Foot Pump Versus Low-Molecular-Weight Heparin for Preventing Deep Vein Thrombosis Following Surgery for Hip and Knee Replacement

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Objective: To evaluate the comparative efficacy and safety of the use of foot pump versus low-molecular-weight heparin (LMWH) for preventing deep vein thrombosis (DVT) and pulmonary embolism (PE) in total knee replacement (TKR) and total hip replacement (THR).

Summary of background data: The use of chemoprophylactic agents in TKR and THR has been shown to result in increased complications like bleeding and wound drainage.

Methods: Relevant publications indexed in PubMed, Cochrane Library, Embas, Web of Science, Wanfang Data, CNKI, and VIPI were identified. Appropriate articles identified from the reference lists of the above searches were also reviewed.

Results: No significant difference in the rate of distal in the lower extremity was observed between the 2 groups (OR: 0.99; CI: 0.61–1.61; Z = 0.03; P = 0.97). No significant difference in the rate of proximal DVT in the lower extremity was observed between 2 groups (OR: 1.60, CI: 0.85–3.03, Z = 1.44, P = 0.15). No significant difference in the rate of PE was observed between 2 groups (OR: 3.84, CI: 0.42 to 34.80, Z = 1.20, P = 0.23). But we found that postoperative drainage in foot pump group was less than that in LMWH group (OR: -68.93, CI: -73.81 to -64.05, Z = 27.68, P < 0.00001), and oozing in foot pump group was less than that in LMWH group (OR: 0.21; CI: 0.10–0.47; Z = 3.86, P = 0.0001).

Conclusion: The foot pump is a suitable alternative for TKR and THR patients in preventing DVT and PE, and can get less postoperative drainage and oozing side effects that are associated with LWMH.

Key words: Foot pump – Low-molecular-weight heparin – Total knee replacement – Total hip replacement – Deep vein thrombosis
Total knee replacement (TKR) and total hip replacement (THR) are considered successful surgeries that improve the quality of life for patients with end-stage knee or hip joint arthritis. However, venous thromboembolism (VTE) incidence after hip and knee arthroplasty is high.

The selection of a prophylactic method depends on a balance between efficacy and safety. The use of chemoprophylactic agents has been shown to result in increased complications like bleeding, hematoma formation, wound drainage, and periprosthetic infection. The use of mechanical devices alone or in combination with chemical prophylaxis, on the other hand, can reduce these complications.

The American Academy of Orthopedic Surgeons documented that patients at elevated risk for bleeding need to use intermittent foot compression. The A-V Impulse System foot pump was developed to reproduce the physiologic mechanism in patients who are unable to bear weight. The foot pump flattens the metatarsal arch, emptying the venous plexus and thus reproducing the effect of normal weight-bearing.

The goal of this meta-analysis was to evaluate the efficacy of venous foot pumps and LMWH in prevention of venous thromboembolism follow joint replacement.

Search Strategy and Criteria

We carried out a literature search using PubMed, Cochrane Library, Embas, Web of Science, Wanfang Data, CNKI and VIPI from inception to January 2016. No restrictions were placed on the language of the publications. The following medical subject headings (MeSH) were searched: foot pump, total hip arthroplasty/replacement, total knee arthroplasty/replacement, low-molecular-weight heparin, DVT, thromboembolic disease, and PE. We traced the bibliographies of all retrieved trials and other related publications.

Inclusion Criteria/Exclusion Criteria

All randomized controlled trial (RCTs) comparing foot pump with low-molecular-weight heparin for preventing DVT following surgery for hip and knee replacement were eligible. The participants should be patients who underwent surgery for THP and TKP. If there was more than 1 eligible publication from 1 author, the one with higher quality or the most recent publication date would be included. In addition, if the primary outcome was not deep vein thrombosis or pulmonary emboli, it was excluded.

Data Extraction

Two reviewers independently evaluated the included studies and extracted data into RevMan. Any disagreement was resolved by discussion with a third reviewer. If more data was required, communication through e-mail would be carried out with the authors.

Outcome Measures

The primary endpoint of this meta-analysis was the incidence of DVT identified by ascending venography and bilateral duplex. The secondary outcomes were incidence of PE identified by a ventilation perfusion lung scan and consist of post-operative drainage and oozing.

Quality Assessment

Firstly, all studies were assessed with the Jada Scale Scoring System, in which the best study quality is scored 5 points. Studies with a score ≥3 points were considered as high quality research and were enrolled. Second, studies were also classified by agreement of 2 authors as having a low risk of bias, an unclear risk of bias, or a high risk of bias based on the Cochrane tool. This tool takes into account random sequence generation, concealment of the allocation sequence, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome, and selective reporting.

