PROPHYLAXIS AGAINST DEEP-VEIN THROMBOSIS IN TOTAL HIP REPLACEMENT

COMPARISON OF HEPARIN AND FOOT IMPULSE PUMP

F. S. SANTORI, A. VITULLO, M. STOPPONI, N. SANTORI, S. GHERA

From San Pietro Fatebenefratelli Hospital, Rome, Italy

We performed a randomised controlled study to compare heparin with the A-V Impulse System in the prevention of deep-vein thrombosis (DVT) in 132 consecutive patients undergoing total hip replacement. After the operation, all patients had compression stockings, 65 were treated with calcium heparin and 67 with the intermittent plantar pump. DVT was diagnosed by Doppler ultrasound and thermography, followed by phlebography.

There were 23 cases of DVT (35.4%) in the heparin group, with 16 major and seven minor thromboses. In the impulse pump group there were nine cases (13.4%) with three major and six minor thromboses. The differences for all thromboses and for major thromboses were both significant at \( p < 0.005 \). In the heparin group there was one fatal pulmonary embolism and nine patients (13.8%) had excessive bleeding or wound haematomas, as against none in the impulse pump group.

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There is a high incidence of deep-vein thrombosis (DVT) after total hip replacement (THR), up to 70% in the absence of any prophylaxis (Bergqvist 1983). Subclinical pulmonary emboli (PE) can be detected in over 23% of cases (Harris et al 1984), with a mortality of 1% to 2% (Johnson, Green and Charnley 1977). The incidence of PE is even higher in emergency hip surgery, reaching 4% to 7% (Hull and Raskob 1986). DVT is more probable in elderly or obese patients and in those with a previous history of thromboembolism, varicose veins or a malignant neoplasm and in those taking oral oestrogen (Kakkar et al 1970; Sikorski, Hampson and Staddon 1981). Many patients who have a symptomless DVT develop clinical symptoms later, and suffer from a chronic postphlebitic syndrome (Killewich et al 1985).

DVT is most commonly secondary to blood stagnation in calf veins and the valve pockets of popliteal and femoral veins (Gibbs 1957; Sevitt and Gallagher 1961). Venous stasis occurs both during anaesthetic induction and during the operation (Cotton and Roberts 1977). This is one of the principal pathogenetic factors, together with hypercoagulation due to trauma and surgical stress. Endothelial damage is also a factor and it has been shown that the femoral veins are twisted and possibly damaged during a THR (Planès, Vochelle and Fogala 1990). This favours the development of the proximal thrombi which have been found to cause 75% of fatal pulmonary emboli (Havig 1977). The presence of all these factors confirms that pharmacological or mechanical prophylaxis or both is justified for all patients having a THR.

When calcium heparin is administered subcutaneously, the incidence of DVT has been reported to vary between 28% and 73% (Harris et al 1972; Evarts and Alfidi 1973; Kakkar et al 1985), but when the measured prothrombin time is maintained at between 31.5 and 36 seconds this is reduced to 13% (Leyvraz et al 1983). Other authors have reported that a combination of calcium heparin and dihydroergotamine was associated with an incidence of DVT of 24% to 59% (Fredin, Gustafson and Rosborg 1984; Kakkar et al 1985). The more recent use of low-molecular-weight heparin (Turpie et al 1986; Lassen et al 1991) and the associated use of calcium heparin and antithrombin III (Francis et al 1990) have produced encouraging results with reduction in the
incidence of DVT to 11% to 31% and 4.9% respectively. Both of these methods, however, were associated with a considerable incidence of bleeding and wound haematoma (14.3% and 10%).

In 1983, Gardner and Fox first showed the existence of a physiological venous pumping mechanism in the foot. Phlebographic studies indicate that the large plantar venous system (Fig. 1a) is rapidly emptied when weight-bearing flattens the plantar arch (Fig. 1b). The pulsatile flow produced by walking appears to flush out the valve pockets higher in the limb. The A-V Impulse System (Fig. 2; Novamedix, Andover, UK) was designed to produce the same effect by external pressure. Early reports have shown it to be effective in reducing the incidence of proximal DVT from 32.5% to 5% after THR (Fordyce and Ling 1992), from 23% to 0% after hemiarthroplasty for hip fracture (Stranks et al 1992) and from 18.7% to 0% in total knee replacement (Wilson et al 1992). The combination of heparin and the A-V Impulse System has been compared with heparin alone in 74 patients undergoing hip arthroplasty (Bradley, Krugener and Jager 1993). These authors showed a 25% incidence of proximal DVT in the heparin-treated group, compared with 6.6% in the group treated with heparin and impulse pumping.

