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学　位　論　文 (要約)

Effectiveness of the video-based home exercise on clinical and radiographic outcomes for subjects with osteoarthritis of the knee.

(変形性膝関節症症例に対するビデオプログラムを用いたホームエクササイズの臨床的および X 線学的効果の検討)

２　０　１　７　年　３　月

北　海　道　大　学

黄　于　庭

Yu-Ting, Huang

Background

Osteoarthritis (OA) of the knee is a disease that limits a patient's activity of daily life and affects health-related quality of life [1]. The prevalence of knee OA of the population older than 40 years in Japan is 43% in men, and 62% in women, respectively[2]. Therefore, the majority of patients with osteoarthritis are managed in primary care, and the prevalence of knee OA is such that simple interventions which are effective in a community setting are necessary.

Previous studies and systematic reviews conclude that both strengthening and aerobic exercise therapy have beneficial effects on symptoms physical function and health status of the population with osteoarthritis of the knee [3-8]. Although it is positive effect on pain and physical function, however, these effects declined over time and finally disappear [9]. Several authors have hypothesized that non-adherence to exercise is the main reasons for long-term effectiveness of exercise therapy in patients with osteoarthritis[10, 11]. Poor exercise adherence may significant to reduced effects of exercise intervention in patients with knee osteoarthritis [12, 13]. Therefore, exercise adherence may be an important predictor of long-term outcome in exercise therapy.

Video media is widely used as an effective means of delivering exercise instruction [14]. For example, Petty et al. [15] found a customized videotape to be significantly more effective in helping clients initiate exercise. Roddey et al. [16] also found no similar difference in exercise compliance between videotape instruction and personal sessions. These findings indicate potential usefulness of videotape instructions for cases who cannot easily attend face to face appointments. Therefore, the use of a home exercise video could enhance adherence to prescribed exercise program. To date, no research has investigated the effectiveness of a home exercise video for patients with knee OA compared with conventional home exercise without video media.

Based on these findings, we conducted the present study in order to examine that video-based home exercise could enhance adherence to prescribed exercise program, produce substantial improvements in pain, physical function and quality of life in patients with knee OA, and also prevent radiographic progression of knee OA compared with conventional home exercise without video media. The purpose of the present study was to test this hypothesis by a two-year controlled comparative trial.

Methods

Subjects and methods

This article reports a follow-up study (24 months after inclusion) of an open label trial comparing video-based home-exercise and conventional quadriceps home-exercise in 107 patients with knee OA.

Setting and participants

Twelve orthopaedic surgeons in Hokkaido University Hospital were willing to participate in the study. Patients with OA of the knee were recruited (October 2008–September 2009) by participating orthopaedic surgeons and by the article about the study in a local newspaper. Inclusion criteria were: 1) both genders with an age between 50 and 80 years; 2) radiographic osteoarthritis changes of the knee equivalent to Kellgren-Lawrence Grade 2, 3, or 4; and 3) symptomatic gonarthrosis for a minimum of 3 months. Exclusion criteria were: 1) other pathology explaining the complaints; 2) treatment for these complaints at another hospital or clinic within 4 weeks before the day of agreement to enter the trial; 3) indication for hip or knee replacement; 4) regular or intermittent use of oral steroid or non-steroid anti-inflammatory drug (NSAID) within 4 weeks before the day of agreement to enter the trial; 5) regular or intermittent

intraarticular injection or aspiration of joint fluid within 4 weeks before the day of agreement to enter the trial; and 6) contraindication for exercise due to physical or mental problem. All patients completed written informed consent.

Allocation

First, the participating patients were allocated to the video-based exercise group until 50 subjects or more were assigned to the video-based exercise group. After the date when 50 subjects were allocated to the video-based exercise group, the remaining subjects were assigned to the control group. Allocation was not concealed.

Interventions

Video-based exercise group: We edited a program consisted of active range-of-motion exercises for the knee, muscle strengthening exercises for the hip and knee including stepping exercise, muscle stretching for the lower limbs, and riding a stationary bike in the DVD (Figure 1). This program took approximately 30 minutes to be completed and had been shown to yield significant improvements in pain, physical function, and walk ability in patients with osteoarthritis of the knee at 4-8 weeks with combination of manual physical therapy under close supervision of a physical therapist[17], after the subjects watched the video along side a physiotherapist, they were given a

30-min exercise video to take home and use it during home exercise, and were reinforced at a clinic visit 4 weeks later.

