Translation, Adaptation, and Validation of the Barthel Index for Ischemic Stroke Patients in the West Java Population, Indonesia

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Abstract:

Introduction: Stroke is a major health concern with a high prevalence in the Indonesian population. The high prevalence of this disease indicates the need for monitoring of the extent to which therapy is effective for patients. The Barthel index is a tool to help assess the outcomes of therapy in stroke patients, especially the patient's daily activities. This study aimed to translate, adapt, and validate the Barthel index for stroke patients in the West Java population, Indonesia.

Methods: This study was conducted using a cross-sectional design, and data collection was carried out prospectively in July 2024. It included 55 Indonesian post-stroke patients. The questionnaire was analyzed using reliability and validity tests.

Results: The internal consistency, as measured by Cronbach's alpha value, was ≥ 0.896, indicating excellent reliability (p> 0.7). The validity test yielded a p-value of 0.000 (p < 0.05), demonstrating statistical significance. A strong correlation was observed across most items (r = 0.639-0.846), with the exception of item 10, which showed a moderate correlation (r = 0.591).

Discussion: The analysis showed that this questionnaire was reliable, and the majority of the questions exhibited a strong to very strong correlation, and only one question had a moderate correlation.

Conclusion: Based on these results, it can be concluded that the Barthel index is valid and reliable for use in stroke patients of the West Java population, Indonesia.

Keywords: Barthel index, Cultural adaptation, Ischemic stroke, Translation, Validation, West Java population.

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1. INTRODUCTION

The incidence of stroke is an obstacle to the performance of normal daily activities among patients [1]. Post-ischemic stroke patients often experience reduced functioning across nearly all aspects of daily life, so an algorithm or questionnaire is needed to assess the daily activities of post-ischemic stroke patients. The questionnaire includes bathing activity, walking, urination, and defecation, *etc.* In some patients, these obstacles lead to decreased independence and incre-

ased dependence on caregivers [2]. These reductions in daily activities can affect economic conditions [3], social conditions [4], and mental health conditions [5]. In addition, post-stroke conditions require monitoring of patients' conditions, although there is no specific biomarker that can be recommended for use in clinical practice [6]. Other tests applied in post-stroke patients have some limitations, such as high cost [7], radiation exposure [8], variability of interpretation [9], limited scope of physical examinations [10], invasive procedures [11], non-specific results [6], and relayed results [12]. In 1965, Mahoney and Barthel [13] developed a questionnaire to assess the daily activities of post-stroke patients, which was later named the Barthel index. This questionnaire contains 10 questions related to patients' daily activities, such as bathing, sitting, walking, and buttoning their clothes. This assessment is based on whether the patient is able to perform each activity independently or with assistance from others, with the scoring of each question in the range of 0, 5, 10, and 15, and the final total score ranging from 0 (total dependence) to 100 (independent). Barthel index is one of the oldest measurements, along with the KATZ index, which was discovered in 1963 [14]. In general, both tools share a similar common goal of assessing daily activities. However, the KATZ index has certain shortcomings that are addressed by the Barthel index, particularly in evaluating walking ability, stair climbing, and wheelchair use [15]. In addition to the Barthel index, there are several other measurement tools or questionnaires to help assess patient condition post-ischemic stroke, such as the National Institutes of Health Stroke Scale (NIHSS) [16] and Functional Independent Measurement (FIM) [17]. NIHSS focuses on assessing the severity experienced by patients [16], while the FIM is similar to the Barthel index, measuring patients' daily activities after stroke [18]. In this study, the Barthel index is preferred because it is commonly used by health workers in Indonesia [19-22]. This questionnaire has undergone cultural adaptation in several countries, such as Japan [23], Brazil [24], and Greece [25]. In Indonesia, several translations of the Barthel index are currently in use. Various research studies on the Barthel index have also been conducted to assess its reliability, validity, and applicability in different populations and clinical settings [26-28]. However, there are no publications related to the process of translation, validation, and cultural adaptation of the Barthel index that can be generalized to the entire Indonesian population. This study was conducted to evaluate the process of translation, cultural adaptation, and validation of the Barthel index in ischemic stroke patients at two health facilities in Tasikmalaya. The tests conducted included a criterion validity test and an internal consistency reliability test. The criterion validity test was used to measure the extent to which the questionnaire correlates with an external criterion, in this case, the daily activities of post-stroke patients. The internal consistency reliability test was conducted to measure the extent to which items in the measuring instrument relate to each other. Internal consistency assesses whether items on a test measure the same construct, ensuring that the tool is cohesive and reliable. It is generally easier to assess internal consistency through statistical methods like Cronbach's alpha, making it more straightforward for researchers to implement. While interrater reliability is important for measures involving subjective judgments by different raters, it can be more complex to establish and may be influenced by rater bias. In contrast, criteria validity and internal consistency provide a more streamlined approach to ensure the reliability and validity of measurement tools [29, 30].

