Incidence and natural history of deep-vein thrombosis after total hip arthroplasty

A PROSPECTIVE AND RANDOMISED CLINICAL STUDY

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There are many reports concerning the aetiology and prophylaxis of deep-vein thrombosis (DVT) but little is known about its natural history. The purpose of our study was to identify the incidence and site of DVT, the risk factors for pulmonary embolism and the natural history of DVT after total hip replacement (THR) in patients who do not receive any form of prophylactic or therapeutic treatment for DVT.

Two hundred patients who had a primary THR were included: 100 had one-staged bilateral THR and 100 had unilateral THR and 150 implants were cemented and 150 cementless. Coagulation assays, a full blood count, blood typing and serum chemical profile tests were performed for all patients on three separate occasions. Bilateral simultaneous or unilateral venograms were performed on the sixth or seventh postoperative day and perfusion lung scans preoperatively and on the seventh or eighth postoperative day. Further venograms were performed in all patients who had thrombi six months later.

In the patients with bilateral THR, 52 (26%) venograms were positive for thrombi, while in the patients with unilateral THR 20 (20%) were positive ($p = 0.89$). In the patients with a cemented THR, 31 venograms (20.7%) were positive for thrombi, while in those with a cementless THR 41 (27.3%) were positive ($p = 0.654$). Further venograms in all 72 patients who had thrombi at six months after operation showed that they resolved completely and spontaneously regardless of their site and size. No patients had symptoms of pulmonary emboli and none were seen on the perfusion lung scans. Two patients died from unrelated causes.

Although the prevailing opinion is that patients with proximal venous thrombosis should be treated with anticoagulants, our study has shown that all thrombi regardless of their site and size resolve spontaneously without associated pulmonary embolism.

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Deep-vein thrombosis (DVT) is a common complication of total hip replacement (THR). Its incidence after THR is reported to be as high as 70% without prophylaxis.¹⁻⁷

There are many reports concerning the aetiology and prophylaxis of DVT but surprisingly little is known about its natural history. Proximal thrombosis is an established cause of pulmonary embolism, but the importance of calf-vein thrombosis remains uncertain.^{8,9}

Many authors have recommended prophylaxis in order to reduce the incidence of postoperative DVT on the assumption that it will reduce the incidence of pulmonary embolism, the overall rate of mortality and the incidence of the postphlebotic syndrome.^{2,10-12} Routine thromboprophylaxis, however, has an associated morbidity.^{1,2,13} Furthermore, accurate figures for mortality from pulmonary embolism remain unavailable. Early estimates suggested an incidence as high as 3.4% after THR,^{2,12,14} but recent reviews have reported an incidence of less than 1% for both total hip and total knee replacements.^{5,15-17} Clarke et al¹⁸ and Murray, Carr and Bulstrode¹⁹ reported that the incidence of DVT after THR without prophylaxis was similar to that with prophylaxis.

The aim of our prospective study was to determine if unilateral and bilateral simultaneous THR resulted in different incidences of DVT in patients who did not receive prophylactic or therapeutic treatment against DVT. In addition, the incidence of DVT was compared between patients who received cemented and cementless stems. The most important aims were to identify the site of DVT, the risk factors for pulmonary embolism and the natural history of DVT.

Patients and Methods

A total of 281 consecutive patients who had primary THR between January 1998 and December 1999 were invited to

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participate in our study, which was approved by the Internal Review Board of our institution. Before they gave informed consent, the following information was provided to all patients.

'In Western patients, the incidence of DVT after THR without prophylaxis and that of fatal pulmonary embolism are approximately 70% and 1%, respectively. Therefore, most Western patients who have DVT are treated by anticoagulation, which can be associated with wound or intestinal haemorrhagic complications. In Korean patients, however, a low incidence of DVT and fatal pulmonary embolism has been reported⁵ and DVT would not be treated with anticoagulation therapy prophylactically or therapeutically in order to avoid haemorrhagic complications'.

All patients were informed that they would be investigated by venography on the sixth or seventh postoperative day for the development of DVT and that those who had evidence of thrombi would have another venogram six months later. All patients were also informed that the chance of developing a pulmonary embolism which proved fatal as a result of not treating a DVT was very slim. Twenty-one patients were excluded; 18 had technically inadequate venograms and three declined to enter the study. Subsequently, 200 patients were included and all provided informed consent; 100 had one-staged bilateral and 100 unilateral THR.

There were 52 men and 48 women with a mean age of 58.3 years (51 to 71) in the group with a bilateral THR and 54 men and 46 women with a mean age of 54.9 years (42 to 73) in the group with a unilateral THR.

