Development of a clinical prediction rule for assessing gait ability following total knee arthroplasty

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ABSTRACT

【Introduction】Total knee arthroplasty (TKA) is a common and effective treatment for knee osteoarthritis (KOA), and the number of people undergoing TKA surgery will increase as the population grows older. However, we occasionally encounter patients who cannot walk stably after surgery. If such patients could be identified and sorted in advance, more appropriate and effective physical therapy could be provided. Therefore, the development of a clinical prediction rule (CPR) for gait ability at discharge after TKA surgery is required. The purpose of this study was to develop a CPR to identify patients at high risk of gait instability at discharge using the results of their preoperative assessment. 【Participants and Methods】This retrospective study included 77 patients who underwent primary TKA due to KOA at the Suzuka Kaisei Hospital. Data on patient characteristics (socio-demographic variables, body mass index, etc.) and preoperative physical function were collected. Based on the results of the Timed Up & Go Test on discharge, patients were classified into the “gait stable group” and “gait unstable group.” Differences between the groups were analyzed using the Mann-Whitney U test. Variables with significant differences between the groups were analyzed using receiver operating characteristic curves and Youden’s index to determine cut-off values. A CPR for gait ability was developed from determined cut-off values. 【Results】A CPR with four variables (bilateral knee extension peak torque and bilateral one-leg standing time) was identified. Twenty of the 77 patients were classified into the “gait unstable group.” When the total score for the CPR was 3, the positive likelihood ratio was 14.3 and the positive predictive value was 83.4%. 【Conclusions】The gait ability following TKA on discharge may be predicted from variables collected from the preoperative examination. However, further studies are necessary to validate this CPR.

INTRODUCTION

Knee osteoarthritis (KOA) is one of the most common joint diseases and its incidence to increase with the growing elderly population. An estimated 25.3 million people in Japan are reportedly affected by KOA[1]. Total knee arthroplasty (TKA) is the primary surgical treatment for KOA, with most patients showing improvement in pain and activity limitations. In contrast, approximately 20% of patients undergoing TKA are aware of activity limitations after surgery[2,3]. We occasionally encounter patients whose physical function does not improve and who cannot walk stably after surgery. Previous studies have reported that preoperative physical function is a major predictive factor for postoperative functional recovery[4,5]. However, few studies have examined the preoperative physical function values required to achieve a stable gait after TKA surgery. Thus, it remains a challenge to identify the TKA candidates who will be able to walk stably or will become unstable.

A clinical prediction rule (CPR) consists of combinations of variables obtained from patient-reported outcome measures and clinical examinations. It assists with the subgrouping of patients and supports clinical decision-making of patients by therapists for their treatment[6]. A CPR would greatly enhance the quality of physical therapy provided to patients[7]. Recent overseas studies have reported a few CPRs for TKA[8,9]. However, little has been reported on CPRs that suit the Japanese patient population.

The purpose of this study was to develop a CPR to identify patients at high risk of gait instability on discharge using the results of their preoperative assessment.

PARTICIPANTS AND METHODS

The participants of this study were patients diagnosed with KOA who underwent primary TKA at the Suzuka Kaisei Hospital between April 2010 and March 2019. The inclusion criterion was age ≥ 50 years. The exclusion criteria were history of a prior contralateral TKA, revision knee surgery, complications of severe mental disorders (e.g., depression, schizophrenia, or dementia), and deviation from the clinical pathway owing to postoperative complications (e.g., wound infection, peroneal nerve palsy, deep vein thrombosis). In addition, we excluded patients with missing data from the preoperative assessment. Ultimately, 77 patients meeting these criteria were included in this study.

The present study was approved by the Ethics Committee of the Suzuka Kaisei Hospital (n. 2019-06). Informed consent was obtained in the form of an opt-out on the website.

This study employed a retrospective study design. The survey items were as follows: sex, age, height, weight, and body mass index as patient characteristics; bilateral knee extension/flexion muscle strength, knee pain, bilateral one-leg standing time, and bilateral knee extension/flexion ROM as preoperative physical function; and TUG at discharge. All data were collected from the patients' medical record.