2. MATERIALS AND METHODS

The study design adhered to established guidelines for the cross-cultural adaptation process [31]. The number of samples was calculated based on a previous study [32], where the sample for each question was four (4) to ten (10) samples. This study was conducted at two locations: the neurological clinic and the stroke center of a public hospital in Tasikmalaya, West Java, Indonesia, in July 2024, with the goal of validating the Barthel index in the West Java population. This study included 55 respondents based on the inclusion and exclusion criteria. The inclusion criteria in this study were patients who have undergone treatment after an ischemic stroke, provided informed consent, and were willing to participate in the study. Exclusion criteria in this study were ischemic stroke patients who refused to participate in the study. This study received ethical clearance from the KEPK BTH University with approval no. 023-01/E.01/KEPK-BTH/IV/2024.

The translation, adaptation, and validation procedures in this study were divided into several parts. An interview questionnaire was used to examine respondents' daily activities after the stroke. The questionnaire was administered in the Indonesian language. All respondents signed a written informed consent form. While obtaining the information, approximately 10 minutes were spent discussing the study's goals and outcome with the respondents. The questionnaire took 5 to 10 minutes to complete. In this study, interviews were conducted with patients when they visited the clinic or stroke center. The results of the criterion validity and internal consistency reliability tests were validated by conducting interviews. Due to the close proximity of patients' homes to the clinic and stroke center, the assessments were carried out exclusively *via* interviews. The questionnaire was constructed around 10 domains: feeding, bathing, grooming, dressing, bowel control, bladder control, toileting, chair transfer, ambulation, stair climbing, and four interpreting scores: total dependency, severe dependency, moderate dependency, and slight dependency. Each of the questionnaire domains was elaborated as follows:

[1] Feeding: This domain is used to assess whether the patient can eat on their own without the help of others or whether they have to get help from others. In addition, this domain is used to assess whether the patient can eat normally without having the meal to be cut into pieces first.

[2] Bathing: This domain is used to assess whether the patient can take a bath on their own or needs to be assisted by another person.

[3] Grooming: This domain is used to assess whether the patient can perform personal hygiene processes, such as brushing teeth, shaving, washing face, or whether they need assistance from others.

[4] Dressing: This domain is used to assess whether the patient is able to select and put on all clothes and can button clothes or whether the patient requires assistance

from others.

[5] Bowel control: This domain is used to assess whether the patient can defecate regularly, hold defecation until they get to the toilet and are able to clean themselves or not.

[6] Bladder control: This domain is used to assess whether the patient can urinate regularly, hold urination until they get to the toilet and are able to clean themselves or not.

[7] Toileting: This domain is used to assess whether the patient can access the toilet, undress sufficiently, clean themselves, dress, and leave the toilet.

[8] Chair transfer: This domain is used to assess whether the patient can walk from bed to chair without assistance and whether they can stand on their own.

[9] Ambulation: This domain relates to the patient's walking activities, whether they are able to walk alone at home or the ward without assistance or whether they have to get help from others or use a wheelchair.

[10] Stair climbing: This domain relates to the patient's activity, whether they are able to climb stairs on their own or need the aid of others [23].

[11] Translation process: The translation process was divided into two parts, namely, forward translation and backward translation. The forward translation process from English to Bahasa Indonesia was performed by two translators whose mother tongue was Indonesian. Both were English lecturers. The version from the first translator was labelled T1, and that from the second translator was labelled T2. The results of the forward translation were reviewed, and then the backward translation process was carried out by two native speakers whose mother tongue was English and who had lived in Indonesia for at least five years. The results of the backward translation were then reviewed. The version from the first backward translator was labelled BT 1, and that from the second backward translator was labelled BT 2.

