Extended prophylaxis of venous thromboembolism with fondaparinux in patients undergoing major orthopaedic surgery in Italy: a cost-effectiveness analysis

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
This study examined the cost-effectiveness, from the Italian public payer perspective, of fondaparinux compared with conventional enoxaparin for the prevention of venous thromboembolism in patients undergoing major orthopaedic surgery. The authors concluded that extended prophylaxis with fondaparinux was more effective and cost saving compared with enoxaparin. The study was generally well reported, but had some limitations and the authors’ conclusions need to be corroborated by further studies.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the cost-effectiveness of fondaparinux, compared with conventional enoxaparin, for the prevention of venous thromboembolism in patients undergoing major orthopaedic surgery.

Interventions
Fondaparinux 40mg was compared with enoxaparin 2.5mg. Treatment was administered for 10 days, during the surgical stay, and another 20 days after hospital discharge.

Location/setting
Italy/hospital.

Methods
Analytical approach:
The analysis was based on a decision-tree model with a five-year time horizon. The authors stated that the perspective of the Italian National Health Service was adopted.

Effectiveness data:
The clinical data were from a selection of published sources that included clinical trials and economic evaluations. The patients’ characteristics and the risk of venous thromboembolism with fondaparinux were from four clinical trials. The rate of venous thromboembolism depended on the type of surgery, which was total hip replacement, total knee replacement, or hip fracture repair. The occurrence of these interventions in Italy was from a National database. The rates of deep vein thrombosis and pulmonary embolism were the key inputs for the model.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
Life-years were the summary benefit measure and they were discounted at an annual rate of 3%.

Cost data:
The analysis included the costs of: drugs, laboratory tests, imaging tests, medical visits (specialist and general physician), hospital stay, and out-patient treatments. The resource use was from a panel of six Italian physicians who had expertise in venous thromboembolism; these estimates were supported by some published data. The unit costs were
the nationally agreed acquisition prices for drugs and other items were from national tariffs. The costs were in Euros (EUR), for the price year 2007, and a 3% annual discount rate was applied.

Analysis of uncertainty:
A deterministic sensitivity analysis was undertaken on two of the model inputs: the unit costs for venous thromboembolism-related care and the event rates for both treatments. The ranges of values were assumed by the authors.

Results
At five years, fondaparinux was associated with a small increase in survival of 0.01 life-years and a reduction of EUR 74.36 in costs, compared with enoxaparin. The higher acquisition costs of fondaparinux were more than offset by a reduction in the costs of venous thromboembolism events, making fondaparinux the dominant strategy, with lower costs and more benefits.

This conclusion held with shorter time horizons of 30 days (saving EUR 48.83) and one year (saving EUR 72.13); the increase in survival remained the same in both cases. The sensitivity analysis showed that changes in the event costs changed the amount of the savings more than changes in event rates, but fondaparinux remained dominant.

Authors' conclusions
The authors concluded that extended prophylaxis with fondaparinux was more effective and cost saving compared with enoxaparin.

CRD commentary
Interventions:
The comparators were appropriately selected; conventional prophylaxis was compared against the proposed therapy, which was more effective, but also more expensive.

Effectiveness/benefits:
No systematic review was reported to identify the relevant sources of data. Most of the evidence was from fondaparinux trials and one trial directly compared fondaparinux with enoxaparin. Randomised trials are generally considered to be valid sources of evidence because of their sound methods and design, but few details were given and the methods used to combine their data were not clearly reported. The validity of the clinical analysis cannot therefore be fully assessed. Some data were appropriately from large Italian databases. Life-years were an appropriate benefit measure as they capture the impact of the interventions on the patients’ health.

Costs:
The cost categories and their sources were consistent with the perspective of the Italian National Health Service. No list of cost items was given and the costs were reported as category totals, for each health condition. This reduces the transparency and external validity of the study. The sources of costs were clearly presented and the use of a panel of experts to assess the resource use should have ensured that these data were representative of the Italian context. The price year and discounting were clearly presented.

Analysis and results:
The results were clearly presented, with both absolute and incremental findings reported. A synthesis of the costs and benefits was not required, given the superior economic and clinical profile of fondaparinux. The uncertainty was partly investigated, as a deterministic approach was used to consider the variations in only two types of input. The authors compared their results with those of other published economic evaluations, which were generally similar. This study improved on the earlier studies by assessing the costs and benefits over a longer time horizon. These results might be transferable to settings with similar costs and clinical patterns.

Concluding remarks:
The study was generally well reported, but had some limitations. The authors’ conclusions need to be corroborated by further studies.
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