Control group: Subjects in the control group received detailed verbal and hands-on instruction in a quadriceps home-exercise protocol, which took approximately was identical to that of the previous study shown to improve pain and physical function in patients with knee osteoarthritis at 8 weeks no less than NSAIDs[18]. Subjects in the control group were instructed to exercise their quadriceps muscle by performing straight-leg raise 20 times with each leg for four sets every day and were then reinforced at a clinic visit 4 weeks later.

Outcome measures

Demographics and clinical data: Demographic and clinical data were collected for each patient including age, gender, height, weight, location of complaints, and duration of complaints. X-rays of the knee were scored by an orthopaedic surgeon following a standardized procedure according to the Kellgren and Lawrence (K&L) scale; consisting of five degrees: 0, no OA; 1, doubtful OA; 2, minimal OA; 3, moderate OA and; 4, severe OA .

Primary outcome measures: Pain in the last 48 hours and physical function was assessed with the WOMAC questionnaire with a five-point Likert scale (version LK 3.0). Japanese versions of the WOMAC have been validated [19].

Secondary outcome measures: To evaluate adherence to home exercises, we collected the number of days when the subject performed the allocated prescribed home-exercise in the last 5 weeks from the custom-designed diary at each follow-up. The median of the numbers of days per week in five weeks was represented as the number of home exercises in a week. Patient-oriented health related quality of life (HRQOL) was assessed with the Medical Outcomes Study Short Form-8 (SF-8). The SF-8 was developed as a self-reported HRQOL measure especially for large population studies. The SF-8 consists eight items and it takes only a few minutes to answer all questions of the questionnaire. The SF-8 measures physical and mental health status about eight health concepts, i.e. General Health (GH), Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), Vitality (VT), Social Functioning (SF), Mental Health (MH) and Role Emotional (RE). It is also possible to directly compare the score of each health concepts in SF-8 with that of its corresponding concept in SF-36, which is widely used as a HRQOL measure. Fukuhara et al. [20] have already confirmed validity and reliability of the Japanese version of the SF-8. In the present study, we calculated

physical health component summary score (PCS) and mental health component summary score (MCS) using the algorithm of the Japanese version of the SF-8 based on a large-scale population study conducted in Japan [20]. An independent examiner measured blindly weight and height of all subjects. Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters) squared. Furthermore, subjects were asked if they underwent other treatment, e.g. inra-articular injection, arthroscopic debridement, or total joint replacement, during the study period. If so, the type of treatment and its date were registered.

In addition, we performed radiological evaluation of OA progression to quantify the major OA parameters on plain knee radiographs using the method reported by Oka et al. with a fully automatic program KOACAD (knee OA computer-aided diagnosis)[21]. From a standing AP radiographic view of the fully extended knee, the KOACAD program can automatically measure the joint space area (JSA) and the minimum joint space widths (JSW), the osteophyte area, and the femorotibial angle (FTA). In the present study, we analyzed medial JSA, medial JSW, osteophyte area in the medial tibia site and FTA (Figure 1)

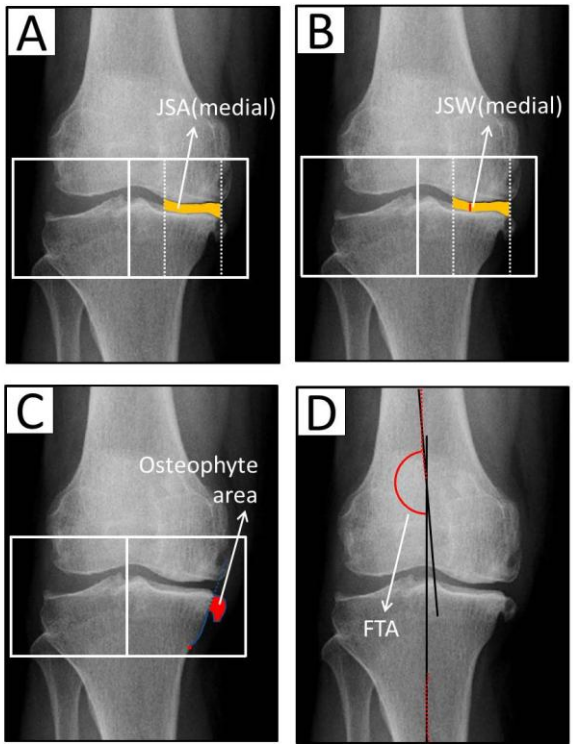


Figure 1 - Radiological parameters of OA progression using an automatic program KOACAD on plain knee radiographs[21]. A: the medial joint space area (JSA). B: the minimum joint space width (JSW) at the medial side. C: the osteophyte area at the medial tibial site. D: the femorotibial angle (FTA).

