Randomized cross-over study of adverse reactions and cost implications of intravenous push compared with infusion of iron dextran in hemodialysis patients

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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
Administration of intravenous iron: intravenous push versus infusion.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with either absolute (serum ferritin concentration < 100 ng) or functional iron deficiency (transferrin saturation <20%). Patients with a documented allergy to iron dextran were excluded from the study.

Setting
Clinic. The economic study was carried out in Minneapolis, USA.

Dates to which data relate
The dates associated with the main effectiveness and resource use data collection were not clearly stated. Although the price date was not stated it appears to be 1994.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
From an eligible group total of 17 patients, 10 patients (8 men and 2 women, 7 whites and 3 African-Americans) were included in the study after giving informed consent. The mean age of the group was 60 (+/-19) years. The mean time from initiating hemodialysis was 35 (+/- 26) months. Power calculations to determine the sample size were made retrospectively. The study protocol established that each patient received a total of four doses(two by each method during 4 separate dialysis sessions).

Study design
The study was a randomized controlled (cross-over) trial. Patients were followed up until 210 minutes after dosing was initiated or until the end of the hemodialysis session before their next session. Only 7 of 10 enrolled patients completed all doses.

Analysis of effectiveness
The analysis of the clinical study was based on treatment completers only. The primary health outcomes used in the analysis were difference in blood pressure, heart rate or other adverse events as reported on a survey. The 0, 5, 30, and 60-minute time points were previously chosen as clinically significant measurements points. The adverse events survey measurement points (before the dose, 60 minutes after the dose, and again before the next dialysis session) were used to assess immediate and delayed side effects.

Effectiveness results
The authors reported that there were "no significant (p<0.05) differences between the two administration methods in terms of blood pressure or heart rate". Based on retrospective power calculations, the study had power to detect a 15% change in either blood pressure or heart rate at individual time points using alpha=0.05 and beta=0.8. The survey data showed "no significant differences in other adverse events between the two methods (according to the authors, previous information about incidence of ‘other events’ was not available to perform a power analysis).

Clinical conclusions
Iron dextran can be administered by either intravenous push or intravenous infusion during the first hour of hemodialysis, with no significant differences between the two methods in terms of blood pressure or heart rate.

Measure of benefits used in the economic analysis
Since the effectiveness study showed no difference between strategies in terms of clinical/health effects, the economic study was based on the difference in costs.

Direct costs
The costs of intravenous infusion and intravenous push were included in the analysis. Although quantities (time required by the nursing staff to prepare and administer iron dextran) were analysed separately from costs, they were not reported in the paper. The quantity/cost boundary adopted was the hospital. The source of unit costs was the average wholesale prices and Medicare reimbursement rates for intravenous supplies. The date of the price data was not clearly stated although it seems to be 1994. The costs associated with using infusion pumps to administer intravenous infusion doses of iron dextran (capital costs) were excluded from the analysis. The authors extrapolated the results to examine the potential one-year savings for the institution based on annual 1994 quantity figures (doses) for iron dextran administration. After statistically analysing the quantities of resource use for each group only those items for which significant differences were found between methods were included in the final cost calculations.

Statistical analysis of costs
Mann-Whitney U tests were used to test differences in quantities of resource use between strategies.

Currency
US dollars ($).

Estimated benefits used in the economic analysis
Not applicable.
Cost results
The cost saving per dose realised by using intravenous push, rather than infusion, was estimated to be $17.72 (annual savings to the institution of $206,084).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Iron dextran can be administered safely whilst incurring less costs by intravenous push compared with intravenous infusion.

CRD COMMENTARY - Selection of comparators
The authors justified the choice of comparator used on the grounds of common practice. Infusion represents the commonly used alternative method of administering intravenous iron dextran to hemodialysis patients.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis may be questionable due to the high proportion of patients who declined to participate in the study. Also the principle used to analyse the data (treatment completers) may generate some biases in the results. It should be noted that the sample method used (choosing participants by selecting hemodialysis days Monday, Wednesday and Friday) may not provide a representative patient sample.

Validity of estimate of costs
Adequate details of methods of quantity/cost estimation were not given. Important cost items (capital costs for the method of infusion) were omitted.

Other issues
The authors' conclusions may not be justified, given the uncertainties in the data. The issue of generalisability to other settings was not addressed, although appropriate comparisons were made with other studies.

Implications of the study
Further studies are needed before valid results can be obtained concerning the effectiveness and efficiency of intravenous administration methods of iron dextran for hemodialysis patients.

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