Effectiveness of an Elastic Knee Sleeve for Patients with Knee Osteoarthritis : A Randomized Single-Blinded Controlled Trial

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Abstract

Objectives : To study the effectiveness of elastic sleeves in patients with knee osteoarthritis (knee OA).

Method : Patients with knee OA attending the outpatient clinic of Siriraj Hospital, who met the eligibility criteria, were randomly allocated to receive an 8-week treatment protocol. The control group received acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs) and education. The study group received the same treatment, in combination with a daytime elastic knee sleeve. Primary outcome variable included change in aggregated functional performance time (AFPT).

Results : In the immediate period after treatment, the study group had a mean improvement in AFPT of 1.63 seconds more than the control group (95% CI: 0.21-3.05, p = 0.025). At the end of the 8th week, the changes of AFPT were not statistically different between the two groups.

Conclusion : This study shows small short-term beneficial effects of an elastic sleeve in patients with knee OA in cases with acute exacerbation.

Key word : Elastic Knee Sleeve, Knee Osteoarthritis, Randomized Controlled Trial

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Knee osteoarthritis (knee OA) is a relatively common musculoskeletal disorder. Its prevalence increases with age[1,2]. It is a highly disabling condition resulting in problems of mobility[3,4]. A survey from Thailand showed that the prevalence rate of knee OA was 11.3 per cent in people 15 years of age or over[5].

The goals of therapy are to decrease pain and to maintain or improve joint function. An evidence-based approach begins with patient education, physical therapy, occupational therapy and proceeds to simple analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) and therapeutic exercise[6-8]. Regarding the physical therapy modalities, a lot of commercially available assistive devices such as an elastic sleeve are frequently used for the treatment of knee OA even though good supporting evidence is lacking.

The aims of this study were to assess the immediate effects of an elastic sleeve on functional abilities and long-term effects on functional abilities, quadriceps strength and endurance in patients with knee OA.

MATERIAL AND METHOD

Subjects

After the research proposal was accepted by the Hospital Ethics committee, patients with unilateral or bilateral knee OA were recruited from the Department of Orthopedic Surgery and the Department of Rehabilitation Medicine at the Siriraj Hospital. Patients were included if they met the current American College of Rheumatology criteria for knee OA[9], were between 40 and 85 years of age, had had mild to moderate knee pain for at least 1 month and had received no drugs for arthritis over the last week. Patients were excluded from the study if they were concurrently receiving physical therapy, were actively involved in any exercise programme or had worn an elastic sleeve within the last 3 months, had indications for knee replacement, had radiographic evidence of knee OA grade IV[10], had an unstable medical condition or had neurological/other musculoskeletal problems interfering with ambulation.

Randomization

Patients who gave written informed consent were randomized to receive an 8-week treatment protocol by using permuted blocks of four. The treatment allocation was concealed within an opaque envelope.

Assessments

Baseline variables included age (year), gender (male/female), body mass index (BMI), association with diabetes millitus (yes/no) and life style (sedentary/walking most of the day/working at floor level). The primary outcome was observed disability measured by a modified aggregated functional performance time (AFPT)[11] by a blinded investigator. The subjects were asked to get up from a chair with arm rests and walk at a comfortable speed along a level corridor for 50 feet. They were asked to go up a straight flight of stairs (consisting of 11 steps each 12 cm high) and to go down a straight flight of stairs at a comfortable speed and pattern. There was a 5 minute rest period between tasks. The time taken to perform each task was recorded using a stopwatch. The series of tasks were randomly assigned. By aggregating the time of the above-mentioned activities, an objective assessment could be obtained called the aggregated functional performance time (AFPT). The assessment for the immediate effect was performed by recording the APFT at baseline and 20 minutes later. The 20 minutes duration was used to assure that all of the subjects had rested until pain from first assessment had subsided. The subjects in the study group wore an elastic sleeve in the second assessment while subjects in the control group did not. The differences between their first and second record were compared between the two groups to find the immediate effect of the elastic sleeve. All the subjects were assessed again at the end of the 8th week. Primary outcome is the long-term effect on functional performance measured by the difference between the first record of the follow-up AFPT and the first record of baseline AFPT.

The following secondary outcome measurement included:

1. The Laquesne index for knee OA[12] used by asking the subjects to rate their pain and disability in ambulation and performing various activities of daily life, scoring between 0-24 points. A lower score indicates better subjective functional abilities.

2. Isometric quadriceps strength of the more severely involved knee was measured during an isometric maximum voluntary contraction (MVC). The patients were asked to lie on a specially constructed bed with their hips and knees fixed to 45-degree flexion. A non-extensible strap was placed just above their malleoli, the other end was attached to a stain

gauge system. Each maximal isometric contraction was monitored for 2 seconds. The subjects were encouraged not to hold their breath, thus avoiding the Valsalva maneuver, which would increase blood pressure and heart rate.