All primary and secondary outcome measures except radiological evaluation of OA progression were obtained at baseline, 6, 12 and 24 months follow-up. All assessments were performed in the presence of a research assistant, who was blinded for the assigned treatment. Patients were repeatedly instructed not to give information about the allocated treatment to the research assistants. Radiological evaluation of OA progression was performed for the data at base line, 12 and 24 months follow-up.

Statistical analyses

Our pilot study suggested that approximately half of subjects refuse their allocation in the control group and that the DVD-based exercise has large-sized effects in the outcome measures pain and physical functioning. Based on these pilot data, the target sample size was 100 patients. This number yields to a power of 90% and large-sized effects (effect-size = 0.8) in the outcome measures pain and physical functioning, at two-sided significance level of 0.5 given allocation ratio (the number of the control group/the number of the DVD-based exercise group) and a maximum loss to follow-up of 20%. For a correct interpretation of the reported effect sizes, potential limitations should be considered to improve comparability of designs, assessments and analyses. Change scores were calculated by subtracting the baseline scores from the post-treatment scores (6, 12 and 24 months, respectively) and were compared for the two intervention groups using Student's t-test. We also compared the post-treatment scores with the baseline score using Fisher's Least Significant Difference (LSD) test following a one-way analysis of variance. The percentage of subjects who underwent other treatment during the study period was compared between the DVD-based exercise and

control groups by chi-square test. Statistical analyses were performed using StatView for Windows version 5.0(SAS Institute Inc., Cary, NC).

Results

Baseline characteristics of the patients

Of the 107 patients, 54 patients of the video-based home-exercise group and 53 patients of the control group were included in the trial (Figure 2). However, 2 and 26 patients refused in the video-based home exercise and control groups, respectively. Patient characteristics are presented in Table 1. From the 79 patients included in the study, 4(7.4%) and 4(14.8%) of the participants were lost to follow-up at 24 months in the video-based home-exercise and control groups, respectively. In the video-based home-exercise group, 5(9.6%), 3(5.8%) and 1(1.9%) subjects underwent intraarticular injection of hyaluronic acid, arthroscopic debridement and total knee replacement, respectively. In the control group, 2(7.4%) and 2(7.4%) underwent intraarticular injection of hyaluronic acid and arthroscopic debridement, respectively. There was no significant difference in age, height and weight of subjects who underwent other treatments during the study period between two groups (χ^2=0.826, p=0.843). For the

present study, these patients who underwent other treatments during the study period were excluded from the analyses.