We could find no report of a direct comparison between heparin and the A-V Impulse System and therefore designed a randomised study.

PATIENTS AND METHODS
Between June 1990 and December 1991, we studied a consecutive series of 132 patients undergoing primary THR under general anaesthesia by a direct lateral approach (Hardinge 1982). The prostheses used were the un cemented Zimmer Anatomic (Zimmer, Warsaw, Indiana), the cemented Exeter-Howmedica (Howmedica International) or a hybrid prosthesis (Harris-Galante acetabular cup, Exeter femoral stem, Zimmer), chosen according to clinical and radiographic criteria.

We excluded patients with a previous history of thromboembolism, varicose veins, venous insufficiency in the legs, or the presence of a malignant neoplasm.

All patients gave informed consent, and on admission to the study, were randomly allocated to receive either pharmacological or mechanical prophylaxis. Randomisation was by a casual numbers table, using sequentially numbered, sealed envelopes. All patients were measured for compression stockings before operation; these were put on to both legs immediately after the completion of surgery.

Pharmacological prophylaxis was by 5000 IU of calcium heparin given subcutaneously three times a day for ten days, starting on the day before the operation. Mechanical prophylaxis was by the fitting of the A-V Impulse System to both feet immediately after the operation. The inflatable pad is placed beneath the plantar arch over the compression stocking and held in place by the retaining slipper. The pads are then connected to the air-impulse generator. This rapidly inflates the pads and then deflates them fully after three seconds. The cycle is repeated at approximately 20-second intervals, the time...
needed to allow the venous plexus of the foot to refill before the next impulse. To facilitate this the feet are kept below the level of the right atrium. Use of the A-V Impulse System continued for seven to ten days. For both groups, physiotherapy with mobilisation of the limb in bed began on the second postoperative day. Patients began walking on the fourth or fifth postoperative day. The foot pump was functional during the entire period in bed; impulse pumping was interrupted only for physiotherapy treatment or when the patient was walking.

**Diagnosis of DVT.** All patients were screened for DVT at eight to ten days postoperatively by liquid crystal thermography and by Doppler ultrasound. Patients in whom the Doppler tests were positive and all doubtful cases with positive clinical signs but a negative Doppler test had phlebography to determine the location and size of any thrombi. Phlebography was performed in 31 of the heparin group and 17 of the impulse pump group. In the group not having early phlebography none had developed any signs or symptoms of DVT by the six-week review. We have assumed negative findings in those not investigated. We defined major thrombi as those involving proximal veins (iliac, femoral, popliteal) or those in the calf shown to be longer than 5 cm. Minor thrombi were recorded when calf thrombi were less than 5 cm in length.

At six weeks after operation, all patients were again assessed using the same methods. Statistical analysis of the results used the chi-squared test.

**RESULTS**

The two groups of patients were well matched for age, sex, indication for THR, duration of operation, total blood loss and amount of blood transfused (Table I).

**Table I. Details of patients in the heparin and A-V Impulse System groups**

<table>
<thead>
<tr>
<th></th>
<th>Heparin (n = 65)</th>
<th>A-V Impulse System (n = 67)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male:Female</td>
<td>15:50</td>
<td>19:48</td>
</tr>
<tr>
<td>Mean age (yr)</td>
<td>69.8 (SD 6.22)</td>
<td>72.4 (SD 6.65)</td>
</tr>
<tr>
<td>Indication for THR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>47</td>
<td>49</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Avascular necrosis</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Duration of operation (min)</td>
<td>65 (SD 9.89)</td>
<td>70 (SD 11.98)</td>
</tr>
<tr>
<td>Mean total blood loss (ml)</td>
<td>520 (SD 189.16)</td>
<td>490 (SD 195.27)</td>
</tr>
<tr>
<td>Mean volume transfused (ml)</td>
<td>300 (SD 267.7)</td>
<td>308 (SD 289.15)</td>
</tr>
</tbody>
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The phlebographic findings in the two groups are shown in Table II. In the heparin group there were 16 major DVTs, 11 proximal, three distal and two both proximal and distal. In the A-V Impulse group there were three major DVTs, two proximal and one distal. The differences for all thromboses and for major thromboses were highly significant at p < 0.005.

