THE JOURNAL OF BONE & JOINT SURGERY (BI)

Two mechanical devices for prophylaxis of thromboembolism after total knee arthroplasty

A PROSPECTIVE, RANDOMISED STUDY

P. F. Lachiewicz,
S. S. Kelley,
L. R. Haden

From the University of North Carolina, Chapel Hill, North Carolina, USA

The optimal characteristics of pneumatic compression for mechanical prophylaxis of thromboembolism after total knee arthroplasty (TKA) are not known. Our study compared two methods of calf compression, with the hypothesis that the device which provided a larger increase in peak venous velocity would produce a lower rate of thromboembolism. We performed a prospective, randomised study on 423 patients (472 knees). Duplex ultrasonography was carried out by experienced technicians who were blinded to the device used. Overall, 206 patients (232 knees) used a rapid inflation, asymmetrical compression (RIAC) device and 217 (240 knees) a sequential circumferential compression device (SCD).

The rate of venous thromboembolism was 6.9% with the RIAC device compared with 15% for the SCD device ($p = 0.007$). The incidence of thrombi with unilateral primary TKA was 8.4% for the RIAC compared with 16.8% for the SCD device ($p = 0.03$). In 47 patients with a bilateral TKA, the incidence of thrombi was 4% for the RIAC compared with 22.7% for the SCD device ($p = 0.05$ per knee). There was a low rate of mortality and pulmonary embolism when using mechanical prophylaxis for thromboembolism after TKA. Our findings show that the use of rapid inflation, asymmetrical calf compression gave a significantly lower rate of thromboembolism.

P. F. Lachiewicz, MD, Professor
L. R. Haden, RN
Department of Orthopaedics, University of North Carolina at Chapel Hill, 3151 Bioinformatics Building, CB 7055, Chapel Hill, North Carolina 27599-7055, USA.

S. S. Kelley, MD, Clinical Professor
North Carolina Orthopaedic Clinic, Duke University Medical Center, 4309 Medical Park Drive, Suite 1008, Durham, North Carolina, 27704, USA.

Correspondence should be sent to Professor P. F. Lachiewicz.

doi:10.1302/0301-620X.86B8.15438 $2.00

J Bone Joint Surg [Br] 2004;86-B:1137-41.
Received 27 February 2004; Accepted after revision 30 April 2004

Deep-vein thrombosis (DVT) is a common complication of total knee arthroplasty (TKA) for which a variety of prophylactic regimens have been recommended.[1-5] Several studies have suggested that pneumatic compression devices are important in this role.[6,7] The use of thigh-high sequential compression and aspirin,[8] foot pumps and aspirin[9] and foot pumps with heparin has also been shown to be effective.[10] New methods of calf compression, which provide for a higher augmentation of venous flow, have been studied in a small group of patients although the optimal characteristics for pneumatic compression devices are not known.[11] In addition, there are no prospective, randomised studies which compare the efficacy of different compression devices.[6] Our aim therefore was to determine which of two pneumatic calf-compression devices, combined with aspirin, resulted in a lower rate of DVT.

One device, a rapid inflation asymmetrical compression (RIAC) device (Venaflow; Aircast, Summit, New Jersey) is a knee-high sleeve with two longitudinal posterior chambers (Fig. 1a). It inflated rapidly once every minute, with a duration of compression of six seconds, at a preset pressure of 45 to 52 mmHg. The other device (Sequential Compression Device (SCD) Kendall, Mansfield, Massachusetts) is also a knee-high sleeve containing three transverse calf chambers (Fig. 1b). The compression cycle was followed by a 60-second venting cycle. The pressure in the chambers was adjusted to 45 mmHg. Our hypothesis was that the RIAC device, which allowed a larger increase in peak venous velocity above and below the junction of the greater saphenous and common femoral veins, would produce a lower rate of thromboembolism.

Patients and Methods

Between April 1999 and March 2003, all the patients who had undergone primary or revision TKA under the care of two surgeons (PFL, SSK) at one institution were considered for our study. Those with a past history of deep-vein thrombosis or pulmonary embolism, heart disease or varicose veins were also included. The only exclusions were patients with either haemophilia, or true allergy to aspirin, or those who were to have removal of an infected knee arthroplasty.