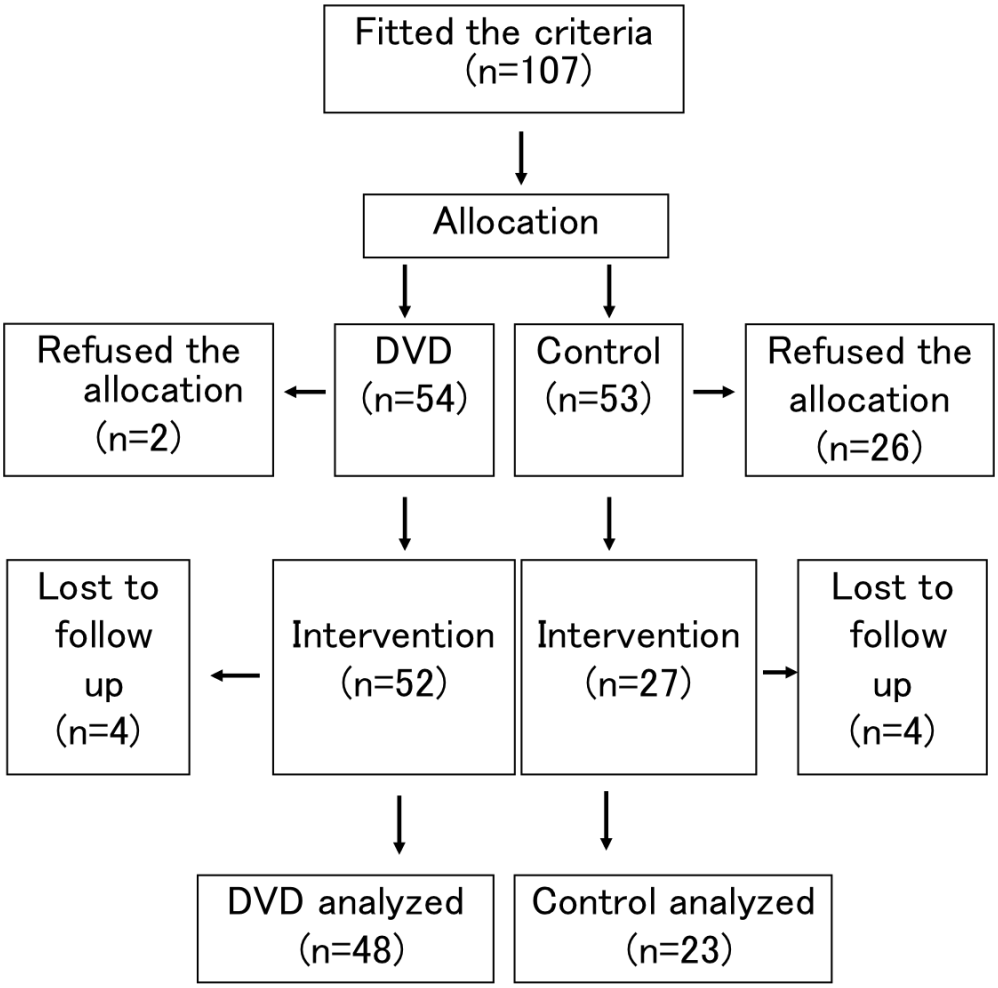


Figure 2 - Flowchart of the study.

Table 1 - Baseline characteristic of the subjects in the video-based exercise and control groups.

	Video-based exercise	Control	Statistical comparison
Males: Females	3:49	4:23	p=0.30
Age(year)	65.8±6.8	68.8±7.2	p=0.13
Height(cm)	153.4±5.4	154.4±7.0	p=0.56
Weight(kg)	56.5±8.9	55.2±7.6	p=0.58
Radiographic grade (Kellgren-Lawrence)	Grade 2: 9 cases Grade 3: 41 cases Grade 4: 2 cases	Grade 2: 9 cases Grade 3: 20 cases Grade 4: 1 cases	p=0.17

Primary outcome measures

Concerning WOMAC pain score, a significant improvement was noted at 6-month, 12-month and 24-month in the video-based exercise group compared to the base line (6-month: p=0.0000, 12-month: p=0.0000, 24-month: p=0.30457). The improvement from baseline value was significantly greater in the video-based exercise group than the control group (Table 2). WOMAC stiffness score was also significant greater improvement in the video-based exercise group compared to the control group. There were significant changes from baseline value in the video-based exercise group at 6-month, 12-month and 24-month (6-month: p=0.0005, 12-month: p=0.0004, 24-month:

p=0.0020). WOMAC physical functional score significantly improved at 6-month, 12-month and 24-month in the video-based exercise group compared to the base line (6-month: p=0.0000, 12-month : p=0.0000, 24-month : 0.0277). The improvement from baseline value was significantly greater in the video-based exercise group than the control group (Table 2).

Table 2 - The improvement of WOMAC subcategory scores from the baseline in the video-based exercise and control groups.

