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Time and Motion Study of Anaemia Management with Erythropoiesis Stimulating Agents in Haemodialysis Units in Poland

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Abstract

Anaemia is a common complication of chronic kidney disease (CKD) contributing to morbidity, mortality and reduced quality of life of patients. Anaemia management is time consuming for healthcare professionals and patients. A major challenge for haemodialysis centers is to improve efficiency while maintaining high standards of care. The objective of our study was to compare time spent by healthcare professionals for routine renal anaemia treatment in haemodialysis centers with short acting erythropoiesis stimulating agents (ESA),which are administered 1-3 times a week vs. long acting agent, administered once a month – methoxy polyethylene-glycol epoetin beta (Mircera®). The study was a multicentre, prospective, observational study using time and motion methodology and conducted in Poland, France and Italy. Here we present the results from the Polish centers only (three Polish centers participated in the study). The observed annual time per patient receiving short-acting ESAs ranged from 176 to 380 minutes, while for Mircera® once per month, the expected time per patient per year ranged from 21 to 68 minutes (from 54 to 111 injections avoided per patient per year; from 82% to 88% reduction of time vs traditional ESAs). Our study showed that a substantial reduction in time spent on ESA administration may be achieved by converting from shortacting ESAs to once monthly treatment with Mircera. Such savings may allow healthcare resources to be reallocated to other aspects of patient management, thereby enhancing the overall quality of dialysis care, and potentially enabling improvements in clinical outcomes.

Key words: Time and Motion, haemodialyses, renal anaemia, erythropoiesis stimulating agents

Background and rationale

Anaemia is an important and frequently occurring complication of chronic kidney disease (CKD). Erythropoiesis-stimulating agents (ESAs) are standard treatment for renal anaemia1. Effective treatment of anaemia using ESAs such as epoetin alpha and its biosimiliars, epoetin beta or darbepoetin alpha requires injections ranging from 3 times weekly to once every 1-2 weeks [2-5]. Mircera® (methoxy polyethylene glycol-epoetin beta) is approved by the European Medicines Agency for the treatment of symptomatic anaemia in patients with CKD. In Phase II and III trials once-monthly Mircera® had similar efficacy to the traditional ESAs [6]. In view of the increasing health care costs it is desirable to improve cost-effectiveness while maintaining high standards of care. A reduction of the frequency of ESA injections may lead to the hospital staff workload savings, thus allowing more time to perform other necessary tasks. A recent study assessing the personnel time and supplies for anaemia management with currently available ESAs in haemodialysis centres showed, that with the use of once-monthly Mircera® the time necessary for anaemia management activities was 79% to 84% shorter vs mix of other ESAs, and additional savings could be generated with respect to nonobservable tasks [7]. The current study compared the time spent by health care personnel in haemodialysis centres on anaemia-related tasks in patients treated with Mircera® vs other ESAs in real-life setting.

Objectives

The primary objective was to document health care personnel time for anaemia management-related tasks when using various ESAs, including Mircera®, in patients with end-stage renal disease (ESRD) undergoing haemodialysis. The secondary objective was to obtain qualitative information on changes in practice patterns observed and/or expected as a result of the introduction of once-monthly Mircera® maintenance therapy.

Methods

Prospective, observational study conducted in several centres in 5 European countries. The time used for ESA-treatment related activities was assessed using the time and motion methodology and qualitative information on less frequent activities was obtained through interviews. The study was conducted in various centrs in Germany, France, Italy, Spain and Poland. This report presents the data and results from the three Polish hemodialysis centres that participated in the study. The time and motion methodology includes dividing a process (i.e. anaemia management) into key tasks, and repeated observations of each task to assess the average time needed to perform it. The sum of the average times spent on each activity yields total average time for the complete process. This study focused on frequent and observable activities related to the management of anaemia using ESA. The time and motion data were collected during haemodialysis sessions during which at least one patient received ESAs (defined as any ESA except for Mircera®) and/or Mircera®. The dialysis sessions when an ESA or Mircera® were administered were classified as "ESA session" or "Mircera® session", respectively. The anaemia management tasks suitable for time and motion observations were the activities related to the preparation, distribution, injection, record-keeping, and inventory/ordering of ESAs. Two types of activities were distinguished: the activities performed in a group of patients called "per group" activities, and the activities performed in an individual patient called "per patient" activities.

Endpoints

The primary study endpoints were: 1) Observed health care personnel time (total and by type of professional) per patient using ESAs vs. Mircera® per session;
2) Time per patient using ESAs vs. Mircera® per year (including average time per session for ESAs multiplied by average number of ESA sessions per patient per year and average time per session for Mircera® multiplied by 12 injections per patient per year);
3) observed time for all patients in the centre per year using ESAs and Mircera®. The secondary endpoints included the extrapolation of the Mircera® uptake for the entire centre from 0% to 100% using estimated time per patient per year for ESAs vs. Mircera. This allowed to calculate time savings obtained by the switch from ESAs to Mircera®.

Statistical analyses

For each sample, descriptive statistics were calculated (N, mean, min, max, standard error). For each activity, 95% confidence intervals (CI) were calculated. For each per group activity, a Generalised Linear model was used to determine if group size was a predictor or time or not. If group size mattered (p value < 0.1), the analysis used the adjusted coefficients for the Mircera sample. If group size did not matter, the unadjusted coefficients were used instead.

Regulatory and ethical considerations

The study did not affect the treatment that patients would have received anyway, so patient informed consent was not required. Patient demographics were not collected.