To measure muscle strength, an isokinetic knee muscular function test was performed using the Cybex Humac Norm System (CSMi, Stoughton, MA, USA). The extensor and flexor of both knee joints were evaluated four times

each at 60° /sec, and the peak torque/body weight (%) was calculated from the results. The ROM of the knee joint was measured passively using a goniometer according to the methods recommended by the Japanese Orthopaedic Association and the Japanese Association of Rehabilitation Medicine and recorded in increments of 5° . Knee pain was assessed using the visual analogue scale. One-leg standing time is an assessment of static balance. We used digital stopwatches to measure standing time on one leg with eyes open. The maximum value for the measurement was 60 s. The TUG assesses mobility, walking ability, and fall risks of older adults. Patients sitting on the chair were required to stand up, walk 3 m, turn around, walk back to the chair, and sit down. The measurement was performed at a "quick yet safe speed."

A previous study reported that TUG score ≥ 13.5 s is the cut-off point to identify elderly individuals who are at risk of falls in community dwellings[10]. Accordingly, in this study, patients with a TUG score ≥ 13.5 s were classified into the "gait unstable group" and those with a TUG score < 13.5 s were classified into the "gait stable group".

To identify the differences between groups, we performed the Mann-Whitney U test. The relationships between the variables that were found to be significant were analyzed using Spearman's rank correlation coefficient and selected accordingly. The selected variables were receiver operating characteristic (ROC) curves' analysis and cut-off values were determined using Youden's index. A CPR predicting gait ability was generated from the determined cut-off values and for the resulting CPR, sensitivity, specificity, area under the ROC curve (AUC), positive predictive value, negative predictive value, and positive and negative likelihood ratios (LR+, LR-) were calculated. All statistical analyses were performed using SPSS Statistics version 23 (IBM, Chicago, IL, USA). The overall significance of the study was assessed at $p < 0.05$.

Table 1. Demographic data of patients.

Characteristic	All Patients (n=77)
Age (years)	72.7 ± 6.6
Sex	Male 18, Female 59
Height (cm)	152.7 ± 8.3
Weight (kg)	61.0 ± 11.3
BMI (kg/m^2)	26.1 ± 3.8

Means ± SD, BMI: body mass index

RESULTS

Demographic data of the patients are shown in Table 1. Twenty of the 77 patients (26%) belonged to the "gait unstable group" and 57 to the "gait stable group." There were significant differences in six variables (bilateral knee extension %body weight (BW), bilateral knee flexion %BW, and bilateral one-leg standing time) between the two groups (Table 2). Only two variables of knee extension were included, as variables of knee extension and flexion strength were highly correlated (operative side: $r=0.809$, $p<0.01$, non-operative side: $r=0.791$, $p<0.01$; Fig. 1 and 2). Therefore, a CPR with four variables (bilateral knee extension %BW and bilateral one-leg standing time) was identified. The CPR and cut-off values are shown in Table 3. Furthermore, the ROC curve and AUC of the CPR are shown in Fig. 3. The AUC was 0.841 and

showed a high diagnostic performance. The cut-off value for CPR obtained using Youden's index was 3 points. The diagnostic feature of this CPR was that when the total score for the CPR was 3, the positive likelihood ratio was 14.3 and the positive predictive value was 83.4% (Table 4).

Table 2. Comparison of variables between two groups.

	gait stable group		gait unstable group		p value
Preoperative knee pain (VAS)	70.0	(75.0－50.0)	74.0	(84.25－49.25)	0.205
One leg standing time (sec)					
non-operated side	7.6	(12.9－3.5)	2.8	(4.8－1.9)	0.003
operated side	6.0	(12.7－3.0)	2.6	(5.7－1.3)	0.007
Knee extension %BW (Nm/kg)					
non-operated side	80.0	(104.0－60.0)	43.5	(67.5－31.5)	<0.001
operated side	57.0	(69.0－45.0)	39.0	(57.0－25.5)	0.005
Knee flexion %BW (Nm/kg)					
non-operated side	39.0	(51.0－30.0)	19.5	(33.8－5.3)	<0.001
operated side	33.0	(42.0－21.0)	21.0	(28.5－9.0)	0.01
Knee extension ROM (°)					
non-operated side	0	(0－－10)	0	(0－－10)	0.995
operated side	-10	(0－－15)	-15	(-5－－20)	0.081
Knee flexion ROM (°)					
non-operated side	135	(140－127.5)	135	(142.5－120)	0.445
operated side	125	(135-115)	125	(137.5-107.5)	0.546

median (interquartile range)

