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RESEARCH ARTICLE

Restitution volumes at the end of dialysis sessions: A potential influencing factor on patients' haemoglobin levels?

Joao Fazendeiro Matos[1] | Ricardo Peralta[1] | Carla Felix[1] | Bruno Pinto[1] | Pedro Goncalves[1] | Vera Carlos[2,3,4] | Ricardo Rodrigues[2,3] | Maria Teresa Parisotto[5] | Maria João Carvalho[6] | Pedro Ponce[7]

[1]NephroCare Portugal, Fresenius Medical Care Portugal, Porto, Portugal
[2]NECE-UBI, Universidade da Beira Interior, Covilhã, Portugal
[3]EMAES, Universidade da Beira Interior, Covilhã, Portugal
[4]Universidade de Aveiro, Aveiro, Portugal
[5]Care Value Management, Fresenius Medical Care, Bad Homburg, Germany
[6]NephroCare Portugal, Fresenius Medical Care Portugal, Gaia, Portugal
[7]NephroCare Portugal, Fresenius Medical Care Portugal, Lisboa, Portugal

Correspondence
João Fazendeiro Matos, Fresenius Medical Care Portugal/NephroCare Portugal; Rua da Boaviagem, nº 35. Lugar de Crestins – Moreira, 4470-210 Maia, Portugal.
Email: jfazendeiro.matos@fmc-ag.com

Abstract

Aim: To evaluate whether haemoglobin (Hb) levels are influenced by the restitution volume (RestVol) at the end of the dialysis session, independently of erythropoiesis-stimulating agents (ESA) and iron doses.

Design: Over 12 months, 4,386 haemodialysis patients from 34 centres were enrolled in this observational descriptive study according to the checklist STrengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Method: RestVol, Hb levels, ESA and iron doses of every patient were assessed on a monthly basis. To determine the ideal RestVol, the clinics were classified into three groups according to the restitution volumes at the end of the dialysis sessions.

Results: Mean age was 69 ± 14 years, and 58.9% were men. The evaluation of 665,712 treatments revealed that RestVol of 380 ml seems to be the most efficient, since the clinics in this group managed to reduce ESA consumption with a negligible reduction in Hb levels.

KEYWORDS
dialysis, haemoglobin, nurses, nursing, restitution volume

1 | INTRODUCTION

Chronic kidney disease (CKD) patients have a diversity of serious health problems, associated with accumulation of uraemic toxins, dyslipidaemia, abnormal calcium/phosphate metabolism, oxidative stress, malnutrition, inflammation and anaemia (Joki et al., 2006; Kalantar-Zadeh, Rodriguez, & Humphreys, 2004; Yao, Pecoits-Filho, Lindholm, & Stenvinkel, 2004). It is well established that malnutrition and chronic inflammation play a crucial role in the progression of uraemic atherosclerotic cardiovascular disease (Stenvinkel et al., 1999) and as well anaemia, which are common causes of morbidity and mortality (Prabhu, Nayak, Sridhar, Subhramanyam, & Nayak, 2012) in these patients. Moreover, strict blood pressure control and regulation of calcium-phosphate metabolism are essential to maintain an optimum haemoglobin (Hb) concentration with erythropoiesis-stimulating agents (ESA) and iron (Locatelli et al., 2013 and KDIGO, 2012).

However, one of the main obstacles for the achievement of this therapeutic goal is the variability of individual responses to ESA, which has been attributed to patient-related factors, such as iron deficiency, malnutrition and chronic inflammation (Agarwal, Davis, & Smith, 2008; Kalantar-Zadeh et al., 2009; Lopez-Gomez, Portoles, & Aljama, 2008; Prabhu et al., 2012). This inflammation is associated with the accumulation of uraemic toxins inhibiting erythropoiesis. There are other factors affecting anaemia such as dialysis adequacy (Ifudu, Feldman, & Friedman, 1996; Locatelli et al., 2011; Movilli et al., 2001) and the microbiological purity of dialysis fluid (Hsu et al., 2004 and Susantitaphong, Riella, & Jaber, 2013).

