ABSTRACT. Objective: In Japan, the number of elderly individuals living alone is increasing, leading to an increase in hospital medical expenses attributed to total knee arthroplasty (TKA). Improvement in balance and functional performance is a priority in the early postoperative stages after TKA. However, there are no reports on the effectiveness of balance training (BT) for inpatients in the early postoperative period. Thus, we aimed to evaluate the effectiveness of early high-intensity BT for early home-life independence after TKA.

Method: This pseudo-randomized controlled trial included 49 inpatients who underwent TKA and had osteoarthritis. Inpatients were categorized into the BT or typical training (TT) group. The BT program began on post-TKA day 4, with 12-14 sessions between day 7 and 10 (i.e., 1-2 sessions per day). The effect of the intervention was assessed using balance ability as the main outcome. Sub-outcomes included evaluation of motion function. The differences in each variable before and after intervention were compared, including covariance analysis adjusted for age and sex.

Results: The mean (standard deviation) balance ability indexes in the left and right directions were BT, pre 4.5 (0.8) and post 4.4 (0.8); TT, pre 4.8 (0.9) and post 4.4 (0.8), and those in the forward and backward directions were BT, pre 4.7 (1.7) and post 5.1 (2.1); TT, pre 6.3 (2.6) and post 5.9 (2.0). No significant differences were found between the preoperative and postintervention scores in the two groups for any measured outcome. Conclusion: BT did not appear to improve balance ability or functional performance.

Key words: total knee arthroplasty, high-intensity balance training, pseudo-randomized controlled trial, osteoarthritis

In Japan, the population of elderly individuals has increased, which has resulted in an increase in national medical expenses, and these increases are a concern. As it is predicted that the numbers of elderly people (aged 75 or older) and elderly households will both continue to increase in the future, it is important to control the medical expenses of elderly people. The Ministry of Health, Labor and Welfare stated that reducing the average length of a hospital stay is one way to optimize medical expenses. Arthrosis is the most common reason for a “You-Kaigo” (“requiring assistance”) diagnosis in the nursing-care insurance system. Establishment of methods for prevention and early treatment of osteoarthritis is important to reduce the number of surgical interventions and medical costs. Often, severe knee osteoarthritis is ultimately treated with total knee arthroplasty (TKA).

Knee osteoarthritis is an age-related degenerative disease, and the number of TKAs performed is increasing as...
the number of elderly people and cases of osteoarthritis are increasing. Moreover, the average length of hospital stay for TKA patients in Japan is longer than that in other countries (within 1 week)\(^3\)-\(^5\), with many patients staying in the hospital for 1 month\(^6\). Therefore, even in Japan, the number of hospitals that are reducing the length of hospital stays for TKA patients is increasing. It is expected that institutional activities of daily living can be performed at home safely immediately after leaving the hospital. Recently, physiotherapy intervention was implemented as early as the day of surgery or on the day after surgery\(^7\). As a result of physiotherapy, the total cost declined\(^8\), adverse events did not increase\(^9\), and body function recovered effectively after surgery\(^9\).

TKA has shown good clinical results, improving not only functional impairment but also daily activities and participation levels\(^10\)-\(^12\). However, patients with knee osteoarthritis have been reported to have decreased joint position perception and reduced balance ability\(^13\)-\(^14\), both of which are thought to contribute to falls in the early postoperative stages. The frequency of falls in elderly patients after TKA is higher than that in healthy elderly people\(^15\)-\(^16\). Matsumoto et al\(^17\) reported that the frequency of falls in TKA patients was 32.9% in half a year, which is more than 10%-20% of the annual fall frequency of the healthy elderly population. In addition, Annette et al\(^18\) reported a fall rate of 24.2% before TKA surgery and 11.7%-11.8% 3 months after surgery, which demonstrates there are fewer falls after TKA surgery than before TKA surgery.

