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Abstract

Objectives; The purpose of this study was to compare the recovery of mobility and self-efficacy following total knee arthroplasty (TKA) between the 5-day and the 28-day protocol. This prospective cohort study was carried out at two hospitals. *Methods;* In total, 104 patients who underwent TKA were enrolled. The primary outcomes measured were Life Space Assessment (LSA) for mobility and modified-Gait Efficacy Scale (mGES) for self-efficacy. Knee Society Score (KSS) was used to estimate the functional outcomes. These assessments were performed in all patients preoperatively, and at 1, 3, and 6 months postoperatively. After calculating the propensity score using covariates, such as patient characteristics, LSA, mGES, and KSS at baseline, propensity score adjusted multivariate analysis of covariance (MANCOVA) was performed. *Results;* MANCOVA revealed significant differences in LSA and mGES, but not in KSS, between the two protocols. The adjusted means of LSA and mGES in the 28-day protocol were significantly greater than those in the 5-day protocol in all the postoperative assessments. *Conclusions;* Mobility and self-efficacy were greater following the 28-day protocol than the 5-day protocol after TKA. Our findings suggest that the modified treatment procedure for improving mobility and self-efficacy is necessary to introduce the early discharge protocol in Japan.

Text

Introduction

Osteoarthritis (OA) of the knee is a chronic degenerative disease resulting in severe knee pain and dysfunction [1]. Total Knee Arthroplasty (TKA) is a major orthopedic procedure for reducing pain and restoring functionality in end-stage knee OA [2, 3]. Recently, shortening the hospital stay after TKA has led to lower medical costs and faster improvements in activities of daily living (ADLs) [4, 5]. The mean length of hospital stay was 2.2 days in USA [6] and 4.0–5.0 days in UK [7, 8], whereas it was 27.2 days in Japan [9], which was significantly longer because it still uses the 28-day protocol. The proportion of the population aged 65 years and above in Japan was 26.7% in 2016 and the rate of its increase is unparalleled in the world [10]. Medical expenses are substantially higher in this age group and their burden on healthcare is expected to increase further [10]. Therefore, the length of the hospital stay after TKA should be shortened to reduce the medical costs. Although the 5-day protocol after TKA has been introduced in some hospitals in Japan [11], the impact of such efforts is lacking in Japan when compared with that in other countries.

TKA improves quality of life (QOL) by relieving pain and enhancing physical function [12]. The improvement in QOL was associated with improvements in physical function and mobility [13-15] but mobility at 6 months after TKA remained at the same level as that before surgery [16, 17]. The reason being the improvement in mobility after TKA was affected by, both, physical function and self-efficacy for walking [18]. Since self-efficacy can be improved through educational guidance and successful experiences [19], a treatment process that provides guidance and repeated exercises for walking and ADL motions resulted in improved self-efficacy. Such guidance and repeated exercises are a part of the 28-day protocol, but not the 5-day protocol. Therefore, between the two different protocols, we hypothesized that the 28-day protocol would have greater recovery of mobility and self-efficacy during 6 months after TKA. However, to the best of our knowledge, no studies have evaluated the recovery processes associated with the 5-day protocol and the 28-day protocol and clarified the association of the two protocols with mobility and self-efficacy for shortening the hospital stay.

Therefore, the purpose of the present study was to evaluate the association of the two different protocols with the recovery of mobility and self-efficacy after TKA.

