A randomised comparison of a foot pump and low-molecular-weight heparin in the prevention of deep-vein thrombosis after total knee replacement

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Patients who undergo total knee replacement (TKR) are at high risk of venous thromboembolism. Low-molecular-weight heparins (LMWH) are the most suitable chemical prophylactic agents but there are some uncertainties about their safety and effectiveness. The foot pump offers an alternative.

We randomised 229 patients undergoing primary, unilateral TKR to receive either the A-V Impulse foot pump or enoxaparin, a LMWH. Ascending venography was undertaken between the sixth and eighth postoperative day in 188 patients without knowledge of the randomisation category. The prevalence of venographic deep-vein thrombosis was 58% (57/99) in the foot-pump group and 54% (48/89) in the LMWH group which was not statistically significant. There were four cases of proximal thrombi and two of fatal pulmonary emboli in the foot-pump group and none in the LMWH group. There were fewer haemorrhagic complications and soft-tissue effects in the foot-pump group.

We conclude that the neither method provides superior prophylaxis.

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Thromboprophylaxis is used to reduce symptomatic venous thromboembolism (VTE) after total knee replacement (TKR). The choice of prophylaxis should depend primarily on two factors: evidence of efficacy and lack of side-effects. In the absence of symptomatic outcome studies, we rely on radiological indicators which, despite their drawbacks, allow us to make reasonable assumptions and comparisons. Without prophylaxis, the prevalence of venographic deep-vein thrombosis (DVT) is about 60%. Low-molecular-weight heparin (LMWH) is the most effective prophylactic chemical agent although even with this treatment there is a prevalence of DVT of 29% to 32%.

The knee has a thin soft-tissue envelope within which a haematoma can be disastrous. The question arises as to whether LMWH therapy is safe after TKR. There are only two placebo-controlled studies, neither of which shows an increase in major bleeding with LMWH. Hull et al have shown, however, that LMWH is associated with more haemorrhagic complications than warfarin.

Since there remains a substantial incidence of DVT with LMWH therapy, and there is a potential for bleeding complications, we should seek both more effective and safer forms of prophylaxis. Mechanical methods may be more suitable.

The A-V Impulse System (Novamedix, Andover, UK) was developed after studies which showed that a venous plexus in the sole of the foot expresses about 30 ml of blood on weight-bearing. This bolus of blood flushes out the venous valve cusps in the lower leg and can promote venous endothelial fibrinolysis. The foot-pump system reproduces the rhythmic expression of blood from the plexus when a patient cannot bear weight. Studies on hip surgery have shown that the foot pump reduces the prevalence of DVT. The effect on DVT is equivalent to LMWH, but with fewer soft-tissue side-effects. There have been four randomised studies which have compared rates of DVT after knee replacement. Two earlier studies showed a substantial reduction in large venographic DVT compared with controls, but in two recent randomised comparisons, the foot pump was not as effective as LMWH (Table I).

We have therefore compared the use of LMWH with the foot pump, with specific reference to both the venographic prevalence of DVT and soft-tissue side-effects.
Patients and Methods

The study was undertaken in a regional orthopaedic centre with eight surgeons agreeing to allow their patients to be involved. The inclusion criteria were patients scheduled for unilateral primary TKR. The exclusion criteria were refusal of consent, long-term warfarin therapy for pre-existing cardiac or cerebral disease, a bleeding tendency, and painful joints or wounds in the feet which would preclude the use of the foot pump. Some patients who were participating in an ongoing study of the early discharge of patients after joint arthroplasty were also excluded.

Between September 1996 and March 1999, we considered 426 patients who were scheduled to undergo primary unilateral TKR of whom 197 were excluded for the following reasons: contraindications to LMWH, foot pump or venography (18), refusal of consent (53), lack of foot pumps (22), time available to perform venography (15) and recruitment into a simultaneous and conflicting study (89). A total of 229 patients was thus randomised, 117 for the foot pump and 112 for LMWH (Fig. 1). All completed the three-month follow-up.

Graduated compression stockings were fitted below the knee before surgery. The stocking on the operated side was removed for the duration of surgery and for a short period thereafter. Regional anaesthesia was used if chosen by the anaesthetist; the type of implant and the use of cement were left to the discretion of the surgeon.

Our study had the approval of the local Medical Research and Ethics Committee. A written information sheet was given to each patient and consent was obtained.