The study was approved by our Institutional Review Board. At the time of their pre-operative

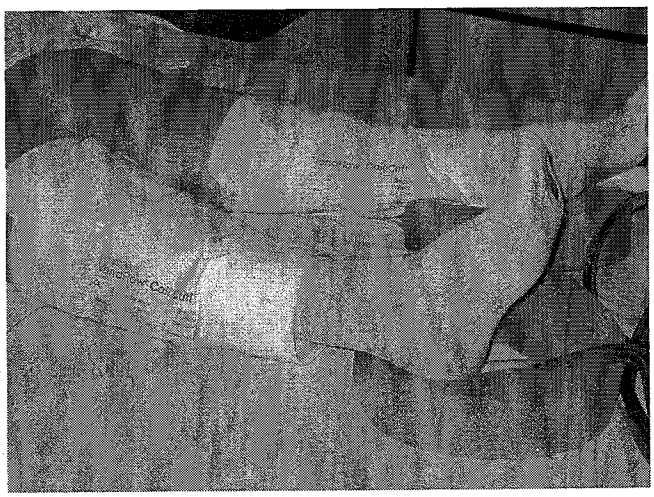

Fig. 1a

Fig. 1b

Photographs of a) the rapid inflation asymmetrical compression (RIAC) device and (b) the sequential circumferential compression device (SCD).

assessment, seven to 14 days before surgery, they consented to the study and were randomised to receiving one of the devices using sealed envelopes. The patients were advised to discontinue taking aspirin, non-steroidal anti-inflammatory preparations and other antiplatelet medications. They were then prescribed 325 mg of aspirin the night before surgery. The surgeons were not blinded to the type of device used. The compression device was applied to the contralateral limb in the operating theatre before the procedure and on the operated limb at the end of the procedure. They wore either knee or thigh-high compression stockings beneath the pneumatic compression devices. The latter were removed for bathing once a day and for physiotherapy sessions twice a day. A timing device was not used to determine the exact length of time the devices were in place, but our nursing staff estimated this to be at least 12 to 16 hours each day. A continuous passive movement machine was used for one hour, three times each day. Aspirin (650 mg) was administered post-operatively twice daily while the patients were either in hospital or in the rehabilitation unit. We also recommend that patients should continue taking aspirin and wearing compression stockings at home, although there was no method to ensure their compliance. They were reminded at the two-week post-operative visit to continue the use of aspirin and compression stockings.

We performed bilateral duplex ultrasonography with an Acuson 128 XP 10 unit (Acuson, Mountainview, California), three to five days after the operation after the post-operative bandage had been removed. Ultrasonography of the calf and thigh, as far cranially as the inguinal ligament, was performed by experienced vascular technicians who were blinded to the type of mechanical device which had been used by the patients.

Ultrasonography, as a method of detection of deep-vein thrombosis, has been previously validated at our institution.[12,13] The treatment of thrombi identified by ultrasonography followed a previously developed protocol.[14,15] Femoral or proximal popliteal thrombi were treated by anticoagulation, initially with heparin or low-molecular-weight heparin, and then warfarin for three months. If calf thrombi were found, treatment with aspirin and compression stockings was continued and the ultrasonography was repeated seven to ten days later. Progression to popliteal or proximal femoral thrombi was treated by anticoagulation. We closely observed the patients for symptomatic thromboembolism for a minimum of six months.

During the period of study, 442 patients were entered and 19 excluded. Subsequently, 12 had their surgery cancelled, two did not have ultrasonography, two did not receive a TKA (one had a resection arthroplasty and one an arthrodesis), and three suffered an acute myocardial infarction in the immediate post-operative period and were treated with intravenous heparin. Thus, 423 patients (472 knees) completed the study.

Statistical analysis. This included two-by-two contingency tables of categorical variables for chi-squared analysis. Independent *t*-tests were used in order to determine group differences for continuous variables (age, weight). Because of the small frequency counts for several cells, Fisher's exact test was used for the chi-squared test, with the level of significance being set at $p < 0.05$. Frequent monitoring of the results of the two devices was performed during the first two years of the study. At that time, a mid-study power analysis determined that 230 knees for each group were needed for a power of 0.8 at the level of significance of 0.05.