Improvement from the baseline	Video-based exercise	Control	Statistical comparison
Pain (points)			
6-month	2.7±2.2**	0.2±1.0	p=0.0001
12-month	2.9±2.2**	0.4±1.1	p=0.0001
24-month	2.2±3.0**	0.6±1.0	p=0.0457
Stiffness (points)			
6-month	0.6±0.9**	-0.2±0.6	p=0.0009
12-month	0.6±1.0**	-0.1±0.4	p=0.0053
24-month	0.6±1.1**	-0.1±0.3	p=0.0210
Function (points)			
6-month	8.0±6.4**	0.5±2.6	p=0.0001
12-month	8.7±6.7**	1.4±2.5*	p=0.0001
24-month	7.3±8.1**	2.3±3.6*	p=0.0277

**Significant improvement from the baseline (p<0.01).
*Significant improvement from the baseline (p<0.05).

Secondary outcome measures

Concerning home exercise adherence, the numbers of home exercise in a week in the video-based exercise group were 5.1±2.0, 4.0±2.3 and 3.6±2.4 times at 6-month, 12-month and 24-month, respectively, those in the control group were 3.7±2.4, 4.2±2.9 and 3.9±3.2 times at 6-month, 12-month and 24-month, respectively. Home exercise adherence in the video-based exercise group were significantly greater than in the control group at 6-month, while there was no significant difference between two groups at 12-month or 24-month (6-month : p=0.0168, 12-month : p=0.7369, 24-month : p=0.6484)(Figure 3).

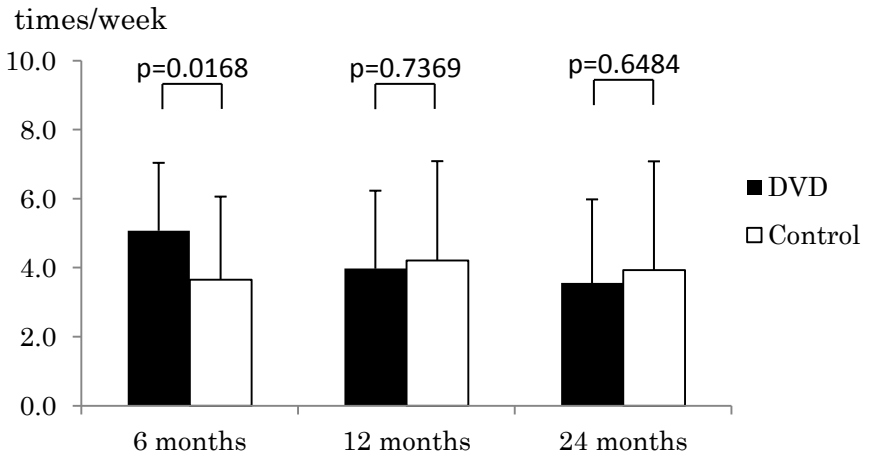
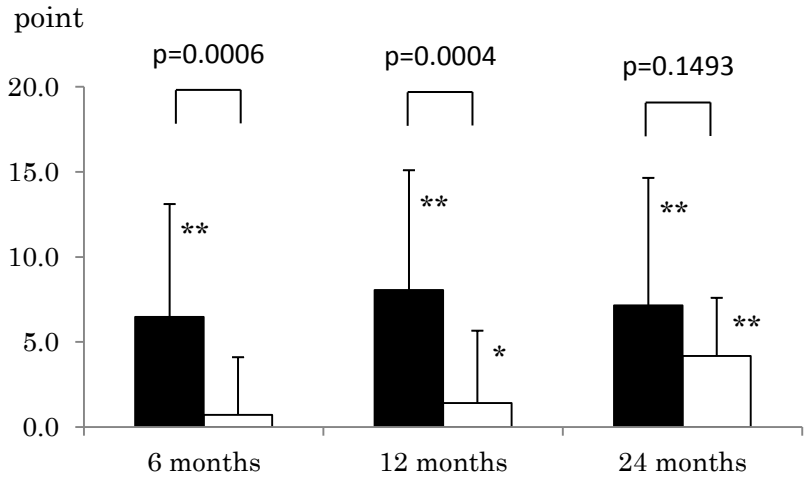


Figure 3 - The numbers of home exercises in a week.

For SF-8, the improvement from the base line, physical component summary score was significantly greater at 6-month and 12-month in the video-based exercise group than the control group, while there was no significant difference at 24-month (6-month : p=0.0006, 12-month: p=0.0004, 24-month : p=0.01493). In the video-based exercise group, the score significantly improved from the baseline value (6-month: p=0.0000, 12-month: p=0.0000, 24-month: p=0.0000). Regarding mental component summary score of SF-8, there was no significantly improved from the base line at 6-month, 12-month or 24-month in either group (the video-based exercise group: 6-month: p=0.4391, 12-month: p=0.5332, 24-month: p=0.3607, the control group: 6-month: 0.1506, 12-month: p=0.1299, 24-month: p=0.4670) (Figure 4). There was no significant difference in the improvement from the baseline value between the video-based exercise and the control groups.

