- 1 Cutoff score of the lower extremity motor subscale of Fugl-
- 2 Meyer Assessment in chronic stroke survivors: a cross-
- **sectional study**

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9 Abstract

10	Objective				
11	To derive an optimal cutoff score for the lower-extremity motor subscale of the Fugl-				
12	Meyer Assessment to differentiate stroke survivors with high mobility function from				
13	those with low mobility function using a data-driven approach.				
14	Design				
15	Cross-sectional study.				
16	Setting				
17	University-based clinical research laboratory.				
18	Participants				
19	Chronic stroke survivors ($N = 80$) recruited from local self-help groups.				
20	Interventions				

22 Main Outcome Measures

Not applicable.

- 23 Lower-extremity motor subscale of Fugl-Meyer Assessment (FMA-LE), Berg Balance
- Scale, Five Times Sit to Stand Test, comfortable walking speed, Six-Minute Walk Test,
- and Timed Up and Go (TUG) Test.

26 **Results**

- 27 K-mean clustering analysis classified 42 stroke survivors in the high mobility function
- 28 group. The receiver operating characteristic curve showed that FMA-LE can differentiate
- stroke survivors based on their mobility level (area under the curve, 0.85). An FMA-LE
- score of 21 of 34 was the best cutoff score (sensitivity, 0.87; specificity: 0.81).

Conclusions

- 32 An FMA-LE score of 21 or higher could indicate a high level of mobility function in
- 33 chronic stroke survivors.
- 34 **Keywords:** Stroke, Cluster analysis, Rehabilitation

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36 List of abbreviation

- 37 BBS Berg Balance Scale
- 38 FMA -LE Lower-extremity motor subscale of Fugl-Meyer
- 39 FMA -UE Upper-extremity motor subscale of Fugl-Meyer
- 40 FTSTS Five Times Sit to Stand Test
- 41 ROC Receiver operating characteristic
- 42 TUG Timed Up and Go Test

The Fugl-Meyer Assessment (FMA) is widely used to measure the extent of motor control of the upper and lower extremities after stroke ¹. A review by Gladstone et.al. ² concluded that the motor subscale of the FMA is reliable and valid for evaluation of the changes in motor impairment of upper and lower extremities after stroke. The FMA comprises a lower-extremity motor subscale (FMA-LE) and an upper-extremity motor subscale (FMA-UE). Both are commonly used as inclusion criteria and for assessment of the level of motor deficit as an outcome measure in clinical trials ². Woytowicz et.al. ³ reported that total FMA-UE scores of 15, 34, and 53 of 66 were the optimal cutoff scores to define severe, severe-moderate, moderate-mild, and mild levels of upper-extremity motor deficit, respectively, in 247 stroke survivors.

Stratifying stroke survivors based on their mobility functions could provide the basis for clinicians to design treatment plans and allocate resources. Besides, researchers could perform subgroup analyses to investigate the effects of mobility functions on the interested outcomes. We hypothesized that the FMA-LE score would be able to differentiate chronic stroke survivors with high mobility function, for instance, those with a better performance in balance, ability in transfer and capacity in walking, from those with low mobility function. However, no cutoff score on the FMA-LE has been defined to differentiate the levels of lower-extremity function in stroke survivors. Therefore, the objective of this study is to derive the optimal cutoff score on the FMA-LE that could differentiate chronic stroke survivors with high mobility function from those with low mobility function with a data-driven approach.

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Methods

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In this cross-sectional clinical study, stroke survivors were recruited from local self-help groups via poster advertisements. Stroke survivors were eligible to participate if they (1) were between 50 and 85 years of age; (2) had received a diagnosis of stroke by magnetic resonance imaging or computed tomographic scanning more than 1 year earlier; (3) were able to walk 3 m independently regardless of the time consumed and the type of walking aid used. This criterion ensures that the subject would be able to complete functional tests used in the current study; and (4) were able to follow instructions and give informed consent. Stroke survivors were excluded if they had (1) any existing medical, cardiovascular, or orthopedic condition that hindered assessments or (2) participated in other drug studies or clinical trials to ensure that the subject's performance would not be influenced by additional intervention. All stroke survivors were assessed with the FMA-LE and other functional tests, including the Berg Balance Scale (BBS), Five Times Sit to Stand Test (FTSTS), comfortable walking speed, Six-Minute Walk Test, and Timed Up and Go Test (TUG). These outcomes assessed walking speed, walking endurance, sit-to-stand performance, and balance performance in multiple functional tasks, which provided a holistic evaluation of the participants' mobility

function. The assessment procedures are available in Appendix 1. All assessments were conducted by a registered physiotherapist during one session, at a university-based clinical research laboratory. The study protocol was approved by the ethics committee of the administering institution. The study was conducted in accordance with the principles of the Declaration of Helsinki for human experiments. All participants gave written consent before the experiment began.