Description of Polish centres

The centres that participated in this study were Ciechanów (C01), Zielona Góra (C02) and Łódź (C03). The number the treated patients with ESRD ranged from 60 (C01) to 136 (C03).

Quantitative results

In all three centres the average time for observed anaemia management tasks per patient per session was 3.25 minutes for ESAs and 3.03 minutes for Mircera®. In C01 and C02, activities were performed for each patient individually, so average times per ESA vs. Mircera® patient were directly comparable. In C03, preparation and distribution activities were performed per group of patients. The average size of groups varied substantially in the two samples: average of 10

patients per session received ESAs while average 2 patients received Mircera®. Based on the current average number of ESA sessions per patient in each centre, a patient switched to Mircera® would generate time savings from 82% (C01) to 88% (C02 and C03). Based on expected time per patient per year for ESAs vs. Mircera, and the number of patients treated with ESAs vs. Mircera, the annual time spent on anaemia management was extrapolated per centre. Total time per centre ranged from 170 hours or 21 working days (C02) to 397 hours or 50 working days (C03). Results cannot be compared across centres because of differences in numbers of patients in each centre, percentage uptake of Mircera, and the expected annual number of ESA sessions per patient.

Efficiency gains were obtained by avoiding injections, and the time used for the observed activities. The number of injections avoided per patient per year ranged from 55 (C01) to 112 (C02). Potential additional time savings could be due to less frequent anaemia management activities, such as inventory, ordering, and storage. In order to compare efficiency gains across centres, time savings (hours) for the extreme scenarios of 100% Mircera® and 0% Mircera® uptake were calculated. Time savings ranged from 221 hours in C02 to 477 hours in C03, translating into reductions ranging from 82% (C01) to 88% (Centres 2 and 3).

Qualitative results

Questionnaire 1 (answered by the head nurse and a nephrologist) included blood sampling, inventory, ordering, storage at the ward and physician visits. Two centres expected a decrease in the frequency of ad hoc tests with a switch to Mircera®. All centrs expected overall time savings for inventory and ordering, and only about half of the refrigerator space needed for ESAs would be used in case of the complete switch to Mircera®. Physician visits for assessment of anaemia status would be reduced from daily/weekly to monthly.

Questionnaire 1 (answered by a pharmacist at the centre pharmacy) included time of inventory or ordering activities. The pharmacy in one centre reported no reduction in time of inventory or ordering activities after the switch to Mircera®, while a pharmacy in another center believed that up to 50% of time dedicated to receiving orders from the ward and ordering ESAs from wholesalers could be saved. Pharmacy in the third center did not respond. Questionnaire 2 (answered by the head nurse) included several questions concerning functional aspects of the switch from ESAs to Mircera® with respect to various personnel activities. All three centers observed/expected functional changes in the unit, including lower frequency and/or less total time required for the inventory of ESA at the pharmacy and at the ward, ordering of ESA at the pharmacy and at the ward, less refrigerator space necessary for ESAs at the pharmacy and at the ward as well as less time spent on the preparation and injections of ESAs.

Conclusions

The results of the study show that 100% conversion to once-monthly maintenance therapy with Mircera® would offer annual time savings on frequent anaemia management tasks in the range of 82% to 88% compared to a scenario where only traditional ESAs are used (absolute time savings with 100% conversion in the range of 221 to 477 hours). These results confirm the findings from the previous study assessing the use of Mircera® administered once per month in Germany and the UK [7]. Total observed annual time per centre ranged from 175 to 397 hours. Comparison of the times in respective centers is difficult due to variations of percentage uptake of Mircera® (from 22% to 34%; average 29%) expected annual number of ESA injections per patient (from 68 to 124; average 93 sessions) and the number of patients treated in the centre (from 60 to 136; average 94 patients). The observed annual time per patient receiving traditional ESAs ranged from 176 to 380 minutes, while for Mircera® once-monthly the expected time per patient per year ranged from 21 to 68 minutes (from 54 to 111 injections avoided per patient per year; from 82% to 88% reduction of time vs traditional ESAs). Information on other less frequent and/or nonobservable anaemia management related activities was assessed qualitatively through interviews with one key centre healthcare staff member (the head nurse). Inventory/ordering frequency for Mircera® was expected to be reduced in all centers. All centers expect that substantially less refrigerator space would be needed if only Mircera® was used. With respect to scheduled blood testing the results varied by center but the conversion to once-

monthly Mircera® maintenance therapy may have some impact on reducing the frequency of blood testing. Two centers expected the frequency of the nephrologist assessment of anaemia status during a daily ward round to be reduced. The pharmacies in all three centres reported less total time needed for inventory, ordering and refrigerator space due to introduction of Mircera®. The analysis has shown that once-monthly Mircera® (12 injections per year) maintenance therapy results in substantial time savings, allowing healthcare resources to be allocated to other important ESRD related healthcare needs. The respondents believed that once-monthly Mircera® leads to significant benefits to the center as a whole and for nursing staff, with somewhat lower benefits perceived for nephrologists and patients. Centers believed that the time freed up from converting to Mircera® would lead to overall improved anaemia management. The respondents believed that this time could be spent on a wide range of activities, but in particular "improving overall CKD care", "instructions on AV-shunt care", and "documenting patient parameters".

In conclusion, with traditional ESAs, hemodialysis centers spend a substantial amount of time per year on tasks related to anaemia management. Our study showed that a substantial reduction in time spent on ESA administration and associated costs may be achieved by converting from traditional ESA regimens to once monthly treatment with Mircera. Such savings may allow healthcare resources to be reallocated to other aspects of patient management, thereby enhancing the overall quality of dialysis care, and potentially enabling improvements in clinical outcomes.

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