Therefore, improvement in balance ability and functional performance is a priority in the early postoperative period. Previous studies reported that balance exercises for postoperative TKA patients improved functional outcomes, including single leg standing time, walking speed, and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).\(^19\)-\(^20\). Physical therapy in the early postoperative days has primarily focused on joint range exercises and muscular strength training; therefore, we did not positively adopt balance exercises in a standing position. Many patients have anxiety with regard to their lives after discharge; therefore, it is important to improve balance ability for safe living quickly after surgery. Training to improve activities and participation as well as impairment training is necessary for self-reliance in daily life immediately after discharge from the hospital. We hypothesized that high-intensity balance training (BT) for inpatients would improve balance function and ability and general functional performance in the early postoperative days. Nevertheless, there are no reports on the effect of BT for inpatients in the early postoperative period; therefore, development of a training program is required. The objective of this study was to evaluate the effectiveness of early high-intensity BT for early home-life independence after TKA.

2. Methods

2-1. Patients

We recruited 51 consecutive inpatients who underwent TKA between September 2015 and April 2016 in 23 wards of two institutions in Tokyo. Inclusion criteria were osteoarthritis, primary surgery, and unilateral or bilateral surgery. Surgery was carried out using a tourniquet in all cases and the midvastus or medical parapatellar approach. Exclusion criteria were unicompartmental knee arthroplasty, severe cardiovascular or nervous system diseases, musculoskeletal disorders, and cognitive diseases. One subject was excluded because a decline in the patient’s cognitive function made assessment too difficult; therefore, a total of 50 subjects were included. Female participants were randomized to either the BT group or the typical training (TT) group. The predicted number of male participants was low, so male participants were allocated alternately to the BT or TT groups in order of recruitment. This was a pseudo-randomized, single-blind subject, controlled trial that compared the efficacy of BT and TT. Randomization was carried out using a computer-generated allocation table. The subjects were not notified which program was being implemented. There were 25 subjects in the BT group and 25 subjects in the TT group; one subject in the BT group was excluded from the analysis because the number of training sessions was less than 12 (Fig. 1).

2-2. Physical therapy program

Clinical pathway

The patients did not undergo preoperative physical therapy; however, the importance of prevention of thrombus early after surgery was explained 1-2 days before surgery, and exercises were taught. For postoperative pain control, epidural anesthesia was continuously administered until the patient left the bed on the next day after surgery, and oral medication was administered regularly for pain relief. The patient left the bed and started physical therapy the day after surgery. On the first postoperative day, the patient practiced transferring to the wheelchair or walking exercise using a walker and started walking exercises gradually with the use of a cane (based on the patient’s walking ability); the patients aimed to walk alone by the 14th postoperative day. Then, patients practiced activities of daily living (ADL), including stair climbing and moving on the floor, and were able to walk alone outdoors using a cane; the aim was to discharge from the hospital on the 21st postoperative day. Physical therapy (60-min sessions, 5 days every week) was performed once a day on the first postoperative day (twice a day from the second postoperative day).

Typical training

Physical therapy for hospitalization consisted of passive range of motion (ROM) movements by a physical therapist, including heel slides for expanding ROM, walk-
High-intensity balance training after TKA

**Figure 1.** Flow diagram of study design and patient progress through the phases of the study

BT: balance training, TT: typical training

| Day       | Program                                                                 |
|-----------|-------------------------------------------------------------------------|
| Preoperative | Prevention of thrombus self-exercises were taught                      |
| Surgery   | Prevention of thrombus self-exercises performed                        |
| 1st       | ROM exercises, basic motion exercises (sitting, standing, transferring) |
| 2nd       | Walking, muscles strengthening exercises, balance exercises            |
| 7th-10th  | Bicycle ergometer, knee extension exercises                             |
| 10th-14th | ADL exercises (stair climbing, moving on the floor), walking outdoors    |
| 21st      | Discharge from the hospital                                            |