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K-mean clustering analysis—an unsupervised machine learning algorithm ⁴—was used to classify stroke survivors into groups using the results of all functional outcomes except the TUG test completion time. The TUG complete time was used to evaluate the validity of the classification model, thus, it did not involve in the model establishment. The K-mean clustering analysis constructed a four-dimensional space using the results of BBS, FTSTS, comfortable walking speed and Six-Minute Walk Test as the 4 axes. The algorithm then identifies k centers (k equal to 2 in the current study) in the fourdimensional space, in which these centers minimize the mean squared distance from each data point (representing a subject) to its nearest center. A shorter mean squared distance would determine the result of classification for each subject. The Silhouette-width ⁵ was used to identify the optimal number of clusters. A receiver operating characteristic (ROC) curve was used to identify the optimal cutoff score for the FMA-LE based on the groups obtained from K-mean clustering analysis. The between-group differences in demographic characteristics and results of functional outcomes were compared with an independent t-test. Since age could be one of the factors that influenced the mobility function, the association between subjects' age and the results of functional outcomes

would be evaluated with the Pearson correlation coefficient. It has been suggested that the sample size of $5*2^k$ (where k refers to the number of independent variables) is preferable in conducting clustering analysis 6 . The number of subjects required in the current study, therefore, would be 80. Besides, under the assumption that the expected area under the curve of the ROC curve analysis would be 0.7, the alpha value would be 0.05, the study power would be 0.8, and the number of stroke survivors in each group would be equal, it was estimated that a total sample size of 60 would have adequate power to identify the cut-off score. All statistical analyses were conducted using R language a in conjunction with the pROC package 7 and NbClust package 8 .

Results

Eighty chronic stroke survivors participated in this cross-sectional study. The median FMA-LE score was 22 of 34 (Table 1). The two-cluster model showed the greatest average silhouette width (0.353). This result indicates that classifying the stroke survivors into two groups maximized the distance between clusters. K-mean clustering analysis classified 42 stroke survivors in the high mobility function group. The ROC curve showed that the FMA-LE can differentiate stroke survivors according to their mobility level (area under the curve, 0.85; Fig. 1). An FMA-LE score of 21 of 34 was the

best cutoff score (sensitivity,0.87; specificity,0.81); that is, an FMA-LE score of 21 or higher indicates better mobility function. An independent t-test showed a significant difference in the results of all functional outcomes between the two groups(P < 0.001) (Table 1). The results indicated that the FMA-LE cutoff score has strong discriminative power to stratify stroke survivors with high versus low mobility functions. An online application (Appendix 2) has been created to provide better visualization of the relationship between the FMA-LE cutoff score and BBS score, FTSTS completion time, walking speed, walking distance and TUG scores. Correlation analyses revealed that subjects' age did not significantly associate with their mobility functions (BBS: r = 0.009, P = 0.934; FTSTS: r = 0.056, P = 0.616; comfortable walking speed: r = -0.004, P = 0.966; 6-minute walking distance: r = -0.006, P = 0.955; TUG: r = 0.048, P = 0.674)

Discussion

On the basis of K-mean clustering and ROC curve and analyses, we propose a total score of 21 as the optimal cutoff score for the FMA-LE. Stroke survivors who score 21 or higher on the scale should be considered as having better mobility function using the data-driven approach. The statistical method deduced the cutoff score by taking into account the contribution of BBS, FTSTS, walking speed and 6-minute walking distance, which are commonly used outcomes for assessing mobility functions in stroke survivors

and also assessed different aspects of lower-extremity functions. In other words, the statistical method reduced the dimension of the data, extracted the useful information from the dataset and finally mapped the information in a one-dimensional space. Instead of having 4 cut-off scores for each outcome, this study suggests a single cut-off score to stratify the subjects.

The significant differences in the TUG test completion time and other functional outcomes between the higher and lower motor function groups indicate that the cutoff score is sensitive enough to distinguish the mobility functions among stroke survivors. In statistics point of view, stroke survivors who were classified as having high mobility function demonstrated better ability in balance, transfer and locomotion in general. It is not surprising that significant between-group differences existed in BBS, FTSTS, walking speed and 6-minute walking distance since these outcomes had been used to construct the classification model. The significant differences in the TUG test completion time further proven the strong discriminative validity of the model.