Statistical Analysis

For each included study, odds ratio (OR) and 95% confidence intervals (CIs) were calculated for dichotomous outcomes, and weighted mean differences and 95% CIs were calculated for continuous outcomes. Statistical heterogeneity was assessed using the value of $I^2 \leq 50\%$ were considered as no statistical heterogeneity and used fixed-effects model to estimate the overall summary effect sizes. Otherwise, random-effects model was used a subgroup analysis or sensitivity analysis would be carried out. We used review management software (RevMan 5.3) and a value of $P < 0.05$ was considered as significant.
Results

Characteristics of selected studies

The details of search and exclusion criteria are displayed in the flow diagram (Fig. 1). We identified 4 randomized controlled trials.7–10 All selected studies in our meta-analysis are in English and were published from 1998 to 2004. The follow-up period ranged from 45 days after operation to 3 months after discharge from the hospital. The selected study characteristics are summarized in Table 1.

Risk of bias

The detailed risk of bias about methodologic quality of the included studies are elaborated and summarized respectively in Fig. 2 and Fig. 3.

Meta-analysis Results

The primary and secondary endpoint

The primary endpoint, “the proximal DVT and the distal DVT,” was reported in 4 studies. The distal DVT was included total of 398 patients in foot pump group and 394 patients in LMWH group to compare distal DVT in the lower extremity. For the high heterogeneity ($P = 0.06$, $I^2 = 60\%$), we used the random-effects model. The rate of distal DVT in the lower extremity did not show a statistical significance between the foot pump group and LMWH group (OR: 1.42; CI: 0.69–2.92; $Z = 0.96$, $P = 0.34$; Fig. 4). After excluding 1 RCT, a further sensitivity analysis was performed (OR: 0.99; CI: 0.61–1.61; $Z = 0.03$; $P = 0.97$; Fig. 5). The sensitivity analysis revealed the rate of distal DVT in the lower extremity did not show statistical significance between the 2 groups with no heterogeneity ($P = 0.88$, $I^2 = 0\%$).

A total of 398 patients were included in the foot pump group and 394 patients were included in the LMWH group to compare proximal DVT in the lower extremity. The rate of proximal DVT showed no statistical significance between the foot pump and LMWH groups (OR: 1.60; CI: 0.85–3.03; $Z = 1.44$, $P = 0.15$; Fig. 6).

The secondary endpoint, the PE, was also reported in 4 studies, including a total of 398 patients in the foot pump group and 394 patients in the LMWH group. No significant difference in the rate of PE was observed between the foot pump and LMWH groups (OR: 3.84; CI: 0.42–34.80; $Z = 1.20$; $P = 0.23$; Fig. 7).

Fig. 1 The graph shows a flow diagram of details search and exclusion criteria.
| Author, year | Design | Population | Hip or knee replacement | Type of LMWH | Foot pump | Outcome assessment of DVT and PE | Duration of follow-up | Quality assessment |
|-------------|--------|------------|-------------------------|--------------|-----------|---------------------------------|----------------------|------------------|
| Warwick, 1998 | One center, Open | United Kingdom | Total hip replacement | Enoxaparin | The A-V impulse System foot pump (Novamedix, Andover, United Kingdom) | DVT was determined by ascending venography, performed on the involved lower limb on the 6, 7, or 8 postoperative day with use of a modified Rabinov-Paulin technique with non-ionic contrast medium (Niopam; Merck Pharmaceuticals, West Drayton, United Kingdom). PE were investigated with ventilation-perfusion scanning. | All patients were contacted by telephone or letter 3 months after discharge from the hospital. | Good |
| Pitto, 2004 | One center, Open | New Zealand | Total hip replacement | Fraxiparin, Sanofi-Synthelabo, Paris, France | The A-V impulse System foot pump (Orthofix Vascular Novamedix, Andover, UK) | DVT shown by serial bilateral duplex studies (Sonoline Elegra, Siemens, Erlangen, Germany) using a 5.0 and 7.5 MHz linear transducer pre-operatively and postoperative days 3, 10, and 45. PE were investigated with ventilation-perfusion scanning. | All patients were contacted 45 days after operation. | Good |
| Warwick, 2002 | One center, Open | England | Total knee replacement | Enoxaparin | The A-V impulse System (Novamedix, Andover, UK) | DVT shown by the results of ipsilateral ascending venography between sixth and eighth postoperative days. A modified Rabinov-Paulin technique was used with a non-ionic contrast medium (Niopam; Merck Pharmaceuticals, West Drayton, UK). PE were investigated with ventilation-perfusion scanning. | Each patient was contacted by letter or telephone 3 months after surgery | Good |
| Blanchard, 1999 | One center, Open | Switzerland | Total knee replacement | Calcium nadroprarin | The A-V impulse System (Novamedix, Andover, UK) | The overall incidence of DVT was assessed by bilateral phlebography 8–12 days after TKR. When phlebography was impossible, venous compression ultrasonography was carried out. | All patients were examined clinically between two and three months after discharge from hospital to detect late DVT or PE. | Good |
Side effects and complications

