Comparison of Tinzaparin and unfractionated heparin as anticoagulation on haemodialysis: equal safety, efficacy and economical parity

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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.

CRD summary

The objective was to assess the costs and outcomes associated with the use of unfractionated heparin (UFH) and a low-molecular-weight heparin (LMWH, Tinzaparin™) for anticoagulation in patients on haemodialysis. The authors concluded that UFH and the LMWH were comparable in terms of safety, efficacy and cost. There were a few limitations to the study's methodology, so the authors' conclusions should be considered with a degree of caution.

Type of economic evaluation

Cost-effectiveness analysis

Study objective

The objective was to assess the costs and outcomes associated with the use of unfractionated heparin (UFH) compared with a low-molecular-weight heparin (LMWH, Tinzaparin™) for anticoagulation in patients on haemodialysis (HD).

Interventions

The two interventions were UFH 1,000 units (U) as a bolus followed by an infusion of 500U to 2,000U per hour for the duration of dialysis, and Tinzaparin™, which was given as a bolus dose of 2,500U from a pre-filled syringe, into the arterial limb of the circuit.

Location/setting

UK/secondary care.

Methods

Analytical approach:

The effectiveness data were derived from a single observational study. The time horizon of the study was 16 weeks. The authors did not report the study perspective.

Effectiveness data:

The effectiveness data were obtained from a prospective single-centre cross-over study. The trial contained 110 HD patients, who were switched from dialysing with UFH to LMWH for anticoagulation. They were monitored for the eight weeks before, and the eight weeks after this switch. The main outcome measures were access failures due to thrombosis, clotted circuits, and haemorrhagic events.

Monetary benefit and utility valuations:

Not relevant.

Measure of benefit:

No summary measure of benefit was used because a cost-consequence analysis was performed. The primary clinical outcomes were adverse events and bleeding times.

Cost data:

The costs were the relative costs of each treatment, which were obtained from the hospital pharmacy and medical supplies. The resource use data were collected prospectively during the clinical trial. All costs were reported in UK pounds sterling (£) and the price year was not reported.

Analysis of uncertainty:
The issue of uncertainty was not addressed.

Results

In 108 patients, 65 of whom were male, for UFH, 1,489 dialysis sessions took place and, for LMWH, 1,823 dialysis sessions took place.

The total number of adverse events decreased after the switch from UFH to LMWH. For example, the number of clotted circuits decreased from 34 to 13, and the number of bleeding events decreased from 4 to 0, although the number of infections increased from 5 to 11. However, these results were not statistically significant.

The average bleeding time was significantly shorter with LMWH ($p = 0.004$).

Using a median of 10,000U of UFH compared with 2,500U of LMWH, the total annual cost of dialysing 108 patients was £10,783 for either therapy.

Authors' conclusions

The authors concluded that UFH and the LMWH were comparable in terms of safety, efficacy and cost.

CRD commentary

Interventions:
Both interventions were well described including their dosage. UFH appears to be a relevant comparator as it represented current practice in the authors' setting.

Effectiveness/benefits:
The effectiveness data were derived from a cross-over trial. This design is one that is subject to a number of limitations and so the possibility of bias in the results cannot be ruled out. Further, power calculations do not appear to have been performed, which does not allow any objective judgement to be made about the adequacy of the sample size.

Costs:
The authors did not report a study perspective, so it was not clear if the appropriate cost categories were included. No statistical analysis of the costs was performed. The price year was not reported, so the results cannot be re-valued in future years.

Analysis and results:
No synthesis of the effectiveness and cost data was carried out. In effect, a cost-consequence analysis was carried out. The study results were relatively well reported. For one of the outcome measures (bleeding times) data were missing for nine patients receiving LMWH, compared with no patients receiving UFH, but it was not clear how this impacted on the study results. The impact of uncertainty, on the study parameters, was not investigated which makes it difficult to assess how robust the results were. The authors highlighted the small number of patients as a limitation to their study.

Concluding remarks:
There were a few limitations to the study's methodology, especially concerning the effectiveness estimates and the lack of sensitivity analysis. For these reasons the authors' conclusions should be considered with a degree of caution.

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