Prevention of pulmonary embolism by a foot sole pump

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We carried out a prospective, randomised study of 62 patients to determine the efficacy of a foot sole pump (the A-V Impulse System) for the prevention of pulmonary embolism (PE) after hip surgery. PE was assessed by pulmonary perfusion scintigraphy before and after operation. We defined a PE as any new scintigraphic defect which was larger than a bronchopulmonary segment.

The incidence of PE was 55% in the control group and 21% in the treatment group. The foot sole pump significantly reduced the incidence of PE ($p = 0.008$) and we encountered no side-effects from its use.

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Deep-vein thrombosis (DVT) and pulmonary embolism (PE) are major complications of hip surgery. Imperiale and Speroff¹ reviewed 25 randomised trials and reported an incidence of DVT after elective hip replacement of 23% when prophylaxis was not used. The incidence of PE was 4%. Collins et al² reviewed 12 randomised trials and reported that the incidence of fatal PE was 1.65%. Because of this potentially fatal complication routine prophylaxis after total hip replacement (THR) is therefore recommended.

Sevitt and Gallagher³ first demonstrated the advantages of prophylaxis by using phenindione. Since then many different prophylactic methods, both mechanical and chemical, have been described. Chemical methods include the use of low-dose heparin, low-molecular-weight heparin and mini-dose oral anticoagulation. Mechanical techniques involve the use of graduated, elastic compression stockings or a foot sole pumping system.

The optimum method of prophylaxis is controversial. Although chemical prophylaxis, particularly with low-molecular-weight heparin, can reduce the incidence of DVT after hip surgery,⁴ there is a risk of haemorrhagic complications. This is not the case with mechanical methods.

In 1983, Gardner and Fox⁵ described a previously unrecognised physiological pumping mechanism in the sole of the foot which is activated by weight-bearing. The A-V Impulse System (Novamedix, Andover, UK) is designed to simulate this physiological action in the bedridden patient. It comprises an electrically-driven air compressor which intermittently inflates a pneumatic pad which is applied to the sole of the foot. On inflation to a pressure of 130 mmHg, the pad flattens the plantar arch and causes a sudden and intermittent increase in venous flow. The pad deflates one second later. This cycle is repeated every 20 seconds, thereby allowing the venous plexus to refill.

Several randomised studies have shown that the system is an effective prophylaxis against thromboembolism after orthopaedic surgery.⁶⁻⁹ In these studies, venous thrombosis was evaluated by venography or ultrasound, and the incidence of PE was not established.

Our aim was to assess the efficacy of the A-V Impulse System in reducing the incidence of PE after surgery on the hip.

Patients and Methods

Between February 1999 and December 1999, we carried out 62 hip procedures on seven men and 55 women with a mean age of 55.4 years (18 to 88). All the patients were studied prospectively to determine the incidence of PE. None had a past history of DVT or PE. They were randomly divided into control and treatment groups.

Table I gives the details of the patients. The control group consisted of two men and 18 women with a mean age of 52.5 years (18 to 78). Of these, 15 had a total hip replacement (THR), four had a rotational acetabular osteotomy (RAO) and one a revision THR. In the treatment group there were five men and 37 women with a mean age of 57 years (19 to 88). Of these 27 had a THR, 11 an RAO and four a revision THR.

Both groups were well matched for age, gender, body

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Table I. Details of the 42 patients in the foot sole pump group and the 20 in the control group who wore elastic compression stockings

	Treatment	Control
Mean (SD) age in years	57.0 (17.5)	52.5 (20.7)
Gender		
Male	5	2
Female	37	18
Mean ($\pm$ SD) body mass index	22.6 (2.8)	23.1 (3.8)
Mean ($\pm$ SD) operation time in minutes	145 (51)	158 (74)
Side		
Left	18	8
Right	24	12
Procedures		
THR	27	15
RAO	11	4
Revision THR	4	1

mass index, operation time, side and surgical procedure. There was no significant difference in the mean values for bleeding time, prothrombin time, activated partial thromboplastin time, and fibrinogen, antithrombin-III and D-dimer levels using a two-sample *t*-test ($p > 0.05$) between the two groups.

All the patients gave informed consent and perfusion scintigraphy was undertaken before operation. An elastic bandage was applied to the opposite limb before surgery and also to the operated limb after surgery. Those in the treatment group received continuous mechanical prophylaxis with the foot sole pumping system while in bed. Patients who had had a THR were in bed for two days, those who had an RAO for a week and those with a revision THR for either two days or a week. The patients in the control group received only elastic bandages after surgery.

Pulmonary perfusion scintigraphy was undertaken one week after the operation. The scintigraphs were reported by two independent radiologists who did not know to which group the patients belonged. We defined PE as a new defect which was larger than a bronchopulmonary segment. To quantify the size of PE we defined the PE score as the number of segments affected. Defects smaller than a segment were counted as 0.5.