Randomisation. On the day before surgery, a sealed envelope was opened which contained the allocation to either the foot pump or enoxaparin. This random allocation had been generated by computer. Enoxaparin (40 mg) was administered, subcutaneously, 12 hours before surgery (in accordance with the UK licence) and every 24 hours thereafter until discharge from hospital. The slippers for the foot pump were applied in the recovery room and the controller

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Table I. Effectiveness of the foot pump after TKR

<table>
<thead>
<tr>
<th>Author</th>
<th>Centre</th>
<th>Control (no of patients)</th>
<th>Control DVT % (total/proximal)</th>
<th>Foot pump (no of patients)</th>
<th>Foot pump DVT % (total/proximal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wilson et al</td>
<td>New York</td>
<td>Nil</td>
<td>32</td>
<td>69/19</td>
<td>28</td>
</tr>
<tr>
<td>Westrich and Šculo</td>
<td>New York</td>
<td>Nil*</td>
<td>83</td>
<td>59/14</td>
<td>81</td>
</tr>
<tr>
<td>Norgren et al</td>
<td>Lund</td>
<td>LMWH</td>
<td>15</td>
<td>0/0</td>
<td>15</td>
</tr>
<tr>
<td>Blanchard et al</td>
<td>Lausanne</td>
<td>LMWH</td>
<td>60</td>
<td>27/3</td>
<td>48</td>
</tr>
</tbody>
</table>

* all patients had aspirin and were diagnosed by ultrasound

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*Fig. 1* Flow chart showing the progress of the patients through the trial.
was then engaged. The foot pump was then used whenever the patient was not weight-bearing until discharge from hospital. The patient lay in bed with the legs parallel to the floor. The controller activated the pump every 20 seconds at a pressure of 130 mmHg for a period of one second.

**Primary outcome measure.** The primary outcome measure was the frequency of DVT as shown by the results of ipsilateral ascending venography between the sixth and eighth postoperative days. A modified Rabinov-Paulin technique was used with a non-ionic contrast medium (Niopam; Merck Pharmaceuticals, West Drayton, UK). The venograms were initially interpreted in case there was a thrombosis which might need prompt treatment. For the purposes of the study, they were later interpreted again by consensus between two consultant radiologists with a particular interest in thromboembolism. These radiologists were not aware of the outcome of randomisation.

Patients with symptoms suggestive of either DVT or pulmonary embolism (PE) were investigated by separate ascending venography or ventilation-perfusion scanning, respectively. Substantial thrombi and PE were treated by anticoagulation with parenteral heparin, followed by oral warfarin.

Each patient was contacted by letter or telephone three months after surgery to enquire about any symptomatic thromboembolic events which might have occurred after discharge from hospital.

**Secondary outcomes.** The secondary outcome measures were those which concerned possible adverse effects of prophylaxis.

*Perioperative blood loss.* A single drain was used routinely and blood loss was derived from a summation of intraoperative blood loss and postoperative drainage at 36 hours.

*Haemoglobin and haematocrit.* These were measured before operation, on the second day after surgery and just before discharge.

*Brightness index.* The transfusion requirements of the patients were noted. This was determined by the equation: brightness index = preoperative haemoglobin - level of haemoglobin before discharge + number of units transfused.

We recorded whether or not the patient had bruising or oozing from the site of the wound on the fourth and seventh postoperative days.

**Swelling.** This was assessed by measuring the circumference of the thigh and calf at 10 cm above and below the joint, respectively on the fourth and seventh postoperative days. The level was marked by an indelible pen to maintain consistency.

*Knee flexion.* We measured active knee flexion with a goniometer on the fourth and seventh postoperative days.

**Statistical analysis.** Our study was an equivalence trial. In such a study, it is assumed that the two interventions have reasonable equivalence with respect to the primary outcome as demonstrated by an acceptably narrow confidence interval (CI), and that each intervention is more effective than no intervention. If reasonable equivalence were shown in the primary outcome, the secondary outcomes would provide information which would help to choose the method of prophylaxis. As there are multiple secondary outcomes, a Bonferroni correction is required to avoid an alpha error (inadvertently producing a false-positive association). We chose to regard a level of $p > 0.008$ as significant for the secondary outcomes (representing a Bonferroni correction of 0.05 divided by six secondary outcomes). The secondary outcomes were, whenever possible, presented on an intention-to-treat basis irrespective of whether or not the patient was using a foot pump.