In the 100 patients who had bilateral THR, one was cementless and one cemented and in the 100 patients who underwent THR, there were 50 cementless and 50 cemented replacements. Randomisation between cemented and cementless replacements in both groups was determined from a sequential pool maintained by statisticians, based on a table of randomised numbers. All randomisation procedures were performed in the operating theatre just before the operation. There was an equal chance of a cementless or a cemented replacement being performed first in a bilateral procedure. All patients were asked to discontinue taking aspirin or aspirin-containing compounds and any other antiplatelet medication 14 days before admission to hospital.

The diagnoses in both groups are shown in Table I. All operations were carried out by the senior author (YHK) under epidural normotensive anaesthesia. No patient wore elastic stockings or bandages either before or during the operation, or postoperatively. Two suction drains were placed in the wound; they were removed after 48 hours. Mobilisation started on the second postoperative day. No patient received prophylactic agents for DVT.

Coagulation assays (platelet count, prothrombin time, partial thromboplastin time, fibrinogen, anti-thrombin III and factor VIII), a full blood count, blood typing and serum chemical profile tests were performed on all patients on three separate occasions: on the day before the operation, on

Table I. The diagnoses in both groups, by number and *percentage*

Diagnoses	Bilateral group	Unilateral group
Osteonecrosis of femoral head	74 (74)	70 (70)
Alcohol abuse	43 (58)	42 (70)
Idiopathic	24 (32)	20 (29)
Steroid induced	7 (9)	3 (4)
Post-femoral neck fracture	-	5 (7)
Osteoarthritis	18 (18)	15 (15)
Rheumatoid arthritis	-	4 (4)
Multiple epiphyseal dysplasia	2 (2)	-
Congenital coxa vara	2 (2)	-
Ankylosing spondylitis	4 (4)	2 (2)
Femoral neck fracture	-	5 (5)
Developmental dysplastic hip	-	4 (4)

seventh postoperative days. Bilateral simultaneous or unilateral venograms were performed on the sixth or seventh postoperative days. The criterion for diagnosing DVT was a filling defect in a deep vein, or defects surrounded by a narrow rim of contrast material. The patients with thrombi had further venograms six months later to document the natural history of DVT. All patients with and without positive venograms were reviewed at six weeks, three months, six months, one year and yearly thereafter. The mean follow-up was 2.4 years (1.5 to 3). Any readmission for thromboembolic complications was recorded.

Variations in the anatomy of the superficial femoral and popliteal veins were studied, and the number of valves in the deep veins from the level of the popliteal fossa to the region of the ischial spine was recorded. The incidence of DVT was correlated with these two factors.

In all cases, ECG, chest radiography and serial measurements of blood gases and serum enzymes were performed. All patients had a standard perfusion lung scan performed preoperatively and on the seventh or eighth postoperative day and ventilation lung scans and pulmonary angiography were performed if the perfusion lung scan showed evidence of embolism.

The blood loss at operation was assessed from the weight of the swabs and by adding this to the amount obtained from wound suction. The total volume obtained by drainage was taken as the postoperative blood loss. The amounts of blood and blood products or blood substitutes used intraoperatively and postoperatively were recorded.

Statistical analysis was performed by the chi-squared test, Student's *t*-test and the Mann-Whitney U test.

Results

Of the 200 venograms in patients with bilateral THR, 52 (26%) were positive for thrombi, and of the 100 venograms in patients with unilateral THR, 20 (20%) were positive. This difference was not statistically significant ($p = 0.89$, confidence interval (CI) -0.105 to 0.113). In the bilateral group, venograms were positive in one limb in six patients (6%) and in both limbs in 20 patients (20%). No patient was

Table II. The sites of thrombi in patients with unilateral THR, by number and percentage

Site	Bilateral THR	Unilateral THR
Hips with no thrombi	148 (74)	80 (80)
Hips with thrombi		
Calf veins	22 (42.3)	8 (40)
Popliteal vein	8 (15.4)	3 (15)
Popliteal and calf veins	6 (11.5)	2 (10)
Femoral vein	6 (11.5)	3 (15)
Femoral and calf veins	6 (11.5)	2 (10)
Femoral, popliteal and calf veins	4 (7.8)	2 (10)
	52 (26)	20 (20)
Total	200 (100)	100 (100)

Table III. The sites of thrombi in patients with cemented and cementless THR, by number and percentage

Site	Cemented	Cementless
Calf veins	12 (38.7)	18 (43.9)
Popliteal vein	5 (16.1)	6 (14.6)
Popliteal and calf veins	3 (9.7)	5 (12.2)
Femoral vein	4 (12.9)	5 (12.2)
Femoral and calf veins	5 (16.1)	3 (7.3)
Femoral, popliteal and calf veins	2 (6.5)	4 (9.8)
Total	31 (100)	41 (100)

readmitted with symptoms related to thromboembolic disease between follow-up at three months and two years.