**Figure 2.** Typical training program

ROM: Range of motion  ADL: Activities of daily living  1st-21st: First postoperative day; Twenty-first postoperative day

51 patients passed the pre-assessment by the surgeon and were eligible

I was not included; I did not meet the inclusion criteria (dementia)

50 underwent baseline assessment

Pseudo-randomized (n=50)

25 were assigned to typical plus balance training (12-14 sessions of the allocated intervention)

25 were assigned to typical training (12-14 sessions of the allocated intervention)

24 underwent assessment after the intervention; 1 did not complete the intervention

25 underwent assessment after the intervention

**Prevention of thrombus**

Self-exercises were taught.

**Prevention of thrombus self-exercises**

- Passive ROM exercises, basic motion exercises (sitting, standing, transferring).
- Walking, muscle strengthening exercises, balance exercises.
- Bicycle ergometer, knee extension exercises.
- ADL exercises (stairs climbing, moving on the floor), walking outdoors.
- Discharge from the hospital.

**Balance training**

The BT group had the same physical therapy start time, discharge goal, number of physical therapy sessions, and ADL practice. ROM exercise was performed as passively as possible with consideration of the pain level. The knee joint flexion angle was aimed to be 90° at the 7th postoperative day, with a proposed flexion angle of 120° and extension angle of 0° at the time of discharge. Patients also practiced using a bicycle ergometer. To reduce inflammation, ice packs were applied after exercises. Load-bearing knee joint extension exercises using a weight band attached to the distal part of the lower leg in the sitting position, squatting, hip joint abduction, and calf raises were performed to strengthen the muscles. Balance exercises such as stepping exercises were also performed. In Japan, in recent years, this training is generally included in postoperative physical therapy after TKA and is part of the TT program (Fig. 2).
and duration as the TT group. BT was performed 12-14 times starting four days after TKA. BT involves a high-intensity, progress-based rehabilitation program, and it was developed by referencing previous studies. The BT program included seven kinds of bilateral and unilateral weight-bearing functional exercises, balance exercises, and activity prescriptions such as squat and calf raises in incremental levels of difficulty (Table 1). In this study, high-intensity balance training is defined as balance training in which the load is intensively increased at an early stage after surgery; this is the key factor that differentiates the BT program from the general training program.

The total time spent on therapeutic exercise was the same in both groups. Several physical therapists conducted the program. To ensure consistency in both the programs and measurement methods, briefing sessions and study sessions were attended by the participating physical therapists at both institutions.

### Table 1. Components of the balance training

| Standing exercises | Stepping exercise |
|--------------------|-------------------|
| 1. Ankle dorsiflexion 30 times | 5. Lunge forwards and backwards, right and left, 3 min in each direction |
| 2. Thirty calf raises | Other exercises |
| 3. Align both feet for 1 minute | 6. Squat for 3 min |
| 4. Stand on the foot and the opposite heel for 1 min | 7. Stand on one leg for 3 min each |

If it is possible to stand on one leg for 20 s, proceed to the stepping exercise:

1st step: Floor surface
2nd step: Balance pad
3rd step: Air stabilizer

The subject stood on the unstable plate, with the mid-point of the foot positioned at the anterior-posterior midpoint of the unstable plate. The distance between the medial aspects of each foot was 20 cm. With the feet carefully positioned on the plate as described, the participants were instructed to bring the board to a horizontal position, look at a target 1 m ahead, and hold the position for 20 s. The plate was set to be able to tilt forward, backward, left, and right. Measurements were carried out twice, and the mean stability index (left and right, forward and backward) was obtained. The stability index is the range of motion of the unstable plate with respect to the horizontal plane, either in the forward-backward or left-right direction. The larger the variation from the horizontal plane, the higher the horizontal index value. The measurement was considered invalid if the balance was broken, the position of the foot changed, or the support was touched.

