral massages, muscle stretches, and other physical modalities such as hot packs and ultrasound diathermy, which were administered one session per day on a working day and with a care-giver performed a hot pack, oral massage, and stretching to the patient. EMG detected spasticity in the bilateral masseter muscles, which was subsequently treated with botulinum toxin injections (BoNT/A), with each muscle receiving 25 units.

A week later, some improvements were observed, though the mouth opening increased only marginally. A subsequent Fiberoptic Endoscopic Evaluation of Swallowing (FEES) produced positive results, highlighting the absence of pharyngeal secretions, sufficient glottic closure, and slightly decreased pharyngeal sensation. Bolus tests demonstrated successful consumption of 4 ml, 10 ml, and straw-drinking of mildly thick liquid (International Dysphagia Diet Standardization Initiative 2, IDDSI 2) without residue in the pharynx, laryngeal penetration or aspiration. Only minimal residue was seen at the left pyriform sinus after ingesting 4 ml of slightly thick liquid (IDDSI 1) which was cleared by repetitive swallows. Following the FEES, the patient participated in direct swallowing training

Table 1. Summarized timeline

Time	Event
2017	MCA infarction results in hemiparesis and cognitive deficits.
2019	LAA occlusion was performed.
2020	Initial rehabilitation admission for ADL improvement and nasogastric tube removal. Incisor gap 1 cm.
Mid-2020	Administration of BoNT/A (25 units to each masseter muscle). Incisor gap 1.5 cm.
One month later	Readmission for aspiration pneumonia; surgical evaluation. Incisor gap 1 cm.
Late-2020	A bilateral coronoidectomy was performed, achieving a 5 cm incisor gap.

MCA, middle cerebral artery; LAA, left atrail appendage; ADL, activities of daily living; BoNT/A, botulinum toxin injections



1a 1b

Figure 1. The computerized tomography imaging of the facial bone shows an irregular left temporomandibular joint (indicated by the red arrow).

using a 300 ml blenderized diet (BD), first with a spoon and then gradually using a straw with minimal BD per sip. The NG tube was removed after he reached acceptable nutrition and hydration, 1,800 Kcal per day. Given the absence of trismus-related complications, the patient continued using a straw to drink with a 1.5 cm mouth opening. The home program, including oral and swallowing exercises, was recommended to be performed by a caregiver at least one session per day.

The second admission and aspiration pneumonia incident in 2020

Four months post-discharge, the patient developed aspiration pneumonia. FEES performed after the pneumonia subsided found significant saliva pooling in the pyriform sinuses and stains on the posterior tongue. Still, the 4 ml mildly thick and clear liquids exhibited no residue in the pharynx and no laryngeal penetration and aspiration. The reduced mouth opening to 1 cm and complications from aspiration led to a multidisciplinary meeting involving a physiatrist, plastic surgeons, dentists, and the patient's family members, to consider surgical intervention. The patient and his family acknowledged the risks and benefits of the procedure, including impaired oral closure, damage to the facial nerve, potential limitations in chewing ability, and the necessity of prolonged oral splint use. After deliberation, a decision was made for coronoidectomy.

Surgery in late-2020 disclosed left TMJ ankylosis. A preoperative incisive opening of 4 mm improved to 5 mm postmuscle relaxation. The surgical approach included partial mandibulectomy and temporomandibular arthroplasty, which resulted in a post-operative incisive gap of 50 mm.

Post-operative care emphasized feeding via NG tube, mobilization, bite block usage, and oral hygiene for 1 month. Then, a post-surgery FEES assessment highlighted residual mild pooling but no laryngeal penetration. Bolus challenges arose with 4 ml and 10 ml mildly thick liquid (IDDSI 2), and pureed food (IDDSI 4) showed slight residue at the pyriform sinus without laryngeal penetration and tracheal aspiration, which cleared with repeated swallowing. The occupational therapist and caregiver applied rehabilitation strategies based on FEES outcomes.