The sites of the thrombi in both groups are shown in Table II. In both groups, about 40% of thrombi were in calf veins; the rest extended proximally into the popliteal and/or femoral vein.

Of the 150 venograms in patients with a cemented replacement, 31 (20.7%) were positive for thrombi and of the 150 venograms in patients with a cementless replacement, 41 (27.3%) were positive. This difference was not statistically significant ($p = 0.654$; CI -0.187 to 0.066). In both groups, about 40% of thrombi were in calf veins (Table III).

Out of a total of 300 venograms, there were multiple superficial femoral veins in 156 limbs (52%), and of these 24 (15.4%) contained thrombi. This was a similar incidence ($p < 0.05$) to that seen in 23 of 144 limbs (16%) with a single superficial femoral vein. There were multiple popliteal veins in 183 limbs (61%); of these limbs, 14 (7.7%) contained thrombi. Of the 117 limbs with a single popliteal vein, 11 (9.4%) contained thrombi. This difference was not significant ($p < 0.05$).

Of all the limbs with detailed venography, 111 (49%) of 228 limbs which did not have a thrombus had more than five valves, whereas only 20 (28%) of 72 limbs which had a thrombus had more than five valves. A total of 52 of 72 limbs (72%) which had a thrombus had less than five valves. There was no correlation between the incidence of DVT and the number of valves ($p > 0.05$).

Using the Bonferroni method,²⁰ the alpha level of each individual test is adjusted downwards to ensure that the overall risk for a number of tests remains at 0.05. In our study, the alpha level should be <0.027 after 18 outcome

measures to have a statistical significance. Therefore, there was no relationship between DVT and the following factors: age (57.8 years in patients with thrombi v 55.4 years in those without); gender (27.4% of men v 18.1% of women); diagnosis (44% of hips with osteonecrosis had positive thrombi, 56% did not); venous anatomical variations; number of valves; the mean length of the operation (65.7 minutes v 72.8 minutes); mean amount of blood loss which was approximately the same in both groups; mean platelet count (288,266/ml and 266,576/ml); mean partial thromboplastin time (26.2 and 27.8 seconds); mean cholesterol level (229.4 mg/ml and 232.6 mg/ml); mean triglyceride level (247.6 mg/ml and 189 mg/ml); mean weight of patients (65.6 kg and 59.6 kg); mean preoperative hematocrit levels; mean preoperative levels of total protein and calcium; and the presence of hypertension.

The mean size of thrombus was 10.8 cm (5 to 25) in the bilateral group and 8.2 cm (2 to 18) in the unilateral group. This difference was not statistically significant ($p = 0.576$). The mean size of thrombus was 9.2 cm in the cemented group (5 to 18) and 9.8 cm (2 to 25) in the cementless group. This difference was also not statistically significant ($p = 0.586$).

Further venograms were performed at six months postoperatively for all 72 hips with associated thrombi and all completely resolved regardless of their site and size. No pulmonary embolism occurred as shown by abnormal perfusion lung scans and the absence of symptoms. Two patients died, one at seven months and one at ten months postoperatively. These patients had negative venograms and lung perfusion scans. The cause of death was not certain. It is possible that they had a fat embolism or thromboembolism despite a negative venogram. Two patients had skin necrosis as a local complication of the venography, caused by leakage of the contrast medium, and one had an allergic reaction to the contrast medium.

Discussion

There was a strikingly low incidence of DVT in our series and our findings confirm those of others^{5,16,18,19} who did not use thromboprophylaxis. Warwick et al¹⁶ reported a mortality rate within 90 days of THR of 1.3% (15 of 1162 patients) and Seagroatt et al²¹ reported a mortality rate of 1.1%. The mortality rate in our series was 1% (two of 200 patients). It is clear from all three studies that mortality figures of between 2.3% and 3.4% after THR^{2,14} are misleading. It should be noted that our patients and those reported by Warwick et al,¹⁶ and Seagroatt et al²¹ were not routinely given chemical thromboprophylaxis.