Materials and methods

Participants

The study design was a prospective cohort study at two hospitals, which implemented either the 5-day protocol or the 28-day protocol, and the hospitals will be referred to as the 5-day-protocol hospital and the 28-day-protocol hospital. Patients who were scheduled to undergo unilateral TKA because of knee OA were enrolled in this study. Patients were divided into the 5-day- or 28-day-protocol group based on the protocol adopted by the hospitals in which they underwent TKA. Inclusion criteria were as follows: (1) the patients underwent primary TKA, and (2) they had the ability to walk at least 10 m preoperatively. The exclusion criteria were as follows: (1) diagnosis of rheumatoid arthritis and osteonecrosis of the knee, (2) the patients underwent revision TKA, (3) patients with history of orthopedic diseases or surgery in the lower limbs at a site other than the knee, and (4) illnesses of the respiratory and circulatory systems that could affect their walking ability. After applying these criteria to the total number of patients undergoing the surgery, 104 patients were recruited in this study between December 2013 and January 2014 in the 5-day-protocol hospital (n = 45), and between December 2013 and December 2014 in the 28-day-protocol hospital (n = 59). The ethics committee of the two hospitals approved the study and the procedures involved (the 5-day-protocol hospital: 2013-6, and the 28-day-protocol hospital: 25-159). Written informed consents were obtained from all participants.

Treatment procedure before and after surgery

The 5-day protocol (Fig. 1): The 5-day protocol consisted of four weeks of outpatient preoperative rehabilitation, intensive 5-day inpatient rehabilitation and 12 weeks of outpatient postoperative rehabilitation. The preoperative rehabilitation was performed once a week and the baseline assessment was performed at the beginning of the preoperative rehabilitation. All patients were hospitalized on the day of surgery, and they underwent primary TKA with a medial parapatellar approach by using a tourniquet. Pain management was performed using intraoperative cocktail therapy with multimodal periarticular injections; loxoprofen, acetaminophen or tramadol acetaminophen, or a combination of tablets were administered three times a day after surgery. The orthopedic surgeon controlled drug dosages depending on the degrees of pain. Additionally, patients were instructed to continue cryotherapy throughout the day, except during daily activity. All patients started postoperative rehabilitation under the supervision of physical therapists on the

postoperative day 1, and aimed to achieve independent ambulation using a walker on the same day. After independent ambulation was achieved using a cane by postoperative day 3, the patients were discharged on postoperative day 5. The patients received 40–60 minutes of rehabilitation twice daily during their postoperative stay at the hospital. At discharge, the participants were instructed to continue the exercises (cryotherapy, and passive knee range of motion, and muscle strength exercises) twice daily. Physical therapists confirmed the self-reported patient compliance at each outpatient visit during the follow-up periods. If necessary, they reinstructed patients to continue the home-based self-exercises. The outpatient postoperative rehabilitation was performed once a week, and continued until 3 months postoperatively. All patients were followed-up by orthopedic surgeons and the outcomes were measured by physical therapists at 1, 3, and 6 months postoperatively.

The 28-day protocol (Fig. 1): The 28-day protocol consisted of an intensive 28-day inpatient rehabilitation postoperatively and no outpatient rehabilitation. The patients were hospitalized the day before the surgery, except for patients that required perioperative anticoagulation therapy or insulin therapy, and underwent the baseline assessment. The surgical approaches used for TKA were either medial parapatellar or midvastus approach by using a tourniquet. Pain management was performed using continuous epidural anesthesia till the initiation of ambulation on the next postoperative day. Subsequently, patients were administered loxoprofen, acetaminophen or tramadol acetaminophen, or a combination of tablets thrice daily; the dosage was regulated by the orthopedic surgeon, if necessary. The cryotherapy was applied on the affected area throughout the day, except during daily activity. All patients were started with ambulation exercises using a walker, or if required using a wheelchair, on postoperative day 1. After independent ambulation using a walker was achieved by postoperative day 3, ambulation exercises with a cane were introduced gradually, and the target was independent ambulation with a cane by postoperative day 14. Then patients were taught ADL exercises, including sit-to-stand on the floor and walking up and down the stairs. The primary mobility-related goal at discharge was independent ambulation without a cane indoors and with a cane outdoors. During their hospital stay, all patients were provided with the same rehabilitation protocol for 40–60 minutes and 5 times per week by a physical therapist. At discharge, the participants were instructed to continue the self-exercises, including cryotherapy, passive knee range of motion and muscle strength exercises once daily, and to increase the physical activity gradually without a limit after hospital discharge. The outpatient rehabilitation was not performed, and the compliance with regard to self-exercises and

exercises of ADL motions were confirmed and re-taught by a physical therapist at 2, 3, and 6 months postoperatively with regular follow-ups with the orthopedic surgeons. The outcomes were measured at 3 and 6 months postoperatively by physical therapists on the days of follow-ups with the orthopedic surgeons. The assessment at 1-month postoperatively was not performed because the patients were still in the hospital at the time.

