

THE FREQUENCY OF VENOUS THROMBOSIS IN CEMENTED AND NON-CEMENTED HIP ARTHROPLASTY

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We randomised 250 patients undergoing unilateral, elective hip arthroplasty for osteoarthritis to receive either a cemented or a non-cemented Mallory Head prosthesis. Aspirin was used as prophylaxis against thromboembolism during the first half of the study and adjusted-dose warfarin during the second half. Postoperatively, all patients were asked to have bilateral venography and 80% agreed. All were evaluated clinically for pulmonary embolism.

There was no difference in the frequency of deep-venous thrombosis between the two groups (50% cemented v 47% non-cemented, $p = 0.73$; 95% CI of the difference -13.6% to 19.3%). Three of the 64 patients (5%) in whom venography had demonstrated isolated distal thrombi developed pulmonary emboli.

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In the absence of prophylactic therapy, deep-venous thrombosis (DVT) occurs in approximately 50% and pulmonary embolism in 5% of patients after elective hip replacement (Imperiale and Speroff 1994; MacMahon et al 1994). The results of two prospective studies have suggested that DVT may occur more often in cemented than in non-cemented hip and knee arthroplasty. Francis, Marder and Evarts (1986) found no thrombi on bilateral venography in 23 patients with a non-cemented hip prosthesis compared with 4 out of 13 (31%) in those with a cemented prosthesis. The mean age of their patients, however, was 72 years in the cemented and 55 years in the non-cemented group ($p < 0.005$). Using unilateral venography, Lynch et al (1988) found an incidence of thrombosis of 32% in non-cemented and 49% in cemented knee prostheses ($p < 0.05$). The patients were not randomised to a cemented or non-cemented prosthesis in either study. We report the results of a randomised trial comparing the incidence of DVT in cemented and non-cemented hip arthroplasty.

PATIENTS AND METHODS

We randomised 250 patients undergoing unilateral, elective hip arthroplasty for osteoarthritis to receive either a cemented or a non-cemented Mallory head prosthesis (Biomet, Warsaw, Indiana) as part of an ongoing trial (Laupacis et al 1993). Randomisation was stratified by age and surgeon. The operation was undertaken by one of two surgeons (CR or RB) using a direct lateral approach. The cement used was surgical Simplex P (Howmedica Inc, Limerick, Ireland), vacuum-mixed and pressurised with a distal cement plug. Initially, aspirin (325 mg twice daily) was used as prophylaxis against thromboembolism but this was changed to adjusted-dose warfarin about half-way through the study. All asymptomatic patients were placed on aspirin, 325 mg twice daily for six weeks, at the time of discharge. Patients with asymptomatic distal thrombi were not treated with warfarin after discharge.

Informed consent was obtained from all patients before venography. On the sixth postoperative day all patients who consented (80%) had conventional bilateral lower-limb venography (Rabinov and Paulin 1972). The venogram was read by one of two radiologists (RR or ADV). Thrombi were diagnosed as proximal if they occurred in the popliteal vein or the more proximal deep veins and distal if they

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Table I. Details of 250 patients who received either a cemented or non-cemented prosthesis

	Cemented (n = 124)	Non-cemented (n = 126)
Mean age in years (\pm SD)	63.9 \pm 7.6	63.9 \pm 7.4
Male (%)	51.6	54.0
DVT prophylaxis (%)		
Aspirin	47.6	46.0
Warfarin	41.6	42.9
Both	8.1	7.9
Neither	3.2	3.2
Anaesthesia (%)		
General	85.5	90.5
Spinal	14.5	9.5
Previous DVT/PE (%)	3.2	4.8

cemented v 47% non-cemented, $p = 0.73$; 95% CI of the difference -13.6% to 19.3% ; Table II).

Five patients had proximal thromboses and 68 had distal thromboses. DVT was present in the non-operated leg only (and absent in the operated leg) in 1 of 5 patients (20%) shown to have a proximal thrombosis and 18 of 68 patients (26%) with a distal thrombosis. Sixty-four patients had isolated distal venous thrombi. Four patients had post-operative non-fatal pulmonary emboli which occurred at 6, 6, 9 and 14 days after operation. Venography had shown a distal thrombosis in three patients, and was technically inadequate in the fourth.