Consistent with previous findings 9 , our results demonstrate that FMA-LE can classify stroke survivors with different levels of lower-extremity function. Pohl et.al. 9 reported that the FMA-LE score was a significant predictor of the 6-Minute Walk Test distance in 72 patients with subacute stroke (β =19.4; SE=7.4). Moreover, Kim et.al. 10 also revealed that the FMA-LE score was significantly correlated (r=0.661) with the BBS score in a sample of 50 chronic stroke survivors.

It should be noted that about 20% of stroke survivors with high mobility function are misclassified by the proposed cutoff score. The relatively low specificity reflected that many participants had low FMA-LE scores, even if they had high mobility function. It might be attributed to the inclusion of the reflex component score (6 points maximum), in the total score of the FMA-LE. Woytowicz et.al. ³ suggested that the reflex component of the FMA-UE demonstrated only fair reliability and that it may not contribute to discriminating the degree of paretic upper-limb motor function in stroke survivors.

Moreover, confirmatory factor analysis showed that the reflex components of FMA-LE measured different construct as other items in the scale did ¹¹. The integrity of the paretic lower-extremity reflexes may not be able to predict the level of mobility function in stroke survivors.

Clinically, the proposed cut-off score for the FMA-LE would enable clinicians to identify stroke survivors with higher or lower mobility function to design an optimal treatment protocol. When conducting clinical research, a cut-off score on the FMA-LE can be used to stratify stroke survivors based on their lower-extremity motor function.

Study limitations

This study has several limitations. Most stroke survivors demonstrated relatively good mobility function as assessed by the TUG test completion time, which could affect the accuracy and generalizability of the classification model. Moreover, the sample size was small; thus, the cut-off score for the FMA-LE reported in this study warrants further investigation with a larger sample with a wider spectrum of mobility function. Therefore, it should be noticed that the FMA-LE cut-off score proposed is likely specific to community-dwelling chronic stroke survivors only.

The results of this study show that the FMA-LE score can predict the level of

mobility function in chronic stroke survivors. An FMA-LE score of 21 or higher could

indicate a high level of mobility function in chronic stroke survivors.

Conclusions

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Supplier

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251	Supplementary materials
252	Appendix 1: Details of assessment procedure
253	Appendix 2: Online application for data visualization.
254	Available on https://kwongwh.shinyapps.io/visualization/
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Figure legends

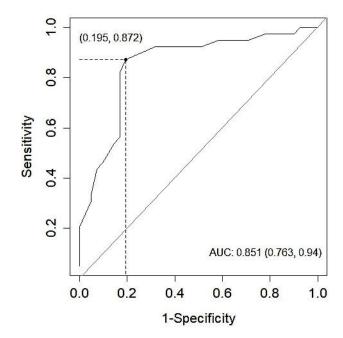


Figure 1: The ROC curve that identified the optimal cutoff score to differentiate stroke survivors with a high mobility function from those with a low mobility function.

Table 1. Summarized demographic characteristics of all subjects and subjects with high and low mobility function and results of between groups comparison.

Variables	All subjects (n = 80)	High mobility function group (n = 42)	Low mobility function group (n = 38)	Between group comparison High mobility vs Low mobility t, P			
Mean (sd)							
Age / yr	62.0 (5.4)	61.9 (5.7)	62.1 (5.1)	0.19, 0.849			
Post stroke	5.4 (2.9)	6.2 (2.6)	4.7 (3.1)	-2.33, 0.023			
duration / yr							
FTSTS	20.8 (8.7)	16.6 (3.8)	24.7 (10.3)	-4.70, <0.001			
completion time /							
S							
Walking speed /	0.77 (0.31)	1.01 (0.25)	0.55 (0.15)	-9.85, <0.001			
ms ⁻¹							
Six-minute	226.9	294.9 (52.4)	162.1 (45.1)	-12.03, <0.001			
Walking Test	(82.7)						
distance / m							
Timed Up and Go	19.2 (8.1)	13.6 (3.1)	24.5 (7.7)	8.42, <0.001			
Test completion							
Time / s							
FMA-LE score	22 (10)	26(7)	18 (5)	-6.61, <0.001			
BBS score	49 (5)	51 (4)	46 (5)	-5.38, <0.001			