

Improving Anemia Therapy in Hemodialysis Patients. Results of a multicentre clinical audit.

Iain C Macdougall,¹ António Sousa,² Carlos Andrade,² Erika Schümann,³ Thomas Ryzlewicz,³ Franz-Ferdinand Becker,⁴ Amelia Fairburn-Beech,⁴ William Kilgallon.⁴

¹Renal Unit, King's College Hospital, London, United Kingdom; ²Fundação Renal Portuguesa, Portalegre, Portugal. ³Via Medis Nierenzentren, Riesa, Germany, ⁴Oxyles Ltd, London, United Kingdom

Overview

Background

A novel universal bloodline (Oxyles), which greatly reduces the contact between blood and air, has been developed for routine hemodialysis. The innovative design of the Arterial Expansion Chamber (AEC) results in a 99% reduction in blood-air contact, provides an outlet for air to escape and does not create turbulence; thus enabling quality dialysis. Reduction in blood-air contact should lead to reduced ESA and iron dose requirements as a result of increased red cell survival. This represents an alternative strategy in managing renal anemia. The aim of this current investigation was to explore the extent to which the use of this bloodline could improve the efficiency of anemia therapy in a routine dialysis patient population.

Methodology

- A 16-month open label, single crossover, prospective audit. One hundred and nine patients were initially entered into this investigation.
- Patients were all, aged > 18 years, stable on dialysis x 3 weekly, for 3 months.
- The patients reverted back to using control bloodlines (Nikkiso and Gambro) during the Crossover phase of the audit.
- All patients were treated with ESAs (epoetin alfa or darbepoetin alfa) and intravenous (IV) iron sucrose according to clinic protocols.
- Routine data on Hb, ESA and IV iron doses were recorded.

Patient profiles

Audited patients	n = 58
Mean age (yrs)	73.0 (36.0 – 93.0)
Males : Females	30 : 28
Mean time on dialysis (yrs)	4
Diabetic : Non-diabetic	24 : 34
Mean weight (kg)	73.2 (42.0 – 115.0)
ESA dose (IU/week/kg)	86.4 (4.0 – 240.0)

The patient population was demonstrably representative of a typical dialysis population as shown by demographic profile and ESA dose levels, alongside co-morbidity profiles.

Results

Data analysis was conducted on 58 patients from two clinics. Patients dropped-out due to death (21), transplantation (3), intercurrent events including access problems, gastrointestinal bleeding and hospitalisation (20) and patients moving clinics (7).

Regression analysis

Multiple time-dependent regression analysis (Imperial College, London) was used to relate ESA dose to the presence and absence of the Oxyles bloodline.

This confirmed that no other variable such as age, sex, weight, diabetic status, iron dose or time on dialysis could have brought about the ESA dose reduction observed ($p < 0.001$).



Results and Analysis

Figure 1 Hb levels, ESA and iron doses during the Run-in, Treatment and Crossover phases

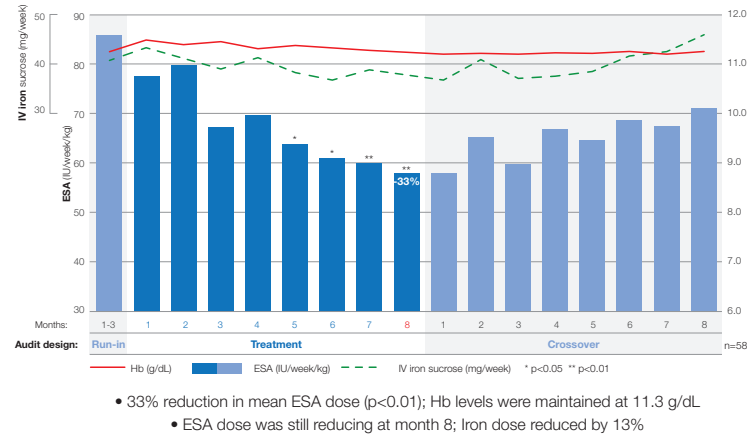


Figure 2 ESA savings by patient dose category

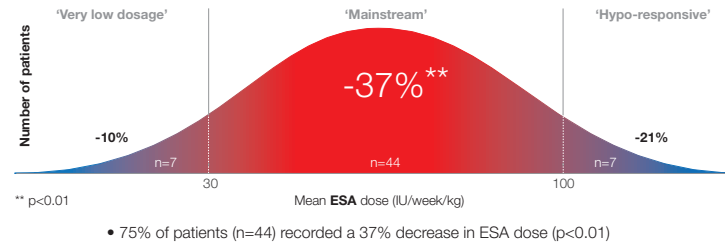
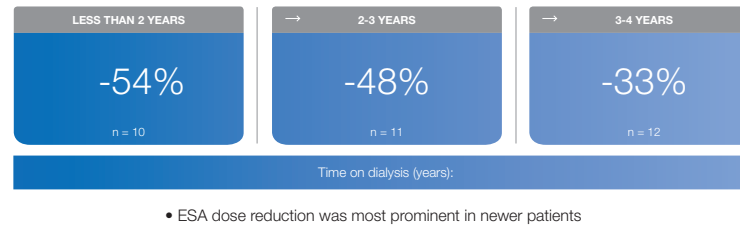


Figure 3 ESA reduction is more pronounced in patients newer to dialysis



The use of this novel bloodline may represent an alternative strategy in managing renal anemia and could have financial benefits for routine hemodialysis service delivery.

Conclusions

Patient population (Figure 1)

Mean ESA dose fell by 33% from 86.4 to 57.9 IU/week/kg.

This equates to a dose reduction from 5,919 to 4,090 IU/week; a per patient reduction of 1,829 IU/week.

This reduction was still on a downward trend at month 8.

The crossover design further validates these results where ESA doses increased to 83% of their Run-in levels.

Iron dose did not influence the reduction in the ESA dose. These iron doses returned to 120% of pre-treatment levels during the crossover phase.

This significant reduction in ESA doses, suggest that this novel bloodline might improve efficiency of anemia therapy, possibly by improving red cell integrity and survival.

Patient profiles (Figure 2)

Mean ESA dose fell from 87.2 to 54.6 IU/week/kg (n=44).

This equates to a per patient dose reduction of 2,157 IU/week.

75% of the patient population fell into this category, recording a 37% fall in ESA dose by the end of the Treatment phase. This increased to 94% of pre-treatment ESA levels by the end of the Crossover.

This is reflective of the practical benefit of the bloodline in a routine dialysis setting.

Patient vintage (Figure 3)

Patients who were relatively new to dialysis i.e. < 4 years, showed a more substantial reduction (54%) in ESA doses.

This reduction was progressive over the intervening years.

This benefit to these patients was irrespective of their diabetic status.

As a result, patients beginning dialysis on the bloodline could benefit from the greater reduction in ESA doses, thereby substantially increasing average savings.