The postoperative drainage was reported in 4 studies: a total of 410 patients in the foot pump group and 409 patients in the LMWH group. A significant difference in postoperative drainage was observed between the foot pump and LMWH groups (OR: 68.93, CI: 73.81 to 64.05, Z = 27.68; P < 0.00001; Fig. 8). It indicated that postoperative drainage in foot pump group was less than that in LMWH group.

The adverse event oozing was reported in 3 studies. It was included in a total of 344 patients in the foot pump group and 343 patients in the LMWH group. For the high heterogeneity, we used the random-effects model. A significant difference in oozing was observed between the foot pump and the LMWH groups (OR: 0.21; CI: 0.10–0.47; Z = 3.86; P = 0.0001; Fig. 9). It indicated that the foot pump group got less oozing than seen in the LMWH group.

Compliance with the foot pump

A total of 5 (3%) of the 147 patients in the Warwick study who were randomized to treatment with the foot pump stopped using it because they found it intolerable. A total of 16 patients in Pitto study discontinued its use before discharge. The main reason was disturbance of sleep at night due to the noise produced by the device. Blanchard reported 25% patients discontinued in mechanical prophylaxis because of discomfort.

Discussion

The incidence of DVT in the retrospective review was not low. It may warrant routine prevention including employment of chemoprophylaxis. A surgeon’s choice is determined by considering the risk of thromboembolic disease against the risk of chemoprophylaxis side effects such as bleeding. Pneumatic compression with foot pumps seems to provide a balance of effectiveness and safety.

We reported 4 included studies related distal DVT, proximal DVT, and PE. It showed that mechanical prophylaxis with foot pumps in THR and TKR achieves the equivalent result compared with chemoprophylaxis with LWMH. The excellent results are related to the constant use of the foot pumps by the patients. Yassin et al also found no statistically significant difference in symptomatic
Fig. 4  The graph shows a forest plot of relative risk with confidence interval for distal DVT.

Fig. 5  The graph shows a forest plot of relative risk with confidence interval for sensitive analysis of distal DVT.

Fig. 6  The graph shows a forest plot of relative risk with confidence interval for proximal DVT.

Fig. 7  The graph shows a forest plot of relative risk with confidence interval for PE.
VTE incidence following the addition of enoxaparin compared with mechanical prophylaxis. Santori et al\(^{13}\) reported a DVT rate of 13.4% in 67 patients in foot pump group compared with 35.4% in 65 patients in heparin group.

Low-molecular-weight heparin is safe and effective but may have caused postoperative bleeding complications in 259 patients in 11 cases reviewed.\(^{14}\) The advantage of the foot pump was that there was significantly less bruising and oozing. There was also less swelling of the thigh and postoperative drainage. In our meta-analysis, we were able to demonstrate that the foot pump group had less postoperative drainage and oozing.

Foot and calf pumping devices appear to prevent DVT, may protect against pulmonary embolism, and reduce mortality, and the potential lack of side-effects with foot pump has been regarded as a major advantage, but compliance remains a problem.\(^{15}\) In our meta-analysis there is 3% to 25% patients discontinued in mechanical prophylaxis because of discomfort and disturbance of sleep at night due to the noise produced by the device.

In three included studies DVT was investigated by venography. But in the Pitto\(^{8}\) study, DVT was detected by serial duplex ultrasonography. Duplex ultrasonography is highly operator-dependent. Thus, in a previous study performed by the same observer as in the Pitto\(^{8}\) study, they investigated the reliability of duplex ultrasonography for the detection of postoperative DVT in their institution. On comparison with venography, duplex ultrasonography demonstrated 93% sensitivity, 98% specificity and 95.5% accuracy with regard to the overall detection of DVT.\(^{16}\)

Although management of patients with foot pumps without graduated compression stockings does not reduce the efficacy of DVT prophylaxis after THR and TKR and improves patient compliance,\(^{17}\) but the patients in 3 of our included studies wore bilateral graduated compression stockings. Further research should focus on the efficacy of foot pump with or without graduated compression stocking.

In our meta-analysis, we found the foot pump to be a suitable alternative for TKR and THR patients who are concerned about the bleeding and soft-tissue side effects that are associated with LWMH.

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