3. Quadriceps endurance of the more severely involved knee was measured at 45-degree hip and knee flexion using a strain gauge. The subjects maintained 40 per cent of maximal isometric contraction for as long as possible. Endurance was presented in kilogram • second.

4. The quantity of analgesic and NSAIDs usage was assessed by pill count.

5. Recovery from baseline was recorded on a six point Likert Scale; "complete recovery, much improvement, little improvement, no change, a little worse, much worse".

6. The subjects' satisfaction was rated on a four point Likert scale "very satisfied, moderately satisfied, unsatisfied, very unsatisfied".

7. Complications (such as contact dermatitis) of wearing the elastic sleeve.

Blinding

All the objective outcomes were assessed by blinded investigators. To optimize blinding, the patients were instructed by an administrative assistant not to reveal any information about their treatment. They were asked to wear a long skirt or trousers in order to conceal both knees during the second record of each assessment.

Interventions

The subjects in study group wore an elastic sleeve in the second assessment of AFPT while subjects in the control group did not. The differences between their first and second record were compared between the two groups to find the immediate effect of the elastic sleeve. To assess the long-term effects of wearing an elastic sleeve, the patients in the study group were asked to wear the elastic sleeve from early morning until late evening for 8 weeks. The knee sleeve used in this study was selected by consensus between the investigators considering its comfort, durability and price. The authors chose a commercially available sleeve called LP support®, registered trademark of LP Pointique Int'l Ltd. Bellevue WA, USA. Regarding the size of the bandage, the patients were asked to choose the most comfortable bandage (large, medium or small). The control group did not receive any specific intervention. Both groups were instructed to use as little medication as possible. The medication preferred was acetaminophen; NSAIDs prescribed were restricted to previous drugs, which the patients had used without complications. If the patients had never used NSAIDs before, ibuprofen was prescribed because it has been found that it produces fewer gastrointestinal adverse effects than the others[13]. The researchers provided patient education for both groups using a brochure; the topics included diagnosis, prognosis, and a knee joint protection programme. The subjects in the study group were asked to complete a diary documenting the duration of knee sleeve use for each day. Compliance was graded into 3 categories; more than 7 hours/day, 4-7 hours/day, and less than 4 hours/day. All of the patients were asked to record if there was any change to the protocol prescribed. The first appointment was arranged at the end of the 4th week to ensure that the patients could follow the instructions. The second appointment was at the end of the 8th week.

Statitical analyis

Intention to treat analysis was used to evaluate the statistical differences between the two groups. All baseline data and outcome variables were analyzed using SPSS for Windows 9.05 (SPSS Inc). The changes in aggregated functional performance times (AFPT), isometric quadriceps force (kg) and endurance (kg • second) of both groups were compared using an unpaired *t*-test. Multivariate analysis was used to detect any effects of the difference in baseline characteristics on primary outcome. The Mann-Whitney U test was used to compare the Laquesne Index for knee OA, the global rating of improvement, and satisfaction between the two groups. The means of the total amount of analgesic and NSAIDs useage of the two groups were compared using an unpaired *t*-test. Any complications that occurred were presented by percentage. Calculation of the sample size was based on the ability to detect the clinically important difference in the mean of the aggregated functional performance time (AFPT) change of at least 3 seconds between the two groups. The result of the pilot study showed that the SD of the results of the control and the study groups were 5.1 and 6.0 respectively. In order to use

α equal to 0.05 (two-tailed) and to have power of study of 80 per cent, the final study population of 110 patients was required.

RESULTS

From March, 2001 to September, 2001, 211 patients with knee OA consulted the orthopedic and rehabilitation clinic at Siriraj Hospital. A total of 128 patients with knee OA fulfilled the eligibility criteria and were willing to join this study. Of the 83 subjects not recruited, 19 were unwilling to participate and 64 were excluded (unable to complete the study because of imminent move = 24, other musculoskeletal problems interfering with ambulation = 14, already wearing an elastic sleeve = 10, actively involved in an exercise programme = 8, had radiographic evidence of knee OA grade IV = 4, had indication for knee replacement = 4) The number of subjects who dropped out of the study were 4 in the control group and 5 in the study group. The total number of cases included in the analysis was 60 and 59 for the control and study group respectively.

The baseline characteristics of the patients are shown in Table 1. The proportions of categorical baseline data of each group were similar as well as means and median of other baseline conditions.

Immediate effects

Table 2 shows the difference in aggregated functional performance time (AFPT) improvement immediately following elastic knee sleeve application in subjects in the study group compared with the control group. Patients in the study group who wore the elastic sleeve were significantly faster than the control group by 1.63 seconds (95 % confident interval: 0.21 to 3.05, p = 0.025). At the end of the 8th week, the difference was in the same direction but was not statistically significant (mean difference = 1.83 seconds, 95 % confidence interval: -2.21 to 5.87, p = 0.315).