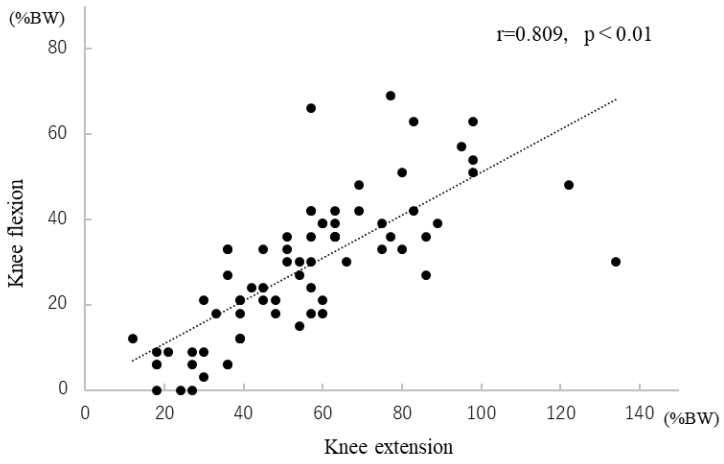

Fig. 1. Correlation between knee extension and flexion muscle strength in operative side.

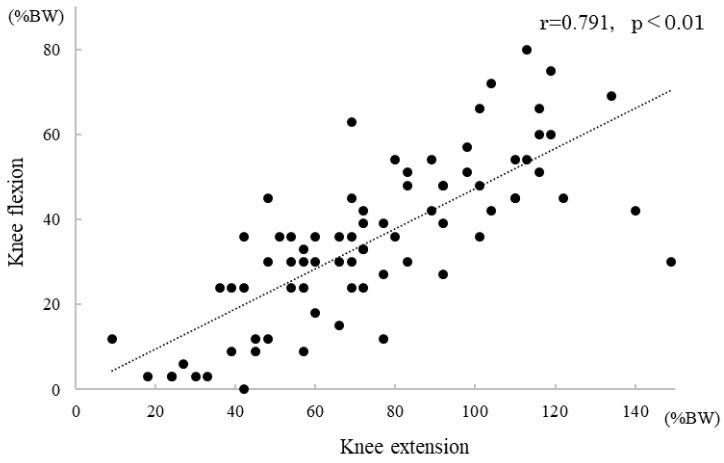

Fig. 2. Correlation between knee extension and flexion muscle strength in non-operative side.

Table 3. The developed CPR and cut-off values.

Item	Cut-off value
① Knee extension %BW of the operated side (Nm/kg)	1 point : <46.5 0 point : ≥46.5
② Knee extension %BW of the non-operated side (Nm/kg)	1 point : <49.5 0 point : ≥49.5
③ One leg standing time of the operated side (sec)	1 point : <2.26 0 point : ≥2.26
④ One leg standing time of the non-operated side (sec)	1 point : <3.22 0 point : ≥3.22
	total score : point

Table 4. The diagnostic characteristics of this CPR.

