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.

CRD summary
The study evaluated the cost-effectiveness of fondaparinux for the treatment of patients with superficial vein thrombosis of the legs. The authors concluded 45 days of fondaparinux treatment was not cost-effective at thresholds of over US $100,000. The methods used to facilitate modelling seemed appropriate, with some uncertainty characterised through probabilistic methods. Whilst the authors’ conclusions appear appropriate, the high level of uncertainty cannot be ignored.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The study evaluated the cost-effectiveness of fondaparinux for the treatment of patients with superficial vein thrombosis of the legs.

Interventions
Fondaparinux 2.5mg daily for 45 days was compared with no treatment for superficial vein thrombosis in a hypothetical cohort of people with an average age of 57 years with acute isolated superficial vein thrombosis.

Location/setting
USA/primary care

Methods
Analytical approach:
A decision tree was used to compare the impact of treatment on patients’ transition along the clinical pathway. The time horizon of the study was patients’ lifetime. The authors stated that the perspective taken was that of the health care system.

Effectiveness data:
The main effectiveness data came from a large placebo controlled trial (3,000 participants) of prophylactic fondaparinux followed for 45 days. The clinical outcomes included: the probabilities of complications including major haemorrhage; venous thromboembolism; pulmonary embolism; deep vein thrombosis; extension to the saphenofemoral junction (with and without treatment); and recurrently superficial vein thrombosis (with and without treatment). These data were combined with other estimates (case-fatality of pulmonary embolism and haemorrhagic complications) from the published literature, which primarily came from a meta-analysis of thromboprophylaxis in medical patients.

Monetary benefit and utility valuations:
Utility data were reported to have been derived from the published literature and expert opinion of two of the authors.

Measure of benefit:
The primary measure of benefit was quality-adjusted life-years (QALYs), which were used to estimate cost per QALY gained. Future benefits were discounted at a rate of 3% per year.

Cost data:
The cost categories included were the costs of drugs, hospitalisations, visits to physicians, and medical procedures. The source of hospital, physician, lab tests and medical procedure prices were Medicare reimbursement schedules; fondaparinux drug costs were from wholesale acquisition cost and warfarin cost as a decrease of 15% on average wholesale costs. All costs were adjusted to 2010 US £ using the medical care component of the consumer price index. Future costs were discounted at a rate of 3% per year.

Analysis of uncertainty:
One-way and probabilistic sensitivity analyses were conducted. In addition, scenario analysis based on a shorter duration of treatment was also undertaken. The results were presented in tornado diagrams and cost-effectiveness acceptability curves.

Results
In a hypothetical cohort of 10,000 patients, the average treatment cost associated with fondaparinux was estimated to be US $1,990 compared with US $256 with no treatment, an incremental cost of $1,734 with fondaparinux.

Treatment with fondaparinux was associated with an average of 17.9358 QALYs compared with 17.9323 with no treatment, an incremental QALY gain of 0.0035 QALYS.

The incremental cost-effectiveness ratio of fondaparinux was US $495,804 per QALY gained compared with no treatment. Results were found to be robust in sensitivity analyses.

Authors’ conclusions
The authors concluded that 45 days of fondaparinux treatment for superficial vein thrombosis was not cost-effective at thresholds of over US $100,000.

CRD commentary
Interventions:
The reporting of the intervention was clear and concise. It was not clear whether other alternative treatments were available, for example those identified in the introduction or in the meta-analysis. The inclusion of other relevant comparators would impact on the incremental results obtained.

Effectiveness/benefits:
The effectiveness data used in the model were reported, but details that allowed an assessment of the trials validity may have been beneficial. The authors did not report the methods used to identify or select the studies from the published literature, or the methods used to extract data from the selected studies. So, it was not possible to assess the validity or appropriateness of the data used. The probabilities used in the model were clearly reported in a table. The methods supporting the estimation of utilities were not provided, so it was not possible to assess the validity of methods used to estimate QALYs. The utility data were very uncertain.

Costs:
The cost categories included in the analysis were consistent with the stated perspective. The cost data were comprehensively reported in a table. The methods used to identify sources of cost data were not described but it appeared that they were relevant to the study setting. The discount rate and adjustment of cost data were reported and appeared appropriate.

Analysis and results:
The model structure was described fully. The use of an incremental analysis was appropriate to compare the cost-effectiveness of treatment for superficial vein thrombosis with no treatment. Uncertainty was investigated using appropriate and comprehensive methods. The level of reporting of the sensitivity analysis results was good. The authors provided a considered critique of the model and some of the key limitations.

Concluding remarks:
The level of reporting for clinical data and utilities was limited. In particular, the utility estimates were uncertain. The methods used to facilitate modelling seemed appropriate. Some of the uncertainty had been characterised through the use of probabilistic methods. However, whilst the authors’ conclusions appear appropriate, the high level of uncertainty...
cannot be ignored.

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