Late effects

After the patients in the study group had worn an elastic knee sleeve for 8 weeks, they were asked to take off their knee sleeves. Both groups showed a significant change in AFPT. The mean (SD) AFPT of the control group and the study group were lower than baseline by 5.08 (12.27) seconds and 6.91 (9.81) respectively. The changes of AFPT from baseline were compared between the two groups. The data

Table 1. Baseline characteristics of patients with knee OA by group. Values are numbers unless indicated otherwise.

Variables	Control (n = 60)	%	Study (n = 59)	%
Mean (SD) of age (years)	56.15 (10.30)		55.54 (9.96)	
Gender				
Male	7	11.7	11	18.6
Female	53	88.3	48	81.4
Mean (SD) of body mass index	25.89 (4.00)		27.01 (4.04)	
Duration of disability				
< 3 months	17	28.3	16	27.1
3-6 months	10	16.7	7	17.9
> 6 months	33	55.0	36	61.0
Grading of X-ray finding				
I	20	33.3	21	35.6
II	34	56.7	25	42.4
III	6	10.0	13	22.0
Life style				
Sedentary	15	25.0	18	30.5
Walking or standing almost entire day	25	41.6	22	27.3
Working at floor level	20	33.3	19	32.2
Associated with DM	6	10.0	4	6.8
Mean (SD) of aggregated functional performance time (sec)	48.06 (16.54)		47.64 (12.89)	
Median (interquartile range) of the Laquesne Index*	9.5 (6.0)		9.0 (5.0)	
Mean (SD) of quadriceps strength (kg)	14.99 (5.25)		15.31 (6.42)	
Mean (SD) of quadriceps endurance (kg • sec)	405.88 (398.95)		415.63 (399.99)	

* pain and disability rating score range from 0-24, higher scores indicate more pain and disability.

Table 2. Outcome variables of patients with knee OA by groups. Values are numbers unless indicated otherwise.

Variables	Control (n = 60)	%	Study (n = 59)	%	Mean difference (95% CI)	P-value
Immediate effects						
Mean (SD) of AFPT change of second test from first test (sec) *	0.97 (3.61)		2.60 (3.81)		1.63 (0.21 to 3.05)	0.025
Late effects						
Mean (SD) of AFPT change from baseline (sec)	5.08 (12.27)		6.91 (9.81)		1.83 (-2.21 to 5.78)	0.315
Median (interquartile range) of Laquesne index	3.0 (5.0)		4.0 (3.2)			0.124
Mean (SD) of quadriceps strength improvement (kg)	1.77 (3.58)		1.25 (3.04)		-0.52 (-1.72 to 0.70)	0.402
Mean (SD) of quadriceps endurance improvement (kg • sec)	23.1 (42.76)		17.03 (52.44)		-6.11 (-23.47 to 11.25)	0.448
Satisfaction						
Very satisfied	39	65.0	42	71.2		
Moderately satisfied	15	25.0	16	27.1		0.409
Unsatisfied	2	3.3	0	0		
Very unsatisfied	4	6.7	1	1.7		
Global rating of improvement						
Complete recovery	0	0	2	3.4		
Much improvement	14	23.3	16	27.1		
Little improvement	22	36.7	21	35.6		
No change	14	23.3	14	23.7		0.257
Little worse	7	11.7	5	8.5		
Much worse	3	5.0	1	1.7		
NSAIDs use (tab)	49.17 (17.16)		52.85 (19.40)			0.440*
Acetaminophen use (tab)	23.72 (17.16)		29.75 (19.98)			0.103*

* The outcome measurements did not show a Guassian distribution, therefore non-parametric tests were used.

Table 3. Compliance, co-intervention and complications in patients with knee OA by treatment received. Values are numbers unless indicated otherwise.

	Control (n = 60)	%	Study (n = 59)	%
Mean (SD) of weight change (kg)	-0.39 (1.62)		-0.31 (1.34)	
Self-rating of knee joint protection				
Good	34	57.6	43	72.9
Moderate	20	33.3	16	19.1
None	6	10.0	0	0
Compliance of elastic sleeve				
More than 7 hours/ day	-	-	51	86.4
4-7 hours/day	-	-	6	10.2
Less than 4 hours/ day	-	-	1	1.7
Contamination	2	3.4	-	-
Co-intervention				
Exercise	4	6.7	1	1.7
Local treatment (heat, drugs)	4	6.7	3	5.1
Complications of NSAIDs				
Severe dyspepsia	2	3.4	3	5.1
Headache	0	0	1	1.7
Complications of elastic sleeve				
Contact dermatitis	-	-	1	1.7
Foot edema	-	-	2	3.4