[12] Adaptation: The adaptation process was carried out in several stages. First, after the forward and backward translation processes, adaptation was made to the translated questionnaire. Then, pilot testing was carried out with eight patients to measure the level of understanding of the researchers and the patients regarding the translated questionnaire. After the pilot testing, the adaptation of the questionnaire was carried out again to attain the best-translated version that could be understood by researchers and patients so that the study results obtained could be generalized to the Indonesian population.

[13] Validation: The validation process was divided into two parts, namely, a validation test of the results of the interviews with patients and a reliability test by the researchers to examine the extent to which the questionnaire is valid and reliable when applied to research in Indonesia. The validation and reliability tests were conducted using Pearson's correlation test and Cronbach's alpha values, with a p-value of <0.05 indicating a valid questionnaire and a p-value of >0.70 indicating a reliable questionnaire. The validation and reliability processes were carried out using SPSS version 22 (SPSS Inc. Chicago, IL, USA).

[14] Pilot Testing: Pilot testing was carried out on eight patients, with a division of three patients using the local language or Sundanese and five using Indonesian. This pilot testing was carried out to measure the similarity of the results of interviews with patients whose communication was in the local language or Indonesian.

3. RESULTS

The demographic data of the patients, including gender, age, education level, and occupation, are presented in Table **1**. The results of the forward translation, backward translation, and common problems observed in the translation process are presented in Tables **2**, **3**, and **4**. This section discusses the process of translating the English questionnaire into Indonesian and then the process of backward translation from Indonesian into English. The results of the reliability test, validity test, and Barthel index assessment are presented in Tables **5**, **6**, and **7**. Table **5** presents the results of the reliability test. It was found that the majority of questionnaires are in good reliability, except for questions 1, 2, and 10. However, the overall reliability test score shows reliable results. Table **6** presents the results of the validity test. All questions on the Barthel index show valid results. Table **7** shows the score levels of patients using the Barthel index, where the majority of patients are in moderate dependency. However, some female patients have a total dependency score.

4. DISCUSSION

This study aimed to translate, adapt, and validate the Barthel index in the Indonesian population. This questionnaire has been used in several diseases and is not limited to stroke patients. However, in this study, we focused on ischemic stroke patients.

Tabel 1. Demographic data.

No.	Parameters	Gender	
		Male (N=31)	Female (N=24)
1	Guardian-Assisted Interview		
	Yes	11	17
	No	20	7
2	Education Level		

(Table 1) contd.....

No.	Parameters	Gender	
		Male (N=31)	**Female (N=24)**
	Elementary School	11	14
	Junior High School	3	3
	Senior High School	10	5
	Undergradute	5	2
	Magister	2	0
3	Patient Residence		
	Tasikmalaya City	12	9
	Tasikmalaya Regency	14	12
	Outside Tasikmalaya	5	3
4	Jobs		
	Work	23	5
	Not Working	8	19
5	Use of Insurance		
	Yes	25	22
	No	6	2
6	Type of Insurance		
	BPJS Health	24	22
	General/Other Insurance	6	2
	Independent/No Insurance	1	0
7	History of Alcohol Use		
	Yes	4	0
	No	27	24
8	Smoking History		
	Yes	21	1
	No	10	23
9	Seeing Doctor Other Than Neurologist		
	Yes	10	8
	No	21	16
10	Use of Other Prescription Drugs		
	Yes	10	7
	No	21	17
11	Use of Non-prescription Drugs		
	Yes	2	0
	No	29	24

Tabel 2. Result of forward translation.