Table III compares the details of the patients who developed venous thrombosis with those who did not. There was

Table II. Frequency of DVT or pulmonary embolism

	Cemented		Non-cemented		p value
	Number	Percentage	Number	Percentage	
Proximal DVT	2/67	3.0	3/63	4.8	0.67
Distal DVT	36/72	50.0	32/69	46.4	0.67
Any DVT	36/72	50.0	33/70	47.1	0.73
Pulmonary embolism	3/124	2.4	1/125	0.8	0.37

occurred in any of the anterior tibial, posterior tibial, peroneal or sural veins. In addition to the routine investigation, all patients who developed any symptoms or signs suggestive of postoperative DVT were also investigated by venography. There was no routine surveillance for pulmonary emboli. Patients in whom there was any clinical suspicion of pulmonary emboli had a lung scan and, if necessary, pulmonary angiography.

All patients were seen at six weeks and at three and six months after surgery, at which time they were asked about any admissions to hospital since they had last been reviewed.

Statistical analysis used the chi-squared and Fisher's exact tests to compare proportions and Student's *t*-test to compare means.

RESULTS

Table I gives the details of the two groups of patients. Their mean age was 64 years, 53% were male, 47% received aspirin prophylaxis, 42% had warfarin prophylaxis, and 8% were given both. There was a history of a previous venous thrombosis or pulmonary embolism in 4%, and 88% had general anaesthesia.

Of the 250 patients, 199 (80%) agreed to have venography on one or both legs. In 126 (63%) bilateral venography was successfully performed and felt to be technically adequate on both sides. Ipsilateral venography was successfully undertaken in 24 (12%). There was no difference in the frequency of DVT in the two groups (50%

Table III. Details of 142 patients with and without DVT

	DVT (n = 69)	No DVT (n = 73)	p value
Mean age in years (\pm SD)	65.3 \pm 6.5	63.0 \pm 8.2	0.06
Male (%)	55.1	53.4	0.84
DVT prophylaxis (%)			
Aspirin	46.4	58.9	0.08*
Warfarin	43.5	28.8	
Both	10.1	8.2	
Neither	0.0	4.1	
Anaesthesia (%)			
General	87.0	83.6	0.57
Spinal	13.0	16.4	
Previous DVT/PE (%)	2.9	6.8	0.44

* aspirin v warfarin or both

no statistically significant difference between the groups for any of the variables, although there was a trend for those with a thrombosis to be older and more likely to have had warfarin.

DISCUSSION

This is the first study in which a large number of patients undergoing primary elective total hip arthroplasty have been randomised to receive a cemented or non-cemented prosthesis. Not all patients had venography, but the nature of the trial should have precluded bias for or against venography in the cemented and uncemented groups. We found no statistically or clinically significant differences in

the frequency of thrombosis between the two groups. The 95% confidence limits around the difference of 3% are reasonably wide, however, suggesting that the frequency of thrombosis could have been as much as 14% higher in the non-cemented or 19% higher in the cemented group. Thus, the replication of our study is desirable.

Hull et al (1990) found similar results to ours while Francis et al (1986) and Lynch et al (1988) found a higher frequency of thrombosis in patients who received a cemented arthroplasty. Francis et al studied only 36 patients and did not randomise patients to the type of arthroplasty. The baseline characteristics of the two groups were therefore not similar; for example, there was a mean difference of 17 years in age. Similarly, Lynch et al did not randomise patients to the type of prosthesis and did not give details of those who received cemented and non-cemented prostheses. Thus, our study provides more rigorous data regarding the effect of the type of prosthesis on thrombosis.

Aspirin was the antithrombotic agent used during the first half of the study, after which adjusted-dose warfarin was used. It is surprising that there was a non-statistically significant trend towards a lower rate of thrombosis in those treated with aspirin compared with those receiving warfarin. The results of a recent meta-analysis indicated that warfarin is more effective than aspirin in decreasing the risk of thrombosis after hip arthroplasty (Imperiale and Speroff 1994) although aspirin certainly has some effect (MacMahon et al 1994). The apparent superiority of aspirin in our study may have been due to chance, or suboptimal anticoagulation with warfarin (the postoperative International Normalised Ratio values were not available). This should not have affected the comparison of cemented with non-cemented prostheses, however, since the use of anti-thrombotic agents was similar in the two groups.

Patients with asymptomatic distal thrombi were not treated with warfarin after they were discharged. Three of the

64 patients in whom venography demonstrated isolated distal thrombi (5%) developed pulmonary emboli, raising the question as to whether such patients should have been treated with warfarin after discharge. To our knowledge, there is no evidence from a randomised trial as to whether the benefits of anticoagulating all patients with asymptomatic distal thrombi (a decrease in subsequent pulmonary emboli) outweigh the risks (the side-effects of venography and an increase in bleeding complications).

Conclusions. In this study of 250 patients randomised to receive a cemented or non-cemented hip prosthesis, we found no difference in the frequency of DVT between the two groups. The decision on whether to use a cemented or non-cemented prosthesis should be made on other grounds.

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