> **What does this paper contribute to the wider global clinical community?**
>
> - An efficient and correct blood reinfusion at the end of haemodialysis treatment helps to reduce anaemia risks and improves safety and quality of patient care.
> - 380 ml seems to be the restitution volume that prevent patient's blood loss with correct and efficient blood restitution until the bloodlines are completely rinsed.

2 | BACKGROUND

With regard to the dialysis technique, convective treatments (CTrs) seem to be more effective in correcting anaemia than standard haemodialysis (HD) (Panichi et al., 2015), as they remove small and medium/large molecules that hinder erythropoiesis. However, studies on the effects of CTrs on ESA resistance have produced conflicting evidence due to their heterogeneous design, execution and outcome. The findings of observational studies have suggested that online haemodiafiltration (OL-HDF) has a more beneficial effect on erythropoiesis and the cardiovascular disease with a lower mortality (Locatelli et al., 2011; Movilli et al., 2001; Bonforte, Grillo, Zerbi, & Surian, 2002; Vaslaki et al., 2006; Panichi et al., 2015; Maduell et al., 2013 and den Hoedt et al., 2014) compared with standard low-flux HD, while others studies have failed to confirm this, neither HDF nor HD played a significant role in increasing Hb levels or decreasing ESA resistance (Wizemann, Lotz, Techert, & Uthoff, 2000; Vilar et al., 2009 and van der Weerd et al., 2014).

In fact, these patients are frequently subject to many external aggressions that also negatively influence Hb level. It is estimated that a CKD patient loses 2–3 g of iron yearly due to: blood remaining in the extracorporeal blood circuit (ECC) (bloodlines and filter); inadequate/incomplete rinsing back of the blood to the patient at the end of the dialysis session; monthly blood sampling for laboratory testing; improper haemostasis and accidental bleeding from the vascular access. Patients with a central venous catheter (CVC) also loose blood during haemodialysis sessions, considering more than 1 ml per branch per treatment.

Against the background of increased treatment costs associated with anaemia management and at the same time optimizing daily activities, the main objective of this study was to determine the influence of restitution volumes (RestVol) (blood restitution at the end of dialysis sessions) on the Hb levels, independently of ESA and iron doses while ensuring a high-quality nursing care.

To study the relation between blood haemoglobin and RestVol in chronic HD patients, our biologically plausible assumption was that a higher RestVol will lead to higher haemoglobin levels due to a better clean-up of the ECC by reducing the waste of blood. If this hypothesis is true, a reduced ESA and iron dose can be expected in clinics where patients typically receive larger restitution volumes.

3 | METHODS

3.1 | Study design

The observational descriptive study, according to the checklist for reporting results the STrengthening the Reporting of OBservational Studies in Epidemiology (STROBE) (von Elm et al., 2007, File S1), was performed. The survey was conducted using data extracted from a database, refined and examined retrospectively for all enrolled CKD patients who underwent HDF with online-prepared substitution fluid (OL-HDF) for 12 months, from January 2013–December 2013 in 34 clinics at Fresenius Medical Care, NephroCare Portugal, S.A. Patients were dialysed three times a week, with a 4-hr schedule, using a Fresenius 5008 CorDiax® machine with high-flux polysulfone dialysers (FX CorDiax 600®). All HDF machines were equipped with a dialysis fluid ultrafiltration system (Diasafe®, Fresenius Medical Care) for the production of ultrapure dialysate [each millilitre containing <0.01 colony-forming units (CFU), <0.01 endotoxin units (IU)] and sterile non-pyrogenic substitution fluid (0 CFU/ml and <0.01 IU/ml), which were monitored at monthly intervals.

The convection volume was controlled automatically using the "auto sub" system of the 5008 machine and the RestVol was done with ultrapure dialysis fluids (On-Line solution) at the end of the treatment at a designated flow rate between 150–200 ml/min. Treatment was performed using a personal Patient Card storing all required treatment parameters from the EuCliD® (Fresenius Medical Care) database on the haemodialysis machines, including medication. At the end of each treatment, data are sent back to EuCliD® confirming reliability of all outputs.