A.



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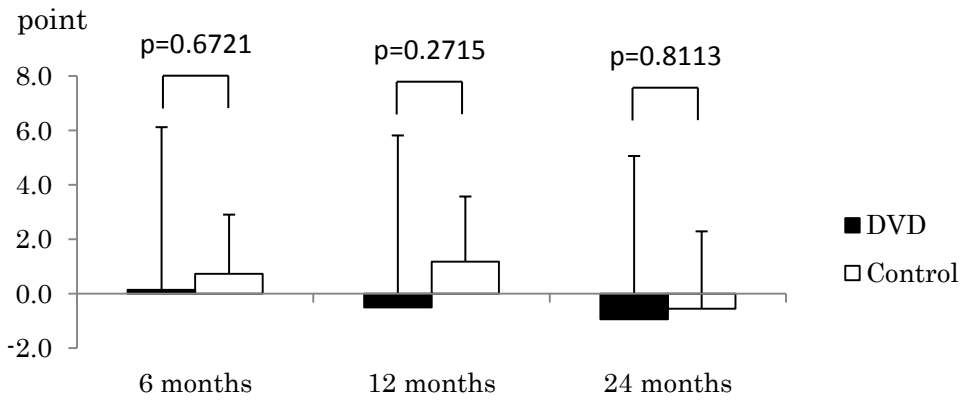

**p<0.001
*p<0.05(versus the base line)

Figure 4- The improvement of SF-8 scores from the baseline in the video-based exercise and control groups

A: physical component summary score, B: mental component summary score.

BMI significantly decreased from the baseline value at the 6-month and 12-month, while there were no significant changes at the 24-month (6-month: p=0.0001, 12-month: p=0.0109, 24-month: p=0.1255) (Figure 5). There were no significant differences in the reduction of BMI between the video-based exercise and the control group.

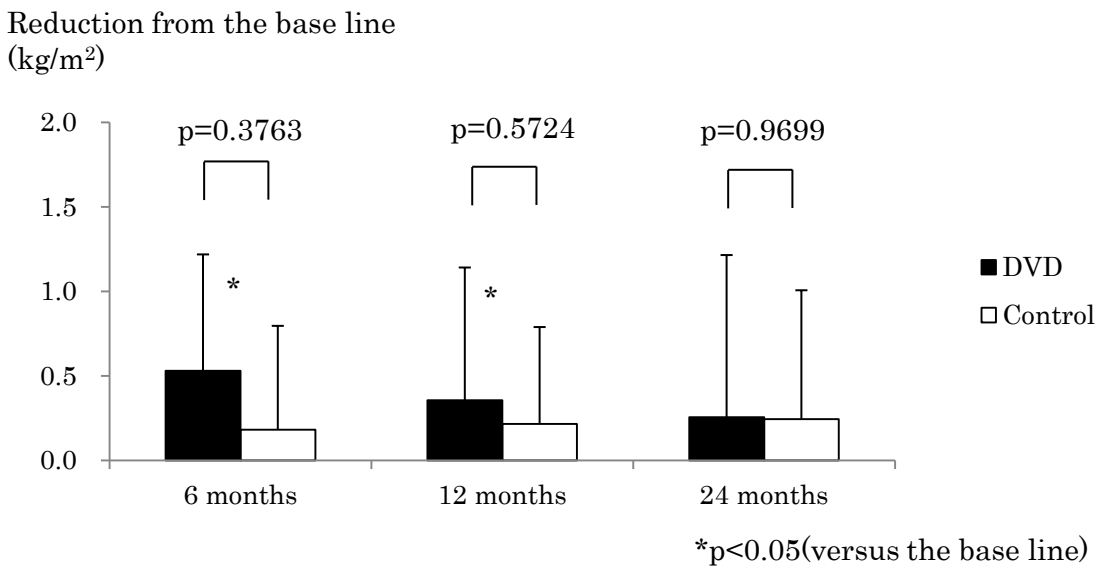

Figure 5 - The reduction of BMI from the baseline in the video-based exercise and control groups.