Outcome measures

The assessments of the outcomes were performed at 1, 3, and 6 months postoperatively. Certain patient data such as age, sex, height, weight, body mass index (BMI), contralateral knee OA grade (OA grade represented by Kellgren/Lawrence, K/L, scale), and comorbidity (diabetes: DM, hypertension: HT) were collected from the medical records.

The primary outcome was Life Space Assessment (LSA) as a measure of mobility and the modified-Gait Efficacy Scale (mGES) as a measure of the participant's self-efficacy. LSA estimates mobility regarding activities during four weeks before the assessment at one's home environment and surrounding community [20]. LSA scores the frequency of movement into 5 levels of life-space and the independence of ambulation in each of them. The 5 life-space levels were as follows: (level 1) rooms other than the bedroom; (level 2) an area outside the home in one's own yard or driveway; (level 3) places in the neighborhood other than one's own yard or apartment building (<800 m); (level 4) places outside the neighborhood but within one's town (<16 km); and (level 5) places outside one's town (20). The frequency of movement to each life-space were graded from 1 to 4 (less than once a week = 1, 1-3 times each week = 2, 4-6 times each week = 3, and daily = 4). The values in each level were added and multiplied with the level of life-space, frequency of movement, and independence (no assistance = 2, use of ambulation aids only = 1.5, and use of another person and/or ambulation aids = 1) to get the final score. LSA score ranges from 0 (totally room-bound) to 120 (go outside of town daily without assistance), with higher scores reflecting greater mobility. mGES was used to determine the participant's self-efficacy with regard to ambulation. It is an objective measure of a patient's confidence, and consists of 10 items that assess the patient's degree of self-confidence in ambulating safely, and using steps and stairs outdoors [21]. These items are scored individually on a 10-point scale, with a score of 1 and 10 indicating the total absence of and the presence of best confidence, respectively. The total score is a maximum of 100 points and a high

score indicates higher confidence. As a secondary outcome, the Knee Society Score (KSS, Japanese edition, 2011) was used to estimate the functional outcome [22]. KSS questionnaire is a patient-based outcome measurement tool, and consists of the following four sub-categories: symptoms (25 points), patient satisfaction (40 points), expectations (15 points), and functional activities (100 points). The functional activities are further divided into walking and standing, standard activities, advanced activities, and discretionary activities. The total score of KSS is a maximum of 180 points, and a high score indicates higher resolution of pain, better levels of patient satisfaction, expectations, and physical function. A previous study [22] verified the validity of KSS in the Japanese population and that KSS is associated with muscle strength and ambulation function.

Data analysis

Patient characteristics were compared using student's *t*-test for continuous variables with a normal distribution and the chi-square test for categorical variables. To adjust for differences in covariates between the two protocols at baseline, the propensity score method was used. To calculate the propensity score, as described by Connors et al. [23], a logistic regression analysis was performed with the two protocols as the dependent variable, and the following parameters as independent variables: age, sex, BMI, the contralateral knee OA, presence or absence of comorbidities (DM and HT), LSA, mGES, and KSS at baseline. We calculated the propensity score of each patient. Propensity score adjusted, split-plot multivariate analysis of covariance (MANCOVA) [24, 25] was performed. The adjusted mean differences of each outcome associated with the 5-day and 28-day protocols were estimated to determine the relationship between the two protocols with respect to their outcomes at 1, 3, and 6 months postoperatively. To perform the multiple test, Bonferroni correction was applied. We used the software SPSS (IBM SPSS Statistics, version 22.0, Tokyo, Japan) for all statistical analyses. The level of significance was set at $p < 0.05$.

