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

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Home treatment using a low-molecular-weight heparin (LMWH) for patients with proximal deep vein thrombosis (DVT) and with no symptoms of pulmonary embolism or increased risk of major bleeding.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Male and female patients, between the ages of 18 and 85 years, with clinical symptoms and a confirmed diagnosis of proximal DVT dating from not more than 30 days before enrolment. Excluded patients were as follows: those who had a thrombus located in the inferior vena cava, a floating thrombus, a history of DVT within the preceding 6 months, DVT with an objectively documented symptomatic pulmonary embolism, a clinical context requiring hospitalisation, or a contraindication to anticoagulant treatment (short- or long-term anticoagulants); those who received treatment with heparin (other than prophylactic) within the 48 hours preceding inclusion; those who were pregnant; those for whom home treatment or a hospital stay was impossible; those who lived too far from the study centre; or those who could not give written consent.

Setting
Hospital. The economic analysis was carried out in France.

Dates to which data relate
Effectiveness and resource use data corresponded to those patients recruited to the study between 2 September 1993 and 28 March 1997. The price year appears to have been 1996.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was prospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were used to determine the sample size (based on an estimated rate of complications of 15% among
the hospitalised group, a sample size of 248 patients per group was required to detect an increase to 25% among the home group, with a 1-sided error of 5% and a power of 85%). In total, 201 patients were randomly assigned to either the home group (n= 99) with a mean (SD) age of 64.8 (14.6) years or the hospitalised group (n=102) with a mean (SD) age of 62.8 (13.6) years.

Study design
This was a randomised, multicentre, controlled trial, carried out in 17 centres. The duration of the follow-up was 6 months. Loss to follow-up was 38 patients (18.9%) who did not complete 6 months follow-up. Premature withdrawal was twice as frequent in the hospitalisation arm, with the most common reason given being the patient's own wish. Sealed forms were used for randomisation. All patients were systematically examined by duplex ultrasonography on days 10 (SD, 2 days), 30 (5 days), 90 (5 days), and 180 (5 days). Ultrasonography, venography, or both confirmed clinical suspicion of DVT recurrence. Physicians had free choice of which registered LMWH to prescribe.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been treatment completers only. The primary clinical outcomes were the incidence of venous thromboembolism recurrence, pulmonary embolism, or major bleeding. The incidence of minor bleeding was reported as the secondary clinical outcome. The study groups were comparable in terms of demographics and baseline characteristics. The groups were significantly different in terms of the mean (SD) time from clinical suspicion to diagnosis; however after logarithmic transformation due to large variance, the difference was no longer significant.

Effectiveness results
No differences in clinical outcome were detectable between the 2 groups.

There was no increase in the rates of primary efficacy outcome in the patients treated at home versus those treated in the hospital (3% versus 3.9%).

Twenty-eight patients (11 inpatients and 17 outpatients) experienced minor bleeding. Most of these events occurred before day 10.

There was no significant difference in incidence between the two study groups, (p<0.20).

Clinical conclusions
The results confirm those of previous studies demonstrating that the two treatments are equivalent in their efficacy and overall safety.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only individual clinical outcomes were reported. As the clinical results for efficacy and safety were similar between the two treatment groups, a cost minimisation analysis was performed.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs, and some cost items were reported separately. Cost analysis covered the costs of treatment, the duplex ultrasonographic scans, biochemical analyses, and physician or specialist visits. The numbers of duplex ultrasonographic scans and physician visits were collected based on 45 outpatients only, which was later averaged and applied to all outpatients. Cost data for inpatients in private hospitals were based on reimbursement rates versus actual costs for inpatients in the public hospitals. The perspective adopted in the cost analysis was that of the health insurance company. The price year appears to have been 1996. Due to inadequate documentation, the cost analysis did not cover the costs of
complications.

**Indirect Costs**
Indirect costs were not included.

**Currency**
French francs (Ffr).

**Sensitivity analysis**
No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**
See effectiveness results reported above.

**Cost results**
The mean (SD) cost of outpatient treatment for the initial 10-day period was Ffr9,230 (2,005), compared with Ffr20,932 (1,482) for inpatient treatment, which is 2.25 times higher. Thus, outpatient management showed a cost reduction of 56%.

**Synthesis of costs and benefits**
Costs and benefits were not combined since the economic analysis was reduced to a cost-minimisation analysis.

**Authors' conclusions**
For patients with proximal deep vein thrombosis and no symptoms of pulmonary embolism or increased risk of major bleeding, home treatment using a low-molecular-weight heparin is an effective, safe, and cost-saving strategy.

**CRD COMMENTARY - Selection of comparators**
The strategy of hospital treatment, as the standard procedure, was regarded as the comparator. You, as a database user, should consider whether this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness results are likely to be internally valid given the randomised nature of the study design. However, the study did not succeed in achieving the target sample size required to be able to detect a small difference between the two study groups. Whilst the study groups were comparable in terms of demographics and baseline characteristics, they were significantly different in terms of the mean (SD) time from clinical suspicion to diagnosis; however, after logarithmic transformation due to large variance, the difference was no longer significant. It was reported that risk factors and comorbidities were higher in the home treatment patients. A subgroup analysis of this difference was not carried out; which was claimed to enhance the efficacy and safety of the home treatment. The study sample appears to have been representative of the study population.

**Validity of estimate of measure of benefit**
The analysis of benefits was based upon therapeutic equivalence of treatment alternatives. The economic analysis therefore included only costs.
Validity of estimate of costs
Some quantities were reported separately from the costs and adequate details of methods of cost estimation were given. The price year and the perspective adopted in the cost analysis were both reported. All cost components were included in the cost analysis, such as the costs of complications. Costs of complications was not deemed to be detrimental to the cost calculation due to the fact that complication rates were not significantly different between the two study groups. The effects of alternative procedures on indirect costs were partially addressed by noting that the age of the study patients meant that no earning loss was involved, but the possibility of indirect costs to caregivers was not addressed. Statistical analyses appear to have been performed on some resource consumption data, but not on cost data. The cost results may not be generalisable to other countries.

Other issues
The authors’ conclusions appear to be justified given the uncertainties in the data. The issue of generalisability to other settings was not addressed, although some comparisons were made with other studies. The degree to which the study sample was representative of the study population was not discussed.

Implications of the study
The results suggest that home treatment with an LMWH for DVT can be recommended if there is no clinical suspicion of a pulmonary embolism or a bleeding complication, and if the patient has no known hemostatic disorder. The study indicates that an effective strategy would be a combination of the 2 treatments, in which a 1-day hospitalisation would be followed by outpatient care.

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