No.	Original Version	Translator 1	Translator 2
1	Feeding (if food needs to be cut up = help)	makan (jika makanan perlu dipotong = bantuan)	Menyuapi (jika makanan perlu dipotong-potongkan)
2	Moving from wheelchair to bed and return (includes sitting up in bed)	Berpindah dari kursi roda ke tempat tidur dan kembali lagi (termasuk duduk di tempat tidur)	Berpindah dari kursi roda ke tempat tidur dan sebaliknya (termasuk posisi duduk di tempat tidur)
3	Personal toilet (wash face, comb hair, shave, clean teeth)	Toilet pribadi (cuci muka, sisir rambut, cukur, bersihkan gigi)	Bersih-bersih diri (mencuci muka, menyisir rambut, mencukur, membersihkan gigi)
4	Getting on and off toilet (handling clothes, wipe, flush)	Masuk dan keluar dari toilet (menangani pakaian, mengelap, menyiram)	Masuk dan keluar kamar mandi (memegang pakaian, mengelap, menyiram)
5	Bathing self	Mandi sendiri	Mandi sendiri
6	Walking on level surface (or if unable to walk, propel wheelchair) *score only if unable to walk	Berjalan di permukaan yang rata (atau jika tidak mampu berjalan, gerakkan kursi roda) *beri skor hanya jika tidak mampu berjalan	Berjalan di permukaan yang rata (atau jika tidak dapat berjalan, mampu mendorong kursi roda) *skor hanya jika tidak dapat berjalan
7	Ascend and descend stairs	Naik dan turun tangga	Naik dan turun tangga
8	Dressing (includes tying shoes, fastening fasteners)	Berpakaian (termasuk mengikat sepatu, mengencangkan ikat pinggang)	Berpakaian (termasuk mengikat Sepatu, mengencangkan sabuk)
9	Controlling bowels	Pengawasan/pengontrolan isi perut	Mengontrol buang air besar
10	Controlling bladder	Pengawasan/pengontrolan kandung kemih	Mengontrol buang air kecil

Tabel 3. Result of backward translation.

No	Original Version	Indonesian Questionnaire	Back Translator 1	Back Translator 2
1	Feeding (if food needs to be cut up = help)	Makan (jika makanan perlu dipotong = bantuan)	Eating (if food has to be reduced = help)	Eating (if food needs to be cut up = assistance)
2	Moving from wheelchair to bed and return (includes sitting up in bed)	Berpindah dari kursi roda ke tempat tidur dan kembali lagi (termasuk duduk di tempat tidur)	Moving from a wheelchair to a bed and back again (including sitting in bed)	Moving from a wheelchair to the bed and back (including sitting on the bed)
3	Personal toilet (wash face, comb hair, shave, clean teeth)	Bersih-bersih diri (mencuci muka, menyisir rambut, mencukur, membersihkan gigi)	Washing oneself (washing face, brushing/combing hair, shaving, brushing teeth)	Self-cares (washing your face, combing your hair, shaving, cleaning your teeth)
4	Getting on and off toilet (handling clothes, wipe, flush)	Masuk dan keluar kamar mandi (memegang pakaian, mengelap, menyiram)	Entering and leaving the bathroom (holding clothing, wiping, squirting water)	Entering and leaving the bathroom (holding clothes, wiping, flushing)
5	Bathing self	Mandi sendiri		
6	Walking on level surface (or if unable to walk, propel wheelchair) *score only if unable to walk	Berjalan di permukaan yang rata (atau jika tidak dapat berjalan, mampu mendorong kursi roda) *skor hanya jika tidak dapat berjalan	Walking on level surfaces (or if unable to walk, able to move in a wheelchair) *score only if unable to walk	Walking on flat surfaces (or if unable to walk, able to push a wheelchair) *score only if unable to walk
7	Ascend and descend stairs	Naik dan turun tangga	Climbing and going down stairs	Going up and down stairs
8	Dressing (includes tying shoes, fastening fasteners)	Berpakaian (termasuk mengikat sepatu, mengencangkan ikat pinggang)	Getting dressed (including tying up shoes, tightening a belt)	Getting dressed (including tying shoelaces, tightening your belt)
9	Controlling bowels	Mengontrol buang air besar	Controlling defecation	Controlling defecating
10	Controlling bladder	Mengontrol buang air kecil	Controlling urination	Controlling urinating

Table 4. Common problems in translation process.