Results

The mean length of hospital stay was 5.1 ± 0.6 days in the 5-day protocol and 27.1 ± 5.2 days in the 28-day protocol. There were no serious complications in either group during the postoperative 6 months. LSA, mGES, and KSS (total and sub-categories of symptoms and function) at baseline were significantly higher

in the 5-day protocol compared with those in the 28-day protocol (Table 1).

MANCOVA indicated significant differences in LSA ($F = 7.44$, $p = 0.008$), mGES ($F = 40.53$, $p < 0.001$), and satisfaction ($F = 4.32$, $p = 0.040$) and expectation ($F = 4.58$, $p = 0.035$) in the KSS between the two protocols. In contrast, there were no significant differences in the total ($F = 2.22$, $p = 0.140$) and sub-categories of the symptom ($F = 1.03$, $p = 0.313$) and function ($F = 0.61$, $p = 0.437$). Table 2 and 3 showed unadjusted values in each group and adjusted mean differences between the two groups. The LSA in the 28-day protocol was significantly greater than that in the 5-day protocol because the adjusted mean differences were 20.2 points (95% CI 10.3 - 30.0) and 17.3 points (95% CI 7.3 – 27.2) at postoperative 3 and 6 months, respectively (Table 2). The mGES in the 28-day protocol was significantly greater than that in the 5-day protocol, as the adjusted mean differences were 20.3 points (95% CI 13.7 - 27.0), 19.2 points (95% CI 13.6 – 24.9), and 17.6 points (95% CI 11.8 – 23.4) at postoperative 1, 3, and 6 months, respectively (Table 2). Additionally, the total, satisfaction and expectation in the KSS in the 28-day protocol were significantly greater than those in the 5-day protocol at postoperative 3 months (adjusted mean difference 12.6 points [95% CI: 0.4 – 24.9], 5.3 points [95% CI: 1.3 – 9.2], and 2.1 points [95% CI: 0.6 – 3.5], respectively) (Table 3).

Discussion

The results of present study show that LSA and mGES in the 28-day protocol were significantly greater than in the 5-day protocol during 6 months postoperatively. In contrast, there was no significant difference in KSS (sub-categories of functions and symptoms) between the two protocols; thus, the recovery of knee function after TKA was not different between the two protocols. These results support our hypothesis. To the best of our knowledge, this is the first study that has evaluated and compared the recovery processes between the two protocols, and clarified the effect of shorter hospital stay on mobility and self-efficacy.

A previous study [7] reported that the recovery of knee function was not associated with shorter hospital stay after TKA. Whereas the study [7] evaluated the effects of shorter hospital stay of 2 days, the present study evaluated the recovery processes of two protocols in which the lengths of hospital stay differed by 3 weeks. On the other hand, mobility and self-efficacy in the 28-day protocol showed greater recovery than those in the 5-day protocol. Hence, mobility after TKA was affected by self-efficacy [18], the difference in

recovery of self-efficacy between two protocols could be the reason for the improvement in mobility. The 28-day protocol provides intensive rehabilitation, with adequate sessions and intensity, administered by physical therapists including repetition of ambulation and various ADL exercises. Although a previous study [26] indicated that the number of rehabilitation sessions in hospital were not associated with the recovery of knee function, the results in the present study suggest that intensive rehabilitation in hospital was effective in the recovery of mobility and self-efficacy. Additionally, the adjusted mean differences in LSA and mGES between the two protocols were greater in early postoperative period, they decreased thereafter. This may be due to the outpatient rehabilitation in the 5-day protocol, which was not a part of the 28-day protocol. The treatment procedure should pay attention to mobility and self-efficacy, especially in the early postoperative period. The purpose of the present study was to not only evaluate the differences in the rehabilitation procedures during hospital stay, but it was also to evaluate and compare the recovery of mobility and self-efficacy associated with the general protocol (commonly used in Japan) and the early-discharge protocol with shorter hospital stay during the 6 months after TKA. Although the results of the present study suggest that the 28-day protocol, currently used in Japan, resulted in improved mobility and self-efficacy, it is necessary to reduce the medical costs by introducing the early-discharge protocol at many more hospitals in Japan. The introduction of the 5-day protocol in this study suggested that the treatment procedure to improve mobility and self-efficacy was inadequate; therefore, the modified early-discharge protocol, which strengthened the management, is necessary.