For statistical analysis we used the chi-squared test to test proportions and Welch's *t*-test to compare the distribution of scores with a value of $p < 0.05$ being considered as statistically significant.

Results

The findings of postoperative perfusion scintigraphy are given in Table II. The incidence of PE was 55% (95% confidence interval (CI) 31 to 79) in the control group and 21% (95% CI 9 to 34) in the treatment group. The incidence of PE was significantly reduced in the treatment group ($p = 0.008$, 95% CI 8.5 to 58.7).

The mean PE score of the treatment group was 0.31 (95% CI 0.16 to 0.46) and that of the control group 1.21 (95% CI 0.41 to 2.14). The PE score of the control group was significantly larger than that of the treatment group ($p = 0.032$, 95% CI 0.36 to 1.57).

Only one patient in the control group had chest pain, with a large PE four days after operation. The others had no symptoms. No patient had side-effects with the foot sole pumping system.

Discussion

The incidence of PE of 55% in our control group confirms the high risk after hip surgery for patients who had only prophylaxis with elastic bandages. The incidence of PE without prophylaxis after elective hip replacement has been reported to be about 4%.¹ It is higher in our patients because they were evaluated by pulmonary perfusion scintigraphy, which can detect small emboli. Perfusion scintigraphy is not absolutely reliable since it sometimes demonstrates fibrillation of vessels caused by local hypoventilation.

Small pulmonary emboli may cause no symptoms and require no treatment. However, a reduction in small emboli leads to a reduction in large emboli. Consequently, the evaluation of PE by perfusion scintigraphy is of some significance. Our patients showed a high incidence of PE and confirmed the necessity for prophylaxis although the best method still remains controversial.

The A-V Impulse System has been shown to maintain the venous circulation as effectively as normal walking. It reduces the incidence of DVT by pneumatically compressing the venae comitantes of the lateral plantar artery, thereby increasing the velocity of blood in the proximal, axial veins. This fully opens the venous valves and removes the relatively stagnant blood from within the valve sinuses in which DVT is thought to originate.¹⁰ Andrews et al¹¹ reported that increased blood flow is best achieved by high-pressure low-frequency foot compression. Increasing the duration of compression beyond one second has no effect

Table II. The incidence of PE (%) and the mean PE score (95% CI) in both groups

	Treatment group	Control group	p value	95% CI for difference
Incidence of PE (%) (95% CI)	21 (9 to 34)	55 (31 to 79)	0.008	8.5 to 58.7
Mean PE score (95% CI)	0.31 (0.16 to 0.46)	1.28 (0.41 to 2.14)	0.032	0.36 to 1.57

on the blood flow in the deep veins. It was for this reason that we selected a foot compression pressure of 130 mmHg, a compression frequency of three cycles per minute with a duration of one second.

Several randomised trials have shown that the A-V Impulse System is an effective device for prophylaxis against thromboembolism in orthopaedic patients. Wilson et al⁶ reported that the incidence of major DVT after TKR was reduced from 59.4% in a control group to 17.8% in a pumped group, with a decrease in proximal thrombosis from 18.7% to 0%. Fordyce and Ling⁷ also showed a significant reduction in venographically-proven DVT after THR, from 40% in a control group to 5% in a group treated by the A-V Impulse System. Bradley et al⁸ reported a significant reduction in venographically-proven DVT after THR from 27% in a control group to 6.6% in a group treated by the A-V Impulse System. Santori et al⁹ reported a reduction of major DVT detected by venography and ultrasound after THR from 24.5% in a control group to 4.5% in a group treated by the foot sole pump.

Low-molecular-weight heparin is currently one of the most effective and widely used prophylactic measures against thromboembolism. Warwick et al¹² compared the A-V Impulse System and low-molecular-weight heparin for the prevention of DVT after THR and reported that the incidence of DVT was 18% in the foot pump group and 13% in a group treated with enoxaparin. The difference was not significant. There were more side-effects in the soft tissues in the patients who received enoxaparin than in those who used the A-V Impulse System. There was also more bruising of the thigh and oozing of the wound ($p < 0.001$), greater postoperative drainage (578 v 492 ml, $p = 0.014$) and increased thigh swelling (20 mm v 10 mm, $p = 0.03$) in the enoxaparin group.

Hull et al¹³ reported the efficacy and complications of prophylaxis with low-molecular-weight heparin or warfarin. The rate of major bleeding was 1.2% in the group which received warfarin and 2.8% in those who had low-molecular-weight heparin. Wound haematomas developed in 4.0% of those who received warfarin and in 7.1% of those who had low-molecular-weight heparin.

Chemical prophylaxis may cause haemorrhagic complications which are avoided when using the A-V Impulse System. Its use can significantly reduce the incidence of PE after hip surgery.

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