Results

In total, 206 patients (232 knees) were randomised to the RIAC device and 217 patients (240 knees) to the SCD. The

Table I. Details of the patients in the two groups

	RIAC	SCD	p value
Number of patients	206	217	-
Men	78	72	
Women	128	145	0.26
Mean age in yrs (range)	67.3 (23 to 89)	66.4 (30 to 94)	0.37
Mean weight in kg (range)	87.7 (50 to 146.8)	86.6 (45.4 to 147.7)	0.70
Mean height in m (range)	1.66 (1.45 to 1.97)	1.65 (1.47 to 1.95)	0.39
Diagnoses			
Osteoarthritis	154	153	
Rheumatoid arthritis	15	10	
Osteonecrosis	5	8	
Traumatic arthritis	3	4	0.45
Failed arthroplasty	27	37	
Other	2	5	
Anaesthesia			
Spinal	163	183	
General	30	26	
Epidural	3	4	0.22
Spinal and epidural	9	3	
Spinal and general	1	1	

details of the randomisation (Table I) showed no statistically significant differences between the groups for any of the parameters involved.

The in-hospital mortality was 0.2% (one of 423 patients). The patient was a 78-year-old man, with hypertension and hypercholesterolaemia, and a loose, unstable TKA, who had been randomised to the SCD. He developed an acute myocardial infarction 12 hours after operation and died on the second post-operative day despite undergoing angioplasty and the insertion of a coronary artery stent. One patient, who had had bilateral TKA and was randomised to the SCD device, had a symptomatic, non-fatal pulmonary embolism on the 12th post-operative day while in the rehabilitation unit. Bilateral ultrasonography on the fourth post-operative day was negative but a repeat scan on the 12th post-operative day showed a large right calf thrombus. She was treated with anticoagulation and had no further sequelae.

The overall rate of DVT diagnosed by ultrasonography was 6.9% (16 thrombi in 232 knees) with the RIAC device and 15% (36 thrombi in 240 knees) with the SCD (Table II). This difference was statistically highly significant ($p = 0.007$). The rate of DVT was analysed by the type of procedure (Table III). In the group of 313 unilateral primary TKAs, there were 12 ipsilateral calf thrombi and one ipsilateral popliteal thrombus in 155 knees (8.4%) with the RIAC device compared with 25 ipsilateral (24 calf thrombi and one popliteal thrombus) and one contralateral femoral

Table II. The rate of thromboembolism in both groups

	RIAC	SCD	p value
Number of patients	206	217	-
Number of knees	232	240	-
In-hospital mortality (%)	0 *(0)*	1 *(0.46)*	-
Pulmonary embolism (%)	0 *(0)*	1 *(0.46)*	-
Number of thrombi (%)	16 *(6.9)*	36 *(15)*	0.007
Calf	15	30	-
Proximal (popliteal or femoral)	1	6	-

Table III. The rate of DVT in both groups

	RIAC	SCD	p value
Number of unilateral primary replacements			
Knees	155	158	
Thrombi (%)	13 *(8.4)*	26 *(16.5)*	0.03
Number of bilateral primary replacements			
Patients (knees)	25 (50)	22 (44)	
Patients with thrombi (%)	1 *(4)*	5 *(22.7)*	0.09
Limbs with thrombi (%)	2 *(4)*	7 *(15.9)*	0.05
Number of unilateral revision replacements			
Patients	25	36	
Patients with thrombi (%)	1 *(4)*	3 *(8.3)*	0.45
Limbs with thrombi	1	4	
Number of bilateral revision replacements			
Patients	1	1	
Thrombi	0	0	

thrombus in 158 knees (16.5%) with the SCD device ($p = 0.03$). In the group of 47 bilateral primary TKA patients, one patient had bilateral calf thrombi (4%, two of 50 limbs at risk) with the RIAC device and five with seven thrombi (three calf, one bilateral calf, one calf and popliteal thrombus, 15.9%, seven of 44 limbs at risk) with the SCD device. When comparing the difference in the rate per knee at risk, this was statistically significant ($p = 0.05$).

There were no complications from the use of either pneumatic compression device. One patient developed severe hiccoughs from an oesophageal ulceration, presumably related to aspirin. No patient required re-operation for haemarthrosis, but one patient with pigmented villonodular synovitis required post-operative aspiration. No patient developed a symptomatic DVT within six months of discharge.