There were several limitations in the present study. First, the present study did not investigate the medical costs between the two groups. Previous studies [27, 28] have suggested that the early discharge protocol was useful to reduce the medical costs. Therefore, we estimated that the medical costs associated with the 5-day protocol were lower than those associated with the 28-day protocol. Second, our results from this observational study could not account for unmeasured confounding variables, such as surgical techniques, compliance with regard to self-exercise, and environmental factors between the two hospitals. Thus, caution is warranted when generalizing these results. Finally, because the postoperative follow-up period was short, we could not observe the long-term association. However, it is reported that the recovery of physical function reaches a plateau by 6 months after TKA [29-31]. Therefore, we believed that the major part of recovery process after TKA could be observed in this time period. Further studies with an increased number of patients and hospitals are need for a more precise assessment of the effects of the treatment protocols on

clinical outcomes in patients after TKA.

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Conclusion

The recovery of mobility and self-efficacy during 6 months after TKA was associated with the type of protocol implemented. Mobility and self-efficacy in the 28-day protocol were greater than those in the 5-day protocol after TKA. In contrast, the improvement in KSS, especially symptom and function, was not associated with the type of protocol used. Our findings suggest that the modified treatment procedure for improving mobility and self-efficacy using the 5-day protocol is necessary to introduce the early discharge protocol in Japan.

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Conflict of interest statement

The authors have no conflicts of interest to disclose.

Tables

Table 1. Patient characteristics in the 5-day protocol and the 28-day protocol at baseline

	5-day protocol	28-day protocol	p-value
	n = 45	n = 59	
Age (years)	70.6 (7.2)	71.8 (5.5)	0.315
Height (cm)	153.1 (8.6)	151.9 (7.4)	0.432
Body weight (kg)	61.2 (9.4)	62.1 (12.1)	0.682
Body mass index (kg/m^2)	26.0 (2.6)	26.9 (4.7)	0.261
Gender (female/male) (n)	36 / 9	53 / 6	0.157
Contralateral knee OA (n)			
K/L grade 1 or 2	11	15	
K/L grade 3	10	22	0.185
K/L grade 4	24	22	
Comorbidity (n)			
diabetes mellitus	8	12	0.743
hyperpiesia	16	23	0.721
LSA (/120)	79.3 (18.6)	68.4 (24.7)	0.015
mGES (/100)	67.1 (15.3)	40.2 (16.9)	< 0.001
KSS; total (/180)	90.3 (20.4)	74.4 (20.9)	< 0.001
symptom (/25)	10.8 (5.7)	8.1 (5.3)	0.017
satisfaction (/40)	15.3 (7.2)	13.7 (5.1)	0.190
expectation (/15)	14.0 (1.7)	13.6 (1.7)	0.320
function (/100)	50.3 (15.0)	38.8 (15.4)	< 0.001

LSA; life space assessment, mGES; modified gait efficacy scale, KSS; knee society score.