Secondary outcome measures included the Japanese version of the WOMAC, Timed-Up-and-Go (TUG) test, 10-m walking test, active knee ROM (flexion, extension), and strength of the quadriceps. The 10-m walking test measured time (seconds) required to walk in a straight line at a comfortable speed for 10 m, with 1 m spare of additional walking space at both ends. Two measurements were taken and the faster value was used for analysis. The TUG test involves a series of actions. The subject sits in a chair with an armrest, and upon the examiner’s signal stands and walks around a prepared target 3 meters ahead, and then returns to sit in the original starting chair. Before the TUG test begins the subject is instructed to walk as fast as possible without falling. The time required for the entire series of action was measured in seconds. Two measurements were taken and the faster value was used for analysis. Evaluations were conducted 1-2 days before surgery and on the day after the training ended, and variables were compared before and after the intervention. WOMAC scores range from 0 to 100 points, with higher scores corresponding to less pain. Active knee ROM was measured in the supine position using a goniometer. Quadriceps strength was measured with a portable dynamometer (ANIMA Co., Ltd, μ-Tas F-1) with the participant in a seated position and the knee flexed at 90°. The quadriceps strength tests were isometric strength tests. During knee extension, the belt from the dynamometer was positioned perpendicularly to the anterior aspect of the tibia, 5 cm proximal to the medial mal-
intergroup differences, an unpaired t-test was used for continuous variables and the χ² test was used for nominal variables. When the expected frequency in the cell was low, Fisher’s exact test was used. The effects of the interventions were compared using covariance analysis of the independent variables before and after the intervention. All outcome measurements (10-m walking test, TUG, pain, function, quadriceps strength, knee flexion ROM, Knee extension ROM, balance ability stability index) were evaluated as post-minus pre-intervention and adjusted for age and sex. SPSS ver. 26.0 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses, and the significance level was set to P<0.05.

2-5 Ethical considerations, explanation, and agreement

This study was approved by the Akabane Central General Hospital ethics committee (approval number 17) and the Sonodakai Joint Replacement Center Hospital ethics committee (approval number 36). The purpose of the study was explained to all subjects verbally and in writing, and written consent was obtained from all participants before being included in this study.

3. Results

Fifty patients (average age, 73.0 ± 6.0 years) were pseudo-randomized to either the BT group (n=25, 72.3 ± 6.1 years) or the TT group (n=25, 73.9 ± 6.0 years). There were 18 subjects from institution A with the following characteristics: 4 males, 14 females; 9 intervention, 9 non-intervention; 1 cruciate retaining (CR) type, 17 posterior stabilizing post (PS) type; and an average age of 75.5 (standard deviation 3.9). There were 31 subjects from institution B with the following characteristics: 3 males, 28 females; 15 intervention, 16 non-interventions; 26 CR type, 3 PS type, 2 Vanguard XP type; and an average age of 71.7 (standard deviation 6.5). The intervention period for each group was 0 to 2 times a day from the 4th postoperative day to the pre-discharge evaluation. The mean number of interventions in the BT group was 12.5 (standard deviation 0.7, range 12 to 14).

There were no significant differences between the groups in terms of physical or demographic characteristics (Table 2). Changes in primary and secondary outcomes for both groups over time (preoperatively until after intervention) are shown in Table 3.

### Primary outcomes

There were no significant differences between the groups in terms of changes in balance ability stability index score in the left and right directions (p =0.152) or in the forward and backward directions (p = 0.437).