Total score	Sensitivity	Specificity	Positive likelihood ratio (LR+)	Negative likelihood ratio (LR-)	Post-test probability	
					Positive predictive value	Negative predictive value
1	0.9	0.56	2.05	0.18	41.9%	94.1%
2	0.7	0.84	4.43	0.36	60.9%	88.9%
3	0.5	0.97	14.29	0.52	83.4%	84.6%
4	0.3	0.98	16.67	0.71	85.4%	80.0%

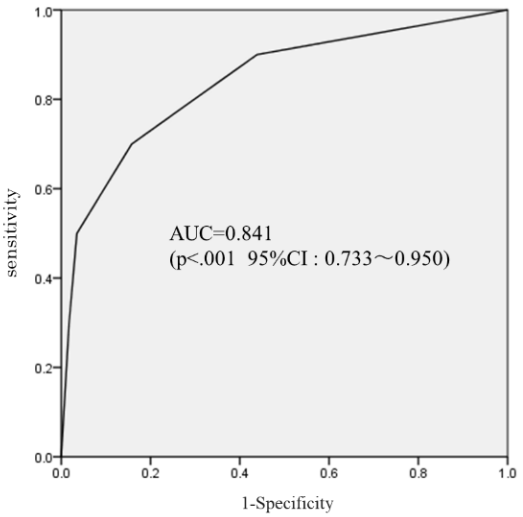

Fig. 3. The ROC curve and AUC of the CPR.
AUC: Area Under Curve, CI: confidence interval.

DISCUSSION

In this study, we collected the results of a preoperative assessment to develop a CPR to identify patients at high risk of gait instability on discharge among those who underwent TKA. The results of the study aided in the development of a CPR consisting of a combination of four items: (1) knee extension %BW of the operated side, (2) knee extension %BW of the non-operated side, (3) one-leg standing time of the operated side, and (4) one-leg standing time of the non-operated side.

The AUC of the CPR in this study was 0.841, which shows a relatively high predictive accuracy[11]. The cut-off calculated from the optimal sensitivity and specificity using Youden's index was 3 points. At this score, both positive and negative predictive values were > 80%, with an LR+ of 14.3. LR+ is considered a clinically valuable test if it is greater than 10[12]. Even with a total score of 4, the positive and negative predictive values were > 80%, and LR+ was 16.7. LR- shows relatively smaller values for a total score of 3 than for a total score of 4. Therefore, we considered that a total score of 3 points was more useful when judged comprehensively. Thus, this CPR can predict with a certain accuracy that patients will be gait unstable on discharge and may help in clinical decision-making.

We have adopted the TUG score as the outcome of this study. TUG scores increase with age and have been reported to be related to history of falls, frequency of outdoor activity, and habitual exercise[13]. Hence, the TUG has been used in many studies as a measure of functional mobility in the elderly and as an indicator of gait and balance ability. Previous studies have reported that weakening of knee extension strength is associated with difficulty in standing up and a decrease in walking speed[14-16]. As mentioned above, several studies have reported the effect of knee extensor strength, suggesting that this study is similarly highly influenced by knee extensor strength. Regarding the one-leg standing time, Tsuda et al.[17] reported that cut-off values for the one-leg standing time required for independent walking were 3.6 seconds for the right side and 2.9 seconds for the left side. Although the participants were different, it is thought that a one-leg standing time of approximately 2-3 seconds is necessary for a stable gait.

The CPR developed in this study can support the decision-making of therapists as a tool for appropriately planning post-operative physical therapy considering the patient's condition. A CPR consists of only objective information in the assessment of physical therapy. Objective assessment has the advantage of quantifying results, making it easier to judge and compare the

effectiveness of the treatment, and providing patients with feedback.

One limitation of our study is that only patients for whom all preoperative assessments could be performed were included. Patients who could not be examined were excluded; for example, patients who could not sit on the Cybex seat or who refused to be examined because of immense pain. Consequently, the use of this CPR may be limited to patients with high levels of physical function.

Thus, in future, it is necessary to perform preoperative prediction using this CPR in different sample populations, confirm whether these findings are reproducible, and verify the validity of the developed CPR. Furthermore, the clinical and financial impacts of using this CPR should be investigated. In recent years, patient-reported outcome measures have been used more widely to assess post-discharge function and Quality of life as a measure of treatment effectiveness. Hence, future research should focus on these outcome measures.

In conclusion, gait ability following TKA on discharge may be predicted by variables collected from the preoperative examination. This CPR could help manage patients after TKA. However, future studies are necessary to validate this CPR.

Conflict of Interest statement: The authors have no conflicts of interest directly relevant to the content of this article.

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