No	Original Questionnaire	Forward Translation	Backward Translation	Problem
1	Feeding (if food needs to be cut up = help)	Makan (jika makanan perlu dipotong = bantuan	Eating (if food needs to be cut up = assistance)	Polysemous word
2	Moving from wheelchair to bed and return (includes sitting up in bed)	Berpindah dari kursi roda ke tempat tidur dan kembali lagi (termasuk duduk di tempat tidur)	Moving from a wheelchair to the bed and back (including sitting on the bed)	Polysemous word
3	Personal toilet (wash face, comb hair, shave, clean teeth)	Bersih-bersih diri (mencuci muka, menyisir rambut, mencukur, membersihkan gigi)	Washing oneself (washing face, brushing/combing hair, shaving, brushing teeth)	Polysemous word
4	Getting on and off the toilet (handling clothes, wipe, flush)	Masuk dan keluar kamar mandi (berpakaian, mengelap, menyiram)	Entering and leaving the bathroom (holding clothes, wiping, flushing)	Syntagmatic word
5	Bathing self	Mandi Sendiri		
6	Walking on level surface (or if unable to walk, propel wheelchair) *score only if unable to walk	Berjalan di permukaan yang rata (atau jika tidak dapat berjalan, mampu mendorong kursi roda) *skor hanya jika tidak dapat berjalan	Walking on level surfaces (or if unable to walk, able to move in a wheelchair) *score only if unable to walk	
7	Ascend and descend stairs	Naik dan turun tangga	Going up and down stairs	Polysemous word
8	Dressing (includes tying shoes, fastening fasteners)	Berpakaian (termasuk mengikat sepatu, mengencangkan pengencang (ikat pinggang, kancing, dll))	Getting dressed (including tying up shoes, tightening a belt)	Syntagmatic word
9	Controlling bowels	Mengontrol buang air besar	Controlling defecation	Polysemous word
10	Controlling bladder	Mengontrol buang air kecil	Controlling urination	Polysemous word

Table 5. Reliability test result.

Item	Corrected Item– Total Correlation	Cronbach's Alpha If Item Deleted	Cronbach's Alpha for The Total Scale
1	0,598	0,890	
2	0,509	0,900	
3	0,751	0,884	
4	0,770	0,879	

(Table 5) contd.....

Item	Corrected Item– Total Correlation	Cronbach's Alpha If Item Deleted	Cronbach's Alpha for The Total Scale
5	0,769	0,882	0,896
6	0,773	0,878	
7	0,759	0,877	
8	0,710	0,881	
9	0,633	0,886	
10	0,479	0,897	

Tabel 6. Validity test result.

Item	Correlation Coefficient	p-value	r-count	r-table	Result
1	0,658	0,000	0,598	0,2656	Valid
2	0,639	0,000	0,509	0,2656	Valid
3	0,789	0,000	0,751	0,2656	Valid
4	0,814	0,000	0,770	0,2656	Valid
5	0,805	0,000	0,769	0,2656	Valid
6	0,846	0,000	0,773	0,2656	Valid
7	0,817	0,000	0,759	0,2656	Valid
8	0,779	0,000	0,710	0,2656	Valid
9	0,707	0,000	0,633	0,2656	Valid
10	0,591	0,000	0,479	0,2656	Valid

Tabel 7. Barthel index assessment result.

No.	Activity Score	Gender	
		Male (N=31)	Female (N=24)
1	Total Dependency	0	3
2	Severe Dependency	8	7
3	Moderate Dependency	10	10
4	Slight Dependency	13	4

The total number of patients in this study was 55 ischemic stroke patients. As mentioned in Table **1**, there were 31 male patients and 24 female patients, with the youngest age being 28 years and the oldest being 87 years; the average age was 60 ± 11.454 years. Several previous studies have reported that men have a higher risk of stroke than women [33, 34]. However, stroke is increasingly affecting younger individuals; in this study, some patients were as young as 28 to 30 years old. This is because of an increase in several risk factors for stroke at a young age, such as obesity, high cholesterol levels, and diabetes [35, 36]. Although in this study, no separate study was conducted on the consistency of interview results across different patient demographics, it was found that three female patients were totally dependent, which may have affected their responses to the questionnaire and may have been a barrier during the interview. In addition, age and education factors can affect the consistency of responses to the questionnaire [37].

The majority of the patients had a primary education level and resided in the Tasikmalaya district. There were 28 patients who were assisted by their guardian or a family member during the interview and 27 patients who were not assisted. Patients were assisted by their guardians for several reasons, including communication difficulties when using Indonesian or because of the stroke disease, as well as difficulty thinking and answering questions, especially patients with severe stroke conditions. The decline in cognitive function in stroke patients varies from 20% to 80% [38].