Concerning radiographic OA progression, there was a significant increase in FTA from the baseline value in the video-based exercise group at the 12-month and 24-month (12-month: p=0.0058, 24-month: p=0.0211), while there were no significant

changes in the control group (12-month: p=0.2378, 24-month: p=0.2760) (Table 3). There was no significant changes between the video-based exercise and the control groups (12-month: p=0.4345, 24-month: p=0.6795). For the JSA, the mJSW or osteophyte area of the medial tibia, there was no significant progression from the base line at 12-month or 24-month.

Table 3 Radiographic parameters of knee OA progression in the video-based exercise and control group.

	Video-based exercise	**Control**	**Statistical comparison of changes from the baseline between groups**
FTA (degree)			
baseline	176.6±3.6	177.6±4.4	
12-month	177.6±3.8**	178.2±4.9	p=0.6683
24-month	177.5±3.7*	178.2±5.0	p=0.5868
Medial JSA (mm^2)			
baseline	86.5±20.3	97.8±34.8	
12-month	93.4±29.8	93.1±40.0	p=0.9738
24-month	95.3±33.1	94.2±40.2	p=0.9214
Medial mJSW (mm)			
baseline	3.1±0.8	3.5±1.1	
12-month	3.2±1.0	3.4±1.5	p=0.5222
24-month	2.9±1.1	3.3±1.6	p=0.2961
Osteophyte area of medial tibia (mm^2)			
baseline	2.3±5.4	0.9±2.5	
12-month	1.5±3.8	0.8±1.2	p=0.4855
24-month	1.8±3.7	2.6±3.6	p=0.4886

**Significant improvement from the baseline ($p<0.01$).
*Significant improvement from the baseline ($p<0.05$).

Discussion

The present study was conducted to test the hypothesis that video-based home exercise could enhance adherence to prescribed exercise program, produce substantial improvements in pain, physical function and quality of life in patients with knee OA, and also prevent radiographic progression of knee OA compared with conventional home exercise without video media. We then found that the numbers of home exercises in a week in the video-based exercise group were significantly greater than those in the control exercise group without video media at the 6-month follow-up period. Concerning pain and physical function, the present study showed improvements of WOMAC scores from the baseline were significantly greater in the video-based exercise group than in the control group until 24-month follow-up. In addition, the improvement of SF-8 physical component summary score from the baseline was significantly greater in the video-based exercise group than in the control group at 6-month and 12-month follow-up. However, we also found that video-based home exercise did not enhance adherence to prescribed exercise program after 12 months compared with home exercise without video media or prevent radiographic progression of FTA of the knee for 24 months. Therefore, the findings of the present study suggested that video-based home exercise can enhance adherence to prescribed exercise program for 6 months and can

produce substantial improvements in pain, physical function and quality of life in patients with knee OA at two years, although our video-based home exercise cannot prevent radiographic progression of the knee OA.

Concerning to the comparability of the present study, we compared the effects of the video-based home-exercise on clinical and radiographic outcomes for the subjects with the osteoarthritis of the knee with those of the straight leg raising (SLR) exercise, which is identical to the exercise method of the previous study reported by Doi et al.[18]. The SLR exercise is widely used for quadriceps muscle strengthening as one of the most popular home-exercises. In their study, Doi et al.[18] compared the effect of the SLR exercise on knee osteoarthritis in comparison with that of NSAIDs by a randomized open-labeled multiclinic trial and found no significant difference in improvement rate of clinical outcomes between groups with the SLR exercise and the NSAIDs. On the other hand, we found that compared the effects of the video-based home-exercise on the improvement of pain and physical function WOMAC scores were significant larger than those of SLR exercise until 24 months after the intervention. Therefore, we assume that the video-based home-exercise has larger effects on the improvement of pain and physical function in the knee OA subjects compared to NSAIDs. It is also considered possible to qualitatively compare the effects

of video-based home-exercise on pain and physical function in the knee OA subjects to other types of pharmalogical or non-pharmalogical intervention which had been previously compared to NSAIDs.