**Table II.** Details of the 229 patients who were randomised to receive thromboprophylaxis with either a foot pump or LMWH

<table>
<thead>
<tr>
<th></th>
<th>Foot pump (n = 117)</th>
<th>LMWH (n = 112)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (± SD) age in years</td>
<td>73 ± 9</td>
<td>71 ± 10</td>
</tr>
<tr>
<td>Number of men (%)</td>
<td>43 (37)</td>
<td>37 (49)</td>
</tr>
<tr>
<td>Left TKR (%)</td>
<td>63 (54)</td>
<td>59 (53)</td>
</tr>
<tr>
<td>Mean (± SD) weight in kg</td>
<td>71 ± 11</td>
<td>69 ± 11</td>
</tr>
<tr>
<td>Previous VTE</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Varicose veins</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>Smokers</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>109</td>
<td>109</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>NSAID* or aspirin use</td>
<td>21</td>
<td>17</td>
</tr>
<tr>
<td>Regional anaesthesia (%)</td>
<td>101 (86)</td>
<td>93 (83)</td>
</tr>
<tr>
<td>Median tourniquet time in min (range)</td>
<td>80 (50 to 140)</td>
<td>85 (50 to 120)</td>
</tr>
</tbody>
</table>

* non-steroidal anti-inflammatory drugs

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346 D. WARWICK, J. HARRISON, S. WHITEHOUSE, A. MITCHELMORE, M. THORNTON

THE JOURNAL OF BONE AND JOINT SURGERY
Table III. Prevalence of venographic DVT in the 188 patients who underwent venography after TKR

<table>
<thead>
<tr>
<th></th>
<th>Foot pump</th>
<th>LMWH</th>
<th>95% CI for difference in proportions</th>
<th>Chi-squared (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>99</td>
<td>89</td>
<td>-10.6 to 17.9</td>
<td>0.25 (0.62)</td>
</tr>
<tr>
<td>Total DVT</td>
<td>57</td>
<td>58</td>
<td>-14.7 to 13.9</td>
<td>0.003 (0.96)</td>
</tr>
<tr>
<td>Calf DVT</td>
<td>53</td>
<td>54</td>
<td>-12.6 to 8.9</td>
<td>0.12 (0.74)</td>
</tr>
<tr>
<td>Subdivisions of calf thrombi*</td>
<td></td>
<td></td>
<td>-14.7 to 13.9</td>
<td>0.003 (0.96)</td>
</tr>
<tr>
<td>Major</td>
<td>16</td>
<td>16</td>
<td>-12.6 to 8.9</td>
<td>0.12 (0.74)</td>
</tr>
<tr>
<td>Minor</td>
<td>37</td>
<td>37</td>
<td>-12.4 to 15.2</td>
<td>0.04 (0.84)</td>
</tr>
<tr>
<td>Proximal DVT*</td>
<td>4</td>
<td>4</td>
<td>-0.9 to 7.9</td>
<td>3.67 (0.06)</td>
</tr>
<tr>
<td>Subdivisions of proximal thrombi*</td>
<td></td>
<td></td>
<td>-0.9 to 7.9</td>
<td>3.67 (0.06)</td>
</tr>
<tr>
<td>Whole leg</td>
<td>1</td>
<td>1</td>
<td>-0.9 to 7.9</td>
<td>0.90 (1.0)†</td>
</tr>
<tr>
<td>Isolated femoral</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Calf, isolated femoral</td>
<td>3</td>
<td>0</td>
<td>-0.3 to 6.4</td>
<td>2.74 (0.25)</td>
</tr>
</tbody>
</table>

* major is defined as >5 cm or >1 vessel group involved; minor is defined as <5 cm; proximal is defined as above the popliteal confluence
† compared with Fisher’s exact test