3.2 | Ethical considerations

The study was reviewed and approved by the institutional review board of Nephrocare Portugal. Because of its retrospective nature, non-interventional, registry-based with large sample data anonymously retrieved from a central database (EuCliD® – Fresenius Medical Care), the anonymity of the studied patients was always maintained, and the requirement for a written consent form was exempted.

3.3 | Participants

The selected participants had to meet the following inclusion criteria: (a) on dialysis for at least 3 months; (b) postdilution OL-HDF treatment modality; (c) receiving ESA therapy at least once per month. The exclusion criteria was considered for all patients with lack of monthly data and the RestVol out of range ≥200 to ≤500 mL.

3.4 | Therapy

The following procedures were recorded for each session: amount of RestVol with On-Line solution, ESA and iron dose, other drugs administered intravenously during or at the end of the session and all inter-dialysis therapies. Routine patient care and all medication prescriptions were decided by the attending nephrologists or physicians. ESA and iron supplements were administered through the venous blood line at the end of the dialysis sessions.

During the study, the clinic objective for haemoglobin levels target was 10–13 g/dl as part of the Capitation system developed in Portugal (Ponce et al., 2012), agreed between the Portuguese Ministry of Health and the Portuguese association of dialysis providers. ESA prescribed was darbepoetin α (Aranesp®), and the respective doses of microgram per week were converted to the international unit per week by means of multiplication with the European label conversion factor of 200, as suggested by Locatelli et al., (2012). Iron sucrose (Venofer®) was used for iron replacement.

3.5 | Laboratory data

Blood samples were drawn at the beginning of the treatment using the same techniques in all NephroCare dialysis clinics and transported to the laboratory, typically within 24 hr. Pre-dialysis levels of Hb were measured at least monthly according to protocol, and iron status was checked at least every 3 months.

3.6 | Statistical analysis

All statistical analyses were performed using software for Windows version 3.1.2 (R Core Team, 2014). Throughout the analysis, $p < 0.05$ was used as significance level. Data are presented as mean ± *SD*.

To study the relation between blood haemoglobin and RestVol in long-term HD patients, our biologically plausible assumption was that higher RestVol leads to higher haemoglobin levels due to a better clean-up of the ECC reducing the waste of blood. If this hypothesis is confirmed, a reduction of ESA and iron consumption could be expected in clinics where the patients typically receive larger reinfusion volumes. Moreover, a higher ESA dose should still result in higher haemoglobin levels over time in the individual patient. Therefore, the examination of longitudinal models at individual level with repeated measures over time should more genuinely reveal the underlying and biologically plausible dose–response associations. To evaluate the relation between RestVol and the Hb independently of ESA and iron doses, the multiple moderate regression analysis was used.

A secondary objective was to evaluate whether the clinics which administer a higher RestVol to their patients would also have a lower consumption of ESA and iron therapy maintaining the same Hb levels. Thus, the analytical unit was the clinic and we continued to collect data individually per clinic level and obtained 34 individual observations. In the Wilcoxon–Mann–Whitney test, using the clinic as analytical unit, we calculated the mean of the metric variables for every clinic.

In these analyses, we revealed that the clinics which infused higher RestVol were those in the 3rd quartile reinfusion volume (over 387 ml). We used a similar procedure with ESA variables (3rd quartile >1.72 μg kg^{-1} $month^{-1}$), iron (3rd quartile >3.72 mg kg^{-1} $month^{-1}$) and combination of ESA and iron (3rd quartile >6.31 μg kg^{-1} $month^{-1}$) was found. Thus, by definition, the top group consisted of approximately one quarter of the clinics (N = 9) and the other group of the remaining 25 for each variable.

To determine the ideal RestVol, the clinics were classified into three groups according to the restitution volumes at the end of the dialysis sessions. Group 1 (G1) comprised the clinics with an average RestVol of <320 ml (13 clinics); Group 2 (G2) ranged from ≥320–<390 ml (13 clinics); and Group 3 (G3) ≥390 ml (8 clinics). A MANOVA analysis was used to study the potential group effect (RestVol) for Hb levels in consideration of the ESA consumption.

A total of 4,386 patients (mean age was 69 ± 14 years; 58.9% were men, distributed per 34