Adherence has been shown to be an important predictor of outcome from exercise by subgroup analyses in previously reported clinical trails[22-25]. For example, Thomas et al.[22] have reported effect sizes at 2-year follow-up are 0.42, 0.34 and 0.16 for high-, medium- and low-adherence groups respectively. In the present study, our program DVD provided better adherence to prescribed exercise for 6 months compared with verbal and hands-on instruction in a quadriceps muscle exercise, while the adherence to prescribed exercise in the video-based exercise group was similar to that in the control group at the 12-month and 24-month. Our prescribed exercise took approximate 30 minutes and 7-8 minutes in the video-based and the control groups, respectively. In the present study, the program of the video-based exercise group is composed of various exercises. The content and strength of the program in the video-based exercise group are different from the program in the control group. The program of the control group is straight leg raising which is widely used. Therefore, the program in the video-based exercise group is difficult to adherence. Considering the

time required for the prescribed exercise, DVD media can improve adherence to prescribed exercise for a long period.

The training program of the present study mainly consisted of range-of-motion exercises and muscle strengthening exercises, while it included two kinds of aerobic exercise (i.e. stepping exercise and riding a stationary bike) for approximately 10 minutes in total. Previous studies have shown that both aerobic and strengthening exercises are effective for knee OA. Concerning to aerobic exercise, previously reported randomized control trails of aerobic walking by Ettinger et al.[25] and Kovar et al.[26] have shown a reduction in pain and an improvement in function, while one clinical control trail by Talbot et al.[27] failed to show an improvement in pain. For strengthening exercise, many randomized control trails have shown strengthening exercise to reduce pain and disability in knee osteoarthritis and improve knee function. For example, a systematic review by Roddy et al.[6] has shown that the effect-size of strengthening exercise on the short-term disability outcome in knee osteoarthritis ranged from 0.19 to 0.63. Effect-sizes of our DVD-based home exercise on disability in knee osteoarthritis at 12- and 24-month follow-up were 0.58 and 0.37, respectively. Therefore, the long-term effect of our DVD-based home exercise on the disability outcome in knee

osteoarthritis is considered to be comparable with the short-term effects of exercises in the previous studies.

Regarding health status, previous randomized control trails failed to show that aerobic or strengthening exercise can improve health status[25, 27, 28], although one randomized control trail has shown the strengthening exercise to improve health status with its effect-size of 0.41[5]. The present study showed that our DVD-based home exercise provided improvement at the 12-month follow-up in health status, i.e. SF-8 physical compartment summary score, with its effect-size of 0.46. Therefore, the effect of our DVD-based home exercise on health status is relatively large compared to those of previous reports. The reasons of a large effect of our DVD-based home exercise on health status might be that our subjects performed exercise in their home for a relatively long period.

In previous studies, radiographic progression has been assessed in different ways: based on either joint space narrowing (JSN) or Kellgren/Lawrence grade. For example, Thorstensson et al.[28] reported radiographic progression was found in 65/67 (97%) with TF OA at baseline over 12 years based on Kellgren-Lawrence grade. However, Kellgren/Lawrence grading is limited in reproducibility and sensitivity due to the subjective judgment of individual observers and the categorical classification into

five-grade scales. In the present study, radiographic progression on joint space area (JSA), minimum joint space width (mJSW), osteophyte area, and femorotibial angle (FTA) has been assessed using a fully automatic program[21]. Our method can provide objective, accurate, simple and easy evaluation of the radiographic knee OA severity. Actually, we detected a significant decrease of FTA in the DVD group at one year, while we could not detect other parameter. We also found no statistical differences in radiographic OA progression between the DVD and control groups. Radiographic progression did not match with the clinical symptoms. The reasons for the contradiction could be that the significant decrease of FTA does not reflect on clinical symptoms. These findings suggest that our video-based home exercise cannot prevent radiographic progression of the knee OA.

The present study has the following limitations. First, we did not blind the subjects to the treatment allocation and participants were aware of whether they were part of the treatment or control group. Therefore, the subjects in the video-based exercise group might change their behaviors due to the attention they are receiving from researchers rather than because of any manipulation of independent variables. Therefore, we should consider our results might include such psychological effects of the subjects and evaluators. Second, a number of the participants refused their allocation in the

control group. In spite of these limitations, the present study suggested that video-based home exercise is one of the most beneficial non-pharmacological treatments for knee OA, while this cannot prevent radiographic progression of knee OA.

Conclusions

1. In conclusion, the present two-year comparative controlled trial showed that video-based home exercise can enhance adherence to prescribed exercise program for 6 months and can produce substantial improvements in pain and physical function in patients with knee OA at two years.
2. However, this video-based home exercise does not prevent radiographic progression of the knee OA.

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