Table IV. Soft-tissue side-effects of thromboprophylaxis after TKR

<table>
<thead>
<tr>
<th></th>
<th>Foot pump</th>
<th>LMWH</th>
<th>95% CI difference (%)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>111</td>
<td>108</td>
<td>-0.9 to 17.9</td>
<td>0.07</td>
</tr>
<tr>
<td>Haematoma</td>
<td>–</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haematemesis</td>
<td>–</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatic artery bleed</td>
<td>–</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (range) transfusion</td>
<td>686 (0 to 2500)</td>
<td>750 (0 to 5500)</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Median (range) blood loss index</td>
<td>3.16 (0.13 to 5.7)</td>
<td>3.93 (0.3 to 13.9)</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Mean (+ SD) postop drainage in cm³</td>
<td>674 ± 188</td>
<td>721 ± 215</td>
<td>-101 to 7</td>
<td>0.086</td>
</tr>
<tr>
<td>Oozing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>108</td>
<td>105</td>
<td>-0.9 to 7.9</td>
<td>0.004</td>
</tr>
<tr>
<td>None day 4 (%)</td>
<td>38 (35)</td>
<td>12 (11)</td>
<td>13 to 35</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>None day 7 (%)</td>
<td>86 (80)</td>
<td>65 (62)</td>
<td>9 to 33</td>
<td></td>
</tr>
<tr>
<td>Bruising</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>108</td>
<td>105</td>
<td>-0.9 to 7.9</td>
<td>0.13</td>
</tr>
<tr>
<td>None day 4 (%)</td>
<td>30 (28)</td>
<td>20 (19)</td>
<td>-3 to 20</td>
<td></td>
</tr>
<tr>
<td>None day 7 (%)</td>
<td>33 (30)</td>
<td>23 (22)</td>
<td>-4 to 19</td>
<td></td>
</tr>
<tr>
<td>Leg swelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median difference from baseline in mm</td>
<td></td>
<td></td>
<td>-0.9 to 7.9</td>
<td></td>
</tr>
<tr>
<td>Calf day 4</td>
<td>22.5</td>
<td>30</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td>Calf day 7</td>
<td>30</td>
<td>30</td>
<td>0.7</td>
<td></td>
</tr>
<tr>
<td>Thigh day 4</td>
<td>30</td>
<td>40</td>
<td>0.009</td>
<td></td>
</tr>
<tr>
<td>Thigh day 7</td>
<td>25</td>
<td>35</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>Flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 4</td>
<td>70</td>
<td>65</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Day 7</td>
<td>85</td>
<td>80</td>
<td>0.13</td>
<td></td>
</tr>
</tbody>
</table>

and statistically significant benefit compared with the established incidence of DVT without prophylaxis of 60%.

Compliance. A meter within the foot pump controller allowed measurement of the time for which the pump was used by each patient in the postoperative period.

Results

The baseline characteristics of the 229 patients who were randomised are shown in Table II. Venography was undertaken in 188. The reasons for exclusion were early discharge in 12, withdrawn consent in six, cancellation of surgery in two, a complication preventing venography being completed according to the protocol in ten, technical difficulties with venography in seven, and death in four.

Of the patients who died, one was in the LMWH group and three in the foot-pump group. All had post-mortems. The death in the LMWH group was due to acute myocardial infarction on the first postoperative day. In the foot-pump group, two were due to PE. The first occurred on the fourth postoperative day in a man with a history of DVT; the post-mortem identified an undiagnosed bronchial carcinoma as a contributing factor. The second occurred on the 26th postoperative day in a woman with a past history of both PE and DVT. She had undergone screening venography according to the protocol which revealed an asymptomatic major calf thrombosis and an isolated femoral thrombosis. Therapeutic anticoagulation was begun.
although it is not known whether the International Normalised Ratio was within the therapeutic range when she died. The third death from pneumonia, sepsis and myocardial infarction occurred 81 days after operation.

The overall prevalence of venographic DVT was 58\% in the foot-pump group and 54\% in the LMWH group (Table III).

Five patients had a clinical diagnosis of DVT before scheduled venography. Early venography or ultrasonography confirmed the diagnosis in each. Four patients had a clinical diagnosis of PE, which was confirmed, in three as a high probability by ventilation-perfusion scintigraphy. Seven patients were readmitted to hospital for the investigation of suspected VTE, three in the LMWH group and four in the foot-pump group. Investigation was negative in all three LMWH patients and two foot-pump patients. The other two foot-pump patients had a minor calf-vein thrombosis which was not treated.

Side-effects were analysed in all 227 patients who were randomised and who proceeded to surgery (intention-to-treat). There were four haemorrhagic complications in the LMWH group (2 haematomata, 1 haematemesis, 1 hepatic artery bleed) and none in the foot-pump group. The soft-tissue side-effects are shown in Table IV.

Five of the 117 patients randomised to use the foot pump stopped using it because of disturbance of sleep and discomfort. The internal compliance meter showed that it was used for a mean of 77.5 hours during the first seven postoperative days (11 hours each day). No patient refused a dose of LMWH.

Discussion

Our results were disappointing as neither LMWH nor the foot pump dramatically reduced the incidence of DVT below the 60\% that is expected without prophylaxis. This can be interpreted in a number of ways.