Table 2. The time course of main outcome measures in the 5-day protocol and the 28-day protocol

	1 month					3 months					6 months				
	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]
	5-day	28-day	5-day	28-day		5-day	28-day	5-day	28-day		5-day	28-day	5-day	28-day	
LSA (/120)	—		—		—	63.0 (18.6)	71.4 (19.7)	56.3 (3.3)	76.5 (2.8)	20.2* [10.3, 30.0]	78.0 (18.3)	83.3 (20.5)	71.2 (3.4)	88.5 (2.8)	17.3* [7.3, 27.2]
mGES (/100)	48.8 (15.3)	48.4 (17.6)	37.0 (2.3)	57.3 (1.9)	20.3* [13.7, 27.0]	59.0 (15.1)	55.6 (16.8)	46.2 (1.9)	65.4 (1.6)	19.2* [13.6, 24.9]	66.9 (15.5)	60.7 (17.6)	53.4 (2.0)	71.0 (1.7)	17.6* [11.8, 23.4]

LSA; life space assessment, mGES; modified gait efficacy scale, SD: standard deviation, SE: Standard error, CI; confidence interval.

*$p < 0.05$; p values represent significant group differences after propensity score adjustment.

The positive value of the adjusted mean difference represents that the values of the 28-day protocol were greater than those of the 5-day protocol.

Table 3. The time course of secondary outcome measures in the 5-day protocol and the 28-day protocol

	1 month					3 months					6 months				
	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]	Unadjusted mean (SD)		Adjusted mean (SE)		Adjusted mean difference [95% CI]
	5-day	28-day	5-day	28-day		5-day	28-day	5-day	28-day		5-day	28-day	5-day	28-day	
KSS; total (/180)	99.3 (23.7)	97.4 (22.2)	93.1 (4.0)	102.1 (3.4)	8.9 [-3.0, 20.8]	115.6 (25.1)	113.7 (23.3)	107.4 (4.2)	120.0 (3.5)	12.6* [0.4, 24.9]	127.9 (25.7)	121.3 (20.1)	120.1 (3.9)	127.3 (3.3)	7.2 [-4.4, 18.7]
symptom (/25)	16.9 (4.7)	16.1 (4.7)	15.7 (0.8)	17.0 (0.7)	1.3 [-1.2, 3.8]	18.7 (4.7)	18.3 (4.5)	17.9 (0.8)	18.9 (0.7)	1.0 [-1.5, 3.4]	19.5 (5.4)	19.6 (4.8)	18.5 (0.9)	20.4 (0.8)	1.8 [-0.9, 4.5]
satisfaction (/40)	20.0 (6.6)	20.7 (6.6)	18.9 (1.2)	21.6 (1.0)	2.7 [-0.8, 6.2]	23.2 (7.2)	24.4 (7.9)	20.9 (1.3)	26.2 (1.1)	5.3* [1.3, 9.2]	26.4 (8.5)	25.3 (6.8)	24.1 (1.3)	27.1 (1.1)	3.0 [-0.9, 6.9]
expectation (/15)	9.2 (3.0)	9.2 (2.2)	8.8 (0.5)	9.5 (0.4)	0.7 [-0.7, 2.1]	8.9 (2.8)	9.8 (2.7)	8.3 (0.5)	10.3 (0.4)	2.1* [0.6, 3.5]	10.0 (2.7)	10.0 (2.8)	9.6 (0.5)	10.3 (0.4)	0.7 [-0.8, 2.2]
function (/100)	53.2 (16.1)	51.3 (14.6)	49.7 (2.7)	54.0 (2.3)	4.2 [-3.8, 12.3]	64.8 (15.5)	61.2 (14.4)	60.3 (2.6)	64.6 (2.2)	4.3 [-3.3, 12.0]	71.8 (14.2)	66.4 (13.1)	67.6 (2.4)	69.6 (2.0)	2.1 [-4.9, 9.1]

KSS; knee society score, SD: standard deviation, SE: Standard error, CI; confidence interval.

*$p < 0.05$; p values represent significant group differences after propensity score adjustment.

The positive value of the adjusted mean difference represents that the values of the 28-day protocol were greater than those of the 5-day protocol.