There were 22 patients with a history of smoking and 4 with a history of alcohol use. Smoking is one of the predictors of future stroke. A meta-analysis study [39] reported that smoking increased the risk of ischemic stroke by 2.2 times and hemorrhagic stroke by 2.7 times when compared to people who do not smoke. The higher risk was found to be caused by increased damage to blood vessels from smoking, increased oxidants in the body, and increased formation of atheroma plaques [40, 41].

As mentioned in Table **1**, several patients sought treatment from other doctors, including taking prescription drugs from other doctors and taking non-prescribed OTC drugs or herbal supplements. Some of the drugs used by the patients, other than antiplatelet, were

insulin, cold medicines, amlodipine, diclofenac, and herbal supplements to reduce cough symptoms. Based on the analysis conducted, there was no drug interaction between antiplatelet and other drugs used by the patients.

Tables **2**, **3**, and **4** present the results of the forward translation and backward translation and highlight the common problems found in the translation process. Several adaptations were made to the words related to controlling bowels and bladder. These adaptations were made to provide a deeper explanation of the process of controlling the bowels and the bladder, which is related to controlling defecation and urination.

Table **5** presents the results of the reliability test. In an initial study, the Barthel index demonstrated a reliability coefficient of 0.87, exceeding the acceptable threshold of 0.70 [42]. Several subsequent studies on stroke patients reported reliability scores of 0.95 [43] and 0.955 [44]. These validation studies demonstrated results consistent with other research conducted on stroke patient samples, confirming the reliability of the test in ischemic stroke populations [45, 46].

Table **6** presents the results of the validation test for each question in the Barthel index. As reported in Table **3**, all questions were valid, with the value for the r-count being greater than the value of the r-table. However, from the perspective of the strength of the correlation in the data, there are three categories of correlations, namely, very strong, strong, and moderate. Question no.10 has a moderate correlation, with a value of 0.591. Questions no. 1, 2, 3, 8, and 9 have a strong correlation, while questions no. 4, 5, and 6 have a very strong correlation. Several factors affect the strength of correlation, including data variability and differences in the characteristics of the sample, such as patients' compliance with taking medication [46], dietary profile [47], physiotherapy [48], and support from family members [49]. Several studies have reported similar findings, confirming the validity of the test in ischemic stroke patients [46, 51].

In the validation process, adaptation was made to a question during interviews with the patients. In the original questionnaire, the word "activity" was not presented at the beginning of the sentence of this question, but in the interview, it was easier for the patients to understand the question if it started with the word "activity."

Table **7** presents the results of the assessment of daily activities performed by the patients. There were patients whose daily activities were totally dependent on the help of others. On the other hand, there were around 17 patients who could still carry out daily activities independently. Of the total sample of patients, the number of patients with moderate dependence was the highest, accounting for 20 patients. In general, patients with mild dependence can still carry out activities independently, except for certain activities, such as climbing stairs.

CONCLUSION

The Barthel index was tested in a sample of ischemic stroke patients in West Java, Indonesia. The results showed that the translated and adapted questionnaire is valid, reliable, and easy for patients to understand and can be used in a diverse population.

LIMITATIONS

Our study has several limitations, including the limited sample size. Although it meets standard requirements, future research would benefit from using a larger sample size to improve the robustness of the findings. Another limitation of this study is that patient assessment was carried out only once. Therefore, future research should consider longitudinal validation to track changes in patient conditions over time.

AUTHORS' CONTRIBUTIONS

The authors confirm their contribution to the paper as follows: conceptualization, writing the original draft preparation, review, and editing: IA, DAP, LA, and IGA; methodology, validation, formal analysis, visualization, supervision, project administration, and funding acquisition: IA, DAP, and LA; investigation, resources, and data curation: IA and IGA. All authors have read and agreed to the published version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Institutional Review Board (or Ethics Committee) of Bakti Tunas Husada University (protocol code no. 023-01 /E-01 /KEPK-BTH/2024 and date of 17/04/2024).

HUMAN AND ANIMAL RIGHTS

All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committee and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent was obtained from all the participants involved in the study. Written informed consent was also obtained from the patients to publish this study.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data in this study are confidential because they relate to the medical conditions of the patients who participated in the study. However, the data can be made available by the corresponding author upon request.

CONFLICT OF INTEREST

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