
Outcomes of Outpatient Anticoagulation Therapy

Boccalon H, Elias A, Chale JJ, Cadene A, Gabriel S. Clinical outcome and cost of hospital vs home treatment of proximal deep vein thrombosis with a low-molecular-weight heparin: the Vascular Midi-Pyrenees study. Arch Intern Med 2000;160:1769-73.

Study Overview

Objective. To determine if outpatient therapy with low-molecular-weight heparin (LMWH) for deep venous thrombosis (DVT) is as safe and efficacious as inpatient therapy and to determine the treatment costs of outpatient therapy.

Design. Multicenter randomized control trial. A parallel economic analysis of the cost of inpatient versus outpatient care was also performed.

Setting and participants. Patients between 18 and 85 years of age with clinical symptoms and a confirmed diagnosis of DVT by either ultrasound or venography who presented to 17 hospital centers in southern France were eligible. Exclusion criteria were pregnancy, DVT within preceding 6 months, pulmonary embolism, contraindications to anticoagulation therapy, floating thrombus, other problems requiring hospitalization, and heparin therapy other than for prophylaxis within the last 48 hours. Patients were followed for 6 months.

Main outcome measures. The primary endpoints were incidence of DVT recurrence, pulmonary embolism, and major bleeding. Patients had duplex ultrasound performed on days 10, 30, 90, and 180. The diagnosis of pulmonary embolism was made by either perfusion ventilation scan or angiography. Major bleeding episodes were defined as a decrease in hemoglobin of 2g/dL or a hemorrhage requiring transfusion of at least 2 units of packed red cells.

Main results. Of all patients screened, 11.8% (204) were eligible; however, 2 were wrongly enrolled and 1 declined to participate after enrollment. Of the remaining 201 patients, 99 were randomized to outpatient treatment at home and 102 to inpatient treatment. Thirty-eight patients (18.9%) withdrew before the end of the 6-month follow-up. Premature withdrawal was twice as frequent in the hospital group. No differences in clinical outcomes were identified between the 2 groups. Two patients died; both were in the

hospitalization group. One outpatient and 2 inpatients had thrombus extension. Two patients in the outpatient and 2 in the inpatient group had major hemorrhage. Economic analysis showed that outpatient management achieved a 56% cost reduction compared with inpatient management.

Conclusion

Outpatient therapy with LMWH for DVT in patients without pulmonary embolism and major risk factors for hemorrhage is a safe, effective, cost-saving strategy.

Commentary

Studies have showed that LMWH is as efficacious as regular heparin in preventing deaths and DVT and that the incidence of major hemorrhage is the same or perhaps less with LMWH [1-3]. In addition, a recent study shows that LMWH can be used safely for uncomplicated pulmonary embolism [4]. This study by Boccalon is the first to unambiguously compare outpatient and inpatient LWMH therapy. The baseline characteristics of the patients were similar in both groups. Interestingly, the mean time to diagnosis was different between the inpatient and outpatient groups (4.9 versus 6.9 days); however, the difference was not statistically significant. Also, the outpatient group had a higher rate of comorbidity, but if this had affected the outcome, we should have seen worse clinical outcomes in that group. Another interesting finding was that the international normalized ratio (INR) was therapeutic in only 52.9% of the patients at the time LMWH therapy was stopped, with 18.5% being subtherapeutic and 28.6% having an INR over 3. This indicates that the treating physicians were not compliant with the general recommendations for the treatment and management of DVT. It is known that if the INR is not therapeutic, there is a 20% chance of recurrence of a DVT [5].

Some weaknesses of the study were the low rate of occurrence of outcomes of interest and the significant drop-out rate (18%). Interestingly, the highest drop-out rate occurred in the inpatient group because of the patients' desire to go home.

Applications for Clinical Practice

Outpatient therapy with LMWH for DVT is probably safe, but further larger studies should be done to confirm the current findings. Until further studies are conducted, a 1-day hospital stay with discharge the following day on outpatient therapy may be a safe approach.

References

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