In the heparin group there was one death due to PE and one patient with pulmonary problems due to microemboli. Nine patients had either bleeding problems or wound haematoma or both. In the A-V Impulse group, three patients developed complications due to the pump; one had superficial skin abrasions on the dorsum of the foot and two had sores in the heel and malleolar regions. These were caused by poor fitting of the slippers, which have since been modified. We found no significant relationship between the incidence of DVT in either or both groups and length of operation or the indication for operation (osteoarthritis or rheumatoid arthritis).

**DISCUSSION**

Without prophylaxis up to 70% of patients having major hip surgery will have a DVT. There is ample evidence that low-dose heparin can reduce this incidence, but with an increased risk of major bleeding. This also applies to the newer low-molecular-weight heparins (Drug and Therapeutics Bulletin 1993).

Interest in mechanical methods of prophylaxis is increasing, since they may be as effective as heparin but with fewer disadvantages. Elastic compression stockings reduce the diameter of vessels and increase the velocity of returning venous blood. Electrical stimulation of leg muscles also increases return velocity but is painful and not well tolerated after operation (Browne and Negus 1970). There are a number of systems which provide intermittent pneumatic compression. These help to empty veins and also to release endothelial factors which stimulate fibrinolysis, but they do not reproduce the physiological mechanisms of venous return (Carn, Miranda and Greene 1986).

The discovery of a physiological pump in the foot which is activated by flattening the plantar arch has led to the development of an apparatus which can provide intermittent plantar compression. This mimics the haemodynamic effects of walking and has been shown to eject venous blood towards the heart with sufficient force to overcome a cuff around the calf inflated to a pressure of 100 mmHg (Gardner and Fox 1993). These origins have used fluoroscopic phlebography to show that such intermittent compression of the venous foot pump creates
turbulent flow in valve pockets, at the most common location for thrombus formation. They have also shown that use of the device induces a hyperaemic state with a reduction in peripheral resistance and an increase in arterial flow (Gardner and Fox 1993).

Other recent studies have shown that shear forces on venous endothelial cells cause the release of endothelial-derived relaxing factor (EDRF). This diffuses into arteriolar afferents, relaxing their musculature and thereby augmenting blood flow (Griffith and Randall 1989; Falcone and Bohlen 1990; Morgan et al 1991). EDRF inhibits platelet aggregation and probably stimulates disaggregation (Griffith and Henderson 1989).

The use of an intermittent impulse device has also been shown to reduce postoperative oedema and pain. Oedema may itself cause a reduction in arterial flow and venous emptying, while venous congestion lowers pH, which contributes to the development of pain (Gardner et al 1990). The removal of accumulated fluid from the calf also lowers compartment pressures and reduces the risk of compartment syndromes (Bourne and Rorabeck 1989; Gardner et al 1990).

The efficacy of the A-V Impulse System has been shown for hip and knee surgery but we are aware of no previous comparison between the use of this system and heparin. The results are encouraging. The findings of others are confirmed, particularly for the important reduction in proximal thrombosis. For major thromboses, the results were significantly better than those for heparin and there were other advantages: the risk of excessive bleeding is avoided, the system is easily used and well tolerated by patients and postoperative pain is reduced. Because of the potential complications of pharmacological prophylaxis, it seems that impulse pumping may become the treatment of choice for the prophylaxis of DVT and PE.

Further investigations are required. These include the study of the combination of mechanical methods with pharmacological prophylaxis by low-dose subcutaneous heparin and the effect of starting impulse pumping during operation rather than immediately after completion. Studies are also required of its efficacy in other orthopaedic conditions and procedures, such as osteosynthesis of the neck of the femur, fractures of the lower limb and osteotomies, tumour surgery and limb replacement.

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REFERENCES


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