### Table 2. Characteristics of the subjects

| Characteristic          | BT (n=24) Mean (SD) | TT (n=25) Mean (SD) | Intergroup differences p-value |
|------------------------|---------------------|---------------------|--------------------------------|
| Age (years)            | 72.3 (6.1)          | 73.9 (6.0)          | 0.38                           |
| Sex (n)                | Male/Female 3 (12.5)/21 (87.5) | 4 (16.0)/21 (84.0) | 0.52                           |
| Operative side (n)     | Single/Both 10/14   | 8/17                | 0.48                           |
| Height (cm)            | 153.2 (7.8)         | 151.9 (4.8)         | 0.49                           |
| Body weight (kg)       | 60.8 (9.8)          | 63.4 (10.1)         | 0.35                           |
| BMI (kg/m²)            | 25.8 (3.4)          | 27.4 (3.9)          | 0.13                           |

* p<0.05 between groups

SD, standard deviation; BMI, body mass index; BT, balance training group; TT, typical training group
Table 3. Mean (SD) of groups, mean (SD) difference within groups, and mean (SD) difference between groups.

|                        | BT (n=24) | Post minus Pre | TT (n=25) | Post minus Pre | P value |
|------------------------|-----------|----------------|-----------|----------------|---------|
| 10-m walking test (s)  | 10.6 (3.5)| 10.7 (3.1)     | 0.13 (3.4)| 11.0 (3.6)     | 11.0 (2.3)| 0.00 (2.6)| P=0.936 |
| TUG (s)                | 10.9 (4.4)| 11.5 (3.5)     | 0.6 (4.3)| 11.9 (3.1)     | 11.6 (2.2)| -0.2 (2.5)| P=0.468 |
| WOMAC pain (0-100)     | 54.9 (15.3)| 77.7 (13.2)   | 22.8 (17.6)| 53.8 (17.9) | 81.6 (13.6)| 27.8 (21.0)| P=0.383 |
| WOMAC function (0-100) | 60.5 (17.2)| 82.7 (11.2)   | 22.2 (16.8)| 63.0 (20.7) | 80.4 (16.8)| 17.4 (21.3)| P=0.363 |
| Quadriceps strength    | 0.8 (0.4)| 0.5 (0.2)      | -0.2 (0.3)| 0.8 (0.4)     | 0.5 (0.2) | -0.2 (0.3)| P=0.952 |
| Knee flexion ROM (°)   | 122.3 (15.2)| 118.0 (10.1)| -4.3 (11.3)| 122.6 (9.9) | 116.1 (9.2)| -6.5 (11.3)| P=0.455 |
| Knee extension ROM (°) | -10.7 (6.0)| -3.6 (4.1)    | 7.1 (5.1)| -9.7 (6.1)    | -3.7 (4.5)| 6.0 (5.9) | P=0.463 |

BT, balance training group; Pre, preoperatively; Post, after intervention postoperatively; ROM, range of motion; SD, standard deviation; TT, typical training group; TUG, Timed-Up-and-Go test; WOMAC, Western Ontario and McMaster Universities osteoarthritis index. No significant differences in the interaction between the groups in any outcome.

Secondary outcomes. There were no differences between the groups in terms of changes in the preoperative and postoperative results for the 10-m walking test (p=0.936), TUG (p=0.468), WOMAC pain (p=0.383), WOMAC function (p=0.363), quadriceps strength (p=0.952), knee flexion ROM (p=0.455), and knee extension ROM (p=0.463).

Additionally, no significant differences were observed between the groups on the basis of the covariance analysis after adjustment for age and sex.

4. Discussion

This pseudo-randomized controlled trial was conducted in two institutions to clarify the effects of intensive BT on balance and function interventions during the early stages after TKA. There were no significant differences observed between the groups. The BT did not show any significantly better effect than TT. No significant difference was observed between the groups because the effect of the BT in this study was small, and the change in the TT control group was large.

Interventions for the BT and TT control groups were conducted with physical therapy simultaneously. Both training methods comprised multilateral training including closed kinetic chain (CKC) training, and the content of the TT program was not limited, as it was not the minimum program. Therefore, improvements in the TT group were large because the training often reached the same load as the BT training. The difference between BT training and TT training was that the BT program was conducted with standard load increases; however, the TT program was tailored to each subject. Individualized programs implemented in the TT group were also effective.