Follow-up and outcomes

Upon discharge, the patient's mouth opening improved, though limited due to pain. A dental examination showcased significant oral hygiene issues. Prescribed treatments included range of motion exercises, chewing exercises, and dietary progressions from pureed (IDDSI 4) to minced and moist food (IDDSI 5).

A multidisciplinary team's year-long follow-up, at one to three-month intervals, revealed improved dietary habits but decreased mouth opening (3 cm). Future considerations include another BoNT/A injection, contingent on the severity of the mouth opening limitation.

Discussion

This case report highlights the complexity of managing spastic trismus in a post-stroke patient, particularly when non-responsive to botulinum toxin injections. Severe trismus, while less common than milder forms, occurs in approximately 10-15% of stroke patients.[1,7] Severe trismus can sometimes result from anatomical factors, such as hypertonicity in the jaw-closing muscles and stroke-related neural damage affecting specific muscle groups. The primary risk factors for severe trismus include prolonged jaw immobilization, increased spasticity, poor oral care, and, potentially, secondary fibrosis from muscle contracture.

Trismus is considered non-responsive to conservative or botulinum toxin treatment when there is minimal to no improvement in jaw opening after repeated interventions over a specified period, typically around 3-6 months.[2,3] In this case, the patient showed no response to an initial conservative approach and subsequently limited improvement following botulinum toxin injections, necessitating further intervention.

The protocol for botulinum toxin injection in the trismus typically targets the masseter and temporalis muscles. Dosage often ranges between 25 and 100 units per muscle, depending on the severity and patient tolerance.[2] In this case, the patient received a standard initial dose, but it proved insufficient to elicit a marked response, suggesting the need for either higher dosing or alternative treatment approaches.

CT imaging is typically indicated when conservative treatments fail or anatomical abnormalities are suspected.[4] For this patient, the CT scan was essential to rule out TMJ ankylosis or osteoarthritic changes, which could impact treatment choices.

This case report highlights the complexity of managing spastic trismus in a post-stroke patient, particularly when unresponsive to botulinum toxin injections. It emphasizes the importance of CT scans for diagnosing TMJ ankylosis and determining the suitability of surgical interventions like coronoidectomy. Dysphagia management in such patients should be comprehensive, targeting oral intake, hygiene, and secretion clearance to prevent complications like aspiration pneumonia.[8]

Failed conservative treatments prompted the need for a surgical solution,[5] in this case, the coronoidectomy, executed via a multidisciplinary approach involving physiatrists, plastic surgeons, dentists, and occupational therapists. Surgical intervention, while beneficial for severe trismus unresponsive to other treatments, carries a risk of potential side effects, including infection, nerve damage, and joint instability. Careful surgical techniques, aseptic protocols, and post-operative care are essential to prevent these complications. Clear patient instructions for exercises and follow-up care can further minimize these risks. The post-operative care was focused on avoiding re-contracture through intensive rehabilitation, including jaw exercises, physical modalities, and oral and dental splints.

Persistent oversight of mouth-opening capabilities and periodic swallowing evaluations, both clinical and instrumental, are vital. Should the need arise, administering botulinum toxin injections remains an option.

Patient perspective

The patient and family expressed satisfaction with the post-surgical improvement in oral function, noting that it significantly reduced the risk of aspiration pneumonia and enabled a better quality of life. They appreciated the multidisciplinary approach and regular follow-ups, which supported the patient's functional progress.

Conclusion

This case report illustrates the importance of a multifaceted approach to managing severe trismus in post-stroke patients. Patient outcomes may be significantly improved through early intervention, comprehensive diagnostic imaging in non-responsive cases, and a structured escalation from conservative to advanced treatments. Establishing a multidisciplinary team and developing a dedicated management protocol for severe trismus could provide clinicians with a robust framework for addressing this challenging condition.

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Conflict of interest declaration

The authors confirm that there are no known conflicts of interest associated with this publication, and no significant financial support has been received that could have influenced the results or conclusions of this work.

Finding

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Data availability

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

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