showed a small difference in favor of the study group but the results of the unpaired *t*-test indicated that the difference was not statistically significant (Table 2). The Laquesne Index for knee OA changes between the two groups were in the same direction but were not significantly different as well as global rating of improvement, patients' satisfaction, amount of analgesics and NSAIDs use. The magnitude of quadriceps strength and endurance improvements in the study group tended to be less than the control group but it was not significant. The details of compliance, co-intervention and complications are shown in Table 3. The data indicate that the results of weight control of both groups were similar. The median of participants' rating in joint protection programme in the study group was better than the control group ($p = 0.033$). Eighty-six per cent of subjects in the study group wore an elastic knee sleeve as in the protocol. There were a few complications reported (contact dermatitis, leg edema). Two patients in the control group used elastic sleeves intermittently.

DISCUSSION

Very little has been reported in the literature regarding the use of an elastic sleeve or elastic bandages for musculoskeletal problems. In this trial, evidence was found for the immediate effect of an elastic knee sleeve on symptomatic knee OA. The beneficial effect was to help the patients walk faster than the control group. One possible factor contributing to the study group improvement might be due to the effects on pain by gate control theory[14] or by enhancing joint proprioception[15] which has been proved to be correlated with stair walking time in a study involving six women with knee OA[16]. However, because it was not possible to keep the subjects blinded to the experimental condition, the ability to move faster was probably due to placebo effect. Furthermore, the difference of 1.75 second might not have clinical significance.

The results of this study did not support the beneficial effect of elastic support for long-term use, even though the patients in the study group stated that they took care of their knee better than the control group did.

The authors tried to avoid methodological flaws by randomization. All of the objective assessments were carried out by blinded investigators. Treatment was documented in both groups and patients' compliance was checked. Nevertheless, some comments can be made. First, data on patients who withdrew from the study were not available because most of them were lost to follow-up. However, the number of subjects who withdrew was small (7.8%) and com-

parable between the two groups. Secondly, some programme violations were registered (11.8%), mostly in the control group. These treatment variations reflect everyday practice especially in outpatient clinics.

SUMMARY

The results of the study showed only a small short-term beneficial effect of an elastic knee support in patients with knee OA in cases with an acute exacerbation. This effect might not be considered to have clinical significance.

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ประสิทธิผลของปลอกสวมเข่าแบบผ้ายืดในผู้ป่วยที่มีข้อเข่าเสื่อม

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วัตถุประสงค์ : เพื่อศึกษาประสิทธิผลของปลอกสวมเข่าแบบผ้ายืด

วิธีการศึกษา : เลือกผู้ป่วยข้อเข่าเสื่อมตามเกณฑ์ที่กำหนด สุ่มเข้ากลุ่มศึกษาหรือกลุ่มควบคุม เป็นเวลานาน 8 สัปดาห์ กลุ่มควบคุมรับประทานยา acetaminophen ยาต้านการอักเสบ และคำคำแนะนำเรื่องการปฏิบัติตัว กลุ่มศึกษาได้รับยา คำแนะนำ และสวมปลอกผ้ายืดรัดเข่าในเวลากลางวัน ตัวแปรประกอบด้วย เวลาที่ใช้ในการลุกขึ้น เดินและขึ้น-ลงบันได, แบบสอบถาม The Laquesne index for knee OA (ภาคภาษาไทย), กำลังและความทนทานของกล้ามเนื้อ quadriceps, จำนวนยาที่รับประทาน, ผลการรักษาโดยรวม, ความพึงพอใจ และภาวะแทรกซ้อน เปรียบเทียบตัวแปรของทั้งสองกลุ่มด้วยวิธี intention to treat analysis

ผลการศึกษา : เมื่อใช้ปลอกสวมเข่า กลุ่มศึกษาลุกขึ้นเดินและขึ้นลงบันไดเร็วขึ้นกว่ากลุ่มควบคุม 1.63 วินาที (ค่าร้อยละ 95 ของความเชื่อมั่น = 0.21 ถึง 3.05 วินาที, ค่า p = 0.025) เมื่อใช้นาน 8 สัปดาห์ เวลาที่ใช้ในการเคลื่อนที่ของทั้งสองกลุ่มดีขึ้นพอ ๆ กัน ตัวแปรอื่นไม่แตกต่างกัน

สรุป : ปลอกสวมเข่าช่วยให้ผู้ป่วยข้อเข่าเสื่อมที่มีการอักเสบเฉียบพลันเคลื่อนที่ได้เร็วกว่ากลุ่มควบคุมเพียงเล็กน้อย เมื่อใช้ระยะยาว ผลที่ได้ไม่แตกต่างกัน

คำสำคัญ : ข้อเข่าเสื่อม, ปลอกผ้ายืดสวมเข่า, การศึกษาประสิทธิผล

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