To the best of our knowledge, only one previous study has shown that intensive early postoperative training is effective\(^\text{27}\), whereas other studies found it to be ineffective\(^\text{23,32,33}\). A prospective cohort study with age-matched and sex-matched control groups concluded that high-intensity training after TKA is effective\(^\text{27}\). Eight patients who participated in the high-intensity rehabilitation program received a total of 25 physical therapies 2-3 times a week until the 12th postoperative week, and eight patients who participated in the low-intensity program received a total of 16 physical therapies in 8 weeks. Compared with the low-intensity program, the high-intensity program improved functional performance outcomes such as short- and long-term quadriceps muscle strength and results of the stair-climbing and TUG tests. Bade et al\(^\text{27}\) used a randomized controlled trial to examine high-load rehabilitation effects of early postoperative intervention for outpatients after TKA, with 2-3 training sessions per week, starting on the fourth postoperative day and lasting until 11 weeks postoperatively. In that study, no significant differences were found between the low-load and high-load rehabilitation groups, despite restricting activities outside the ADL for the first 4 weeks in the control group. However, pain and functional levels in both groups improved after 3 or 12 months. Piva et al\(^\text{23}\) divided 43 postoperative TKA patients into a functional training program group and a group with added balance exercises. The program included 12 training sessions (twice per week for 6 weeks) and 4 months of a home exercise program. Both groups had significantly improved lower limb function, but statistical analyses did not show an additive effect in the balance exercise group. Jakobsen et al\(^\text{26}\) reported that 7 weeks of physical therapy with progressive strength training initiated early in TKA was not more effective at improving functional performance than physical therapy with non-progressive strength training. Therefore, although previous studies examined the effects of high-
intensity training conducted early in TKA, the effects have not been clarified. In the present study, patients were hospitalized for the duration of the early postoperative period, and there were no significant differences between the two groups.

A major limitation of this study is the short training period. Because the subjects were inpatients, the intervention period was 7-10 days, whereas in previous studies it was 4-11 weeks. We investigated balance ability over a short period before discharge. It is thought that a sufficient effect from training could not be obtained because the period was too short. In this study, there are items that use the maximum and minimum values instead of the average of the two measurements, and the data may be biased. Moreover, as two-sides and one-sided enforcers are mixed in the subjects, it is impossible to avoid the data bias. In this study, we used the index of ability to shift and adjust the body’s center of gravity under unstable conditions as the main index to measure the effect of balance ability training for early independent life. However, the balance ability is multifaceted; therefore, in the future, we would like to consider an outcome that can evaluate the overall balance ability.

Furthermore, we did not prohibit interaction or information exchange between groups, so there was insufficient control over unplanned interventions and information contamination. We recommend voluntary training for hospitalized patients; however, the components and amount of voluntary training were not considered in this study. Congestion may occur because there are patients who have had surgery at the same time as patients who have had bilateral surgery in stages.

5. Conclusion

In this study, high intensity balance training was performed early in the postoperative period. Although no training effect was observed at discharge, we suspect that the results were affected by the limited training period and patient utilization of unplanned interventions. In addition, assessment for improved balance ability occurred only at the time of discharge, the effect on activities of daily living and fall prevention after discharge were not assessed.

In Japan currently, the length of stay following TKA has gradually shortened. It is believed that improvement of balance ability is necessary for safe living and to improve the quality of life outcomes immediately after discharge from the hospital. Nevertheless, no program has yet been established to improve these outcomes effectively and efficiently. In the future, in addition to motor function, it is necessary to consider a multilateral intervention program that includes education levels and environmental adjustments. In addition, as outcome indicators of falls, such a program should consider psychological indicators, including fear of falling, satisfaction, and physical endurance.

Acknowledgments: This research was carried out using a subsidy grant for research equipment loan from the 2010 Research Institution Research Promotion Department, Tokyo Metropolitan Physical Therapy Association. We are very grateful to everyone involved in this research.

Conflict of Interest: The authors declare no conflicts of interest.

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