The place of thromboprophylaxis remains controversial. Despite pressure from lawyers and other branches of the medical profession,^{17,22} many orthopaedic surgeons are reluctant to use chemical prophylaxis because of doubts about its efficacy and possible haemorrhagic complications.²³ Charnley abandoned the use of phenindione

because the benefit from a reduction in the mortality rate due to pulmonary embolism was matched by an increased mortality from gastrointestinal haemorrhage.²⁴ Coventry et al² recommended postponing anticoagulation with warfarin until the fifth postoperative day, but this would have failed to prevent three of the four cases of fatal pulmonary embolism which were reported by Warwick et al.¹⁶ Meta-analysis shows that both low-dose, unfractionated and low-molecular-weight heparin substantially reduce the incidence of venographically demonstrated DVT after THR from about 45% to about 23%²⁵ and about 19%,²⁶ although with some haemorrhagic side-effects. This reduction in DVT has been extrapolated to imply a reduction in the incidence of fatal pulmonary embolism, but no study has been powerful enough to demonstrate this. It would require a randomised study of 28 000 patients to show halving of the rate of fatal pulmonary embolism from 0.34% to 0.17% at the 95% significance level with 80% power.

Seagroatt et al²¹ reported a readmission rate for symptomatic thromboembolic complications of 0.73% within 28 days of discharge after THR. Warwick et al¹⁶ reported a readmission rate of 1.39%. The readmission rate for our patients for the same period was 0%. It is uncertain whether the thrombi leading to readmission were present but symptomless at the time of discharge, or whether they developed later. There is no evidence to suggest that prolonged prophylaxis may influence the development of such late complications, and no cost-benefit or risk-benefit studies have been published to support such a policy.

In our study, it emerged that some of the factors widely believed to be associated with DVT did not appear to be so. Despite the common belief, none of the following factors were found to be associated with DVT: advanced age, the underlying disease, one-staged bilateral THR, venous anatomical variations, the number of venous valves, the coagulation assay data, blood type, hypertension, choice of cemented or cementless replacement, the technical difficulty and length of the operation, the amount of operative blood loss and the amount of blood transfused.

Most authors agree that patients with proximal thrombi are at risk for symptomatic pulmonary embolism,^{8,9,27-29} but the clinical significance of calf thrombi is disputed. Some authors consider that asymptomatic calf thrombi pose little or no increased risk,^{8,9,28,30} but others report that patients with calf thrombi have an increased risk of asymptomatic pulmonary embolism.^{27,31}

In order to develop an effective management protocol for thromboembolic disease, the natural history of calf and proximal thrombi must be defined. Kakkar et al²⁷ used venography and serial fibrinogen imaging to evaluate the progress of calf thrombi in a group of postoperative patients. They found that 23% of calf thrombi propagated to the proximal veins. Doouss³¹ performed a similar evaluation and found a propagation rate of 5.6%.

Our study indicates that patients with calf thrombi have no increased risk for either asymptomatic or symptomatic

pulmonary emboli compared with those without thrombi. Contrary to the findings of previous studies,^{4,27-31} we found no evidence of either asymptomatic or symptomatic pulmonary embolism in patients with proximal thrombi.

In addition to their site, the size of the thrombus may also be important. Some authors have shown that thrombi larger than 5 mm are more likely to propagate and embolise.^{27,32} Our data support those^{28,30} who have suggested that thrombi in the calf, whether large or small, are unlikely to produce symptomatic emboli and these patients do not require anticoagulation. It has been suggested that thrombi in the calf are securely attached and resolve spontaneously and rapidly.²⁷ Our study confirmed that all calf thrombi resolved spontaneously as shown by venography at six months after operation. If they do not embolise, they are too small to produce symptoms and only a few are detected by ventilation-perfusion lung scanning.²⁸ We found that thrombi often develop in the thigh after THR (57.7% in the bilateral and 60% in the unilateral group). However, thrombi in the popliteal and femoral veins also completely resolved spontaneously.

It has been reported that a positive ventilation perfusion lung scan in asymptomatic patients is a significant finding.³³⁻³⁵ However, these authors also observed that about one in six patients have an abnormal lung scan after total knee or total hip surgery. Therefore, a lung scan may not be a useful screening test. Contrary to previous reports, no patient in our series had an abnormal lung scan. We suspect that the size of emboli was too small to be detected by lung scanning.

Although the prevailing opinion is that patients with a proximal thrombus should be treated with anticoagulants, our study has shown that all thrombi regardless of their site or size resolved completely and spontaneously without causing pulmonary embolism.

Our study has some limitations. First, the number of patients is small. Secondly, the incidence and natural history of venous thrombosis and pulmonary embolism would seem to be different in Korean patients when compared with Western patients.

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