Discussion

A variety of prophylactic regimens for thromboembolism has been recommended for patients undergoing TKA, including the use of warfarin,[16] intra-operative heparin,[10] low-molecular-weight heparin,[16] aspirin,[17] and a number of mechanical devices.[6,7] Maynard, Sculco and Ghelman,[18] found that in patients with TKA who had undergone phlebography, 86% of thrombi occurred in the first 24 hours after surgery. Prophylaxis should therefore be started intra-operatively, or early post-operatively, in the recovery room. Therapeutic doses of warfarin or low-molecular-weight heparin cannot routinely be used intra-operatively or early post-operatively in patients who have received regional anaesthesia with an epidural or continuous spinal catheter. Consequently, mechanical prophylactic devices which can be applied intra-operatively on the contralateral limb and immediately after surgery on the operated limb, seem to be attractive. Two studies of relatively small numbers of patients have already shown that mechanical devices and aspirin are effective in decreasing the rate of DVT after TKA.[8,9]

Many different mechanical devices, such as foot pumps, foot-calf pumps, calf-thigh pumps and calf compression devices, are available.[6,7] These differ in the length and location of the compression sleeve, the frequency and duration of activation, the rate of rise of pressure and the maximum pressure achieved. The optimal characteristics of these devices for the prevention of DVT after TKA are not known. Westrich et al[11] investigated ten patients who had undergone a primary unilateral TKA for osteoarthritis. They performed a cross-over study in order to establish the haemodynamic effect of several pneumatic compression devices.[11] Ultrasonography was used to determine the mean peak venous velocity augmentation above and below the junction of the saphenous and common femoral veins, as well as the increase in venous volume at that site. Their study established that one type of posterior calf sleeve (RIAC) increased mean peak venous velocity augmentation by 255% (± 91%) compared with 88% (± 56%) for a calf-thigh SCD. However, there was no statistically significant difference in the mean venous volume augmentation between any of the seven devices tested.[11]

The hypothesis of our study was that the device which allowed a greater rise in peak venous velocity (RIAC) would have a lower rate of DVT. This was a prospective, randomised study of all patients who were to have a primary or revision TKA by two surgeons. In addition, 325 mg of aspirin were recommended to be given pre-operatively and 650 mg twice daily post-operatively, as earlier studies of mechanical prophylaxis after TKA suggested this combination.[8,9] Another study, however, stated that aspirin has no beneficial effect after TKA.[19]

Our randomisation of the patients was satisfactory since there was no significant difference in gender, age, height, weight, pre-operative diagnosis, type of anaesthesia or type of procedure performed between the two groups. There was only one death from a fatal myocardial infarction and only one symptomatic pulmonary embolism. However, there was a statistically significant difference in the overall rate of DVT, as detected by Duplex ultrasonography, between the patients who had an RIAC device or an SCD device. This difference applied to the whole group, to those undergoing primary unilateral TKA and to those undergoing primary bilateral TKA when analysed by knee at risk.

It has been suggested that ultrasonography may be insufficiently sensitive to identify all thrombi which may develop after a TKA.[20,21] However, we have had experience with the ultrasonographic diagnosis of deep-vein thrombosis for 25 years and the technique has been previously validated by us. The technicians were also blinded as to the type of mechanical prophylaxis used by the patient. It has been suggested that the peak incidence of DVT after TKA is on approximately the eighth post-operative day. Since the Duplex scan was performed on the third to fifth post-operative days, it is possible that we underestimated the incidence of thrombosis. However, there were no patients with symptomatic DVT within six months of surgery.

There was a low rate of mortality, symptomatic pulmonary embolism and DVT when using a combination of aspirin and mechanical calf compression. However, there was a significantly lower rate of DVT using the RIAC. This may be the result of decreased venous stasis,[22] increased local fibrinolysis,[23] inhibition of the coagulation cascade,[24] or the enhancement of peak venous velocity as measured in the proximal deep venous system,[11] or a combination of several mechanisms. We now exclusively use the higher-flow RIAC device with aspirin for all patients who undergo primary unilateral, primary bilateral or revision TKA.

The authors wish to thank Dr D. Kirkendall for the statistical analyses and Elizabeth Soileau, RN for assistance with patient randomisation and follow-up. Research funds received from Aircast Summit, New Jersey provided salary support for the research nurses who coordinated the study.

No other benefits have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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