With either method, most thrombi were small calf thrombi. The incidence of proximal thrombosis compares well with most published series. It may be that prophylaxis reduces the total thrombus load without reducing the overall number of thrombi. Without a control group this is a matter of conjecture. The interpretation of venograms is subject to considerable variation. Our interpretation may have been very sensitive, thus detecting a large proportion of very small thrombi. It is possible that TKR is resistant to prophylaxis. Other studies have shown that there is a residual incidence of 32\% with LMWH or warfarin. It may be that those thrombi which persist, despite prophylaxis, represent a more ‘malignant’ subgroup so that the potential benefit is even less than suggested by the absolute reduction in the incidence of DVT.

The rate of fatal PE after TKR, without prophylaxis, is reported to be between 0\% and 0.4\%. Although this figure is low, the upper confidence limit in these studies is 1.1\%. When the number of TKRs carried out in the UK (about 45 000 per annum) is multiplied by this figure, there may be up to 500 fatal emboli each year. We recorded two deaths from PE in patients who had been allocated the foot pump; both had a history of VTE.

The rate of symptomatic VTE, in the absence of prophylaxis, may be around 10.5\%, making this the most common complication after TKR. In our study, despite prophylaxis, 4.4\% still developed symptomatic VTE. The rate of chronic venous insufficiency, a morbid and expensive complication, is not known, but it is likely to be related to the incidence of large DVTs.

Our study has shown that the foot pump carried a better profile of soft-tissue side-effects than LMWH. The open-label assessment of side-effects can be criticised but the use of a ‘sham’ foot pump is impractical. It is unclear whether increased bruising, oozing and swelling confer a measurable disadvantage for the patient or health-care provider. Nevertheless, it is a sound surgical principle to minimise the soft-tissue insult, particularly in relation to TKR, when the soft-tissue envelope is unforgiving.

Most thrombi in our study were confined to the calf. Although it is often thought that only a proximal DVT will embolise after TKR, a proportion of calf thrombi will propagate proximally and probably become a precursor to embolism and chronic venous insufficiency. Calf emboli therefore are significant and their prevention is important.

It is now clear that after hip replacement the risk of venographic DVT persists for a few weeks after surgery and that this risk can be reduced by extending the use of prophylactic LMWH beyond discharge from hospital. The epidemiology is different after TKR because the period of risk is closer to the immediate postoperative phase. The evidence for routinely extending prophylaxis after TKR beyond discharge from hospital is currently weak. The case of a fatal PE on the 26th day in our study, in a patient with previous VTE, is a warning that in certain high-risk individuals extended prophylaxis should be considered.

Other methods of thromboprophylaxis after TKR. Intermittent pneumatic compression stockings appear to be remarkably effective, with four randomised studies giving a combined incidence of DVT of only 11\% (95\% CI 8 to 14). Compliance may limit their use. Regional anaesthesia confers a modest benefit, probably by increasing venous blood flow and promoting fibrinolysis. There are no data to support the use of graduated compression stockings after TKR. When TKR is carried out under tourniquet, markers of thrombogenesis accumulate. On release of the tourniquet, showers of microemboli can be seen by transoesophageal echocardiography to pass through the heart. There is no strong evidence, however, that this translates into an increased frequency of thrombosis or PE. It may be that the ‘flushing-out’ effect of deflating the tourniquet negates the effect of accumulated thromboplastins.

Continuous passive movement devices confer no benefit.
Future directions. Neither the foot pump nor LMWH provides sufficient thromboprophylaxis after TKR. This must prompt a search for more effective methods which may take several directions. A combination of mechanical and chemical methods may reduce the incidence of DVT in a synergistic way by addressing more than one aspect of Virchow’s triad. The foot pump could be enhanced, perhaps by altering the pressure or frequency settings. Its use must be meticulous, keeping the legs in neutral or preferably dependent to maximise preload. The need for coincident graduated compression hosiery is not clear. Other mechanical methods could be reconsidered. In particular, sequential pneumatic compression devices have shown the greatest effect of any measure in thromboprophylaxis after TKR. The number of studies is small. A large randomised study is required. Concerns about compliance with these cumbersome devices must be recognised, either by redesign or by education of patients and staff. Chemical methods could be improved. Agents are being developed such as direct thrombin inhibitors and pentasaccharides, which may be more effective against DVT. After TKR, greater effectiveness against DVT should not carry an increased risk of soft-tissue side-effects.

In our study, LMWH and the foot pump had an equivalent effect on the venographic prevalence of DVT and TKR. The foot pump had fewer soft-tissue side-effects. There is a pressing need for more effective yet safe prophylaxis after TKR.

One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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