Figure

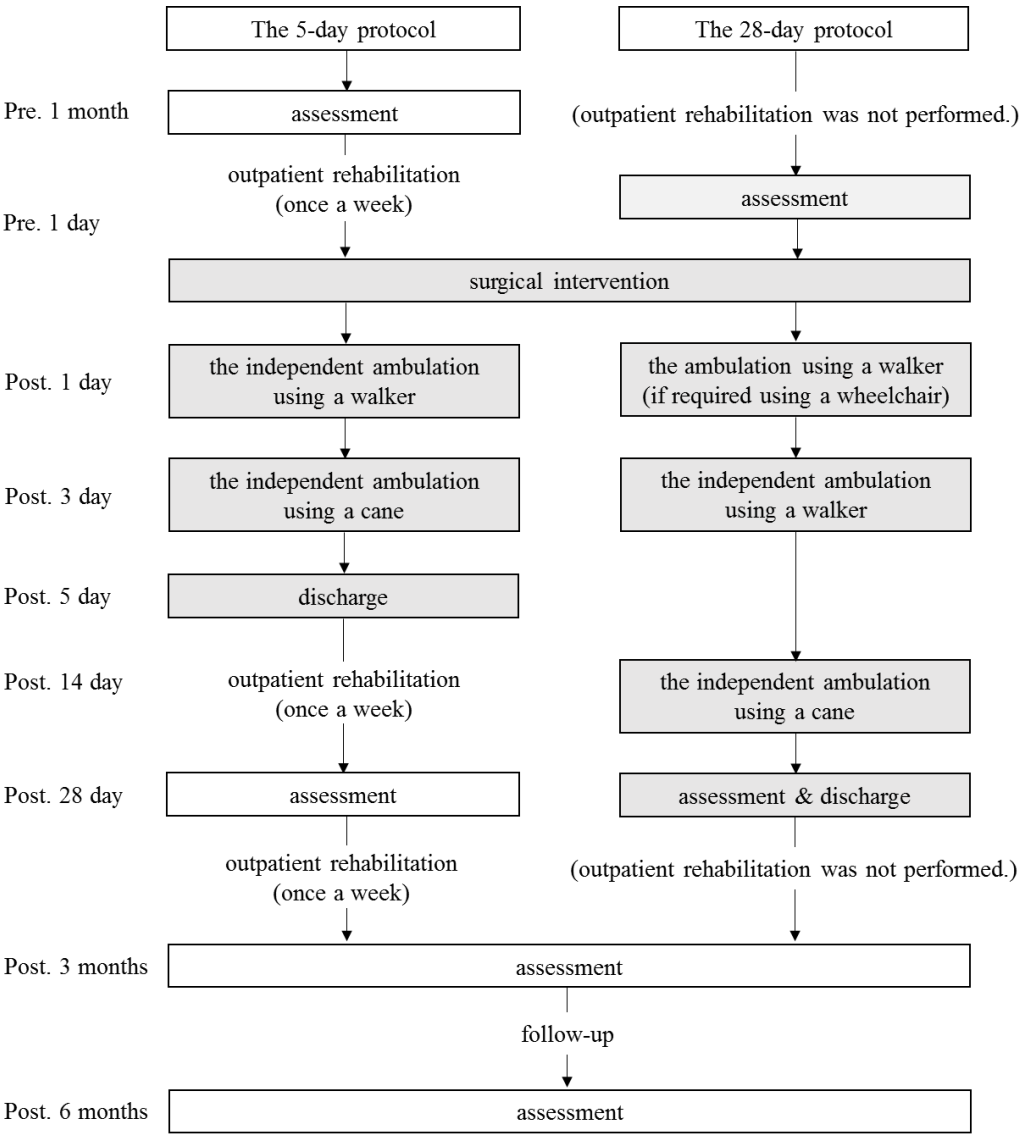

Figure 1. A flow diagram of the treatment procedure before and after surgery.

Figure legends

Gray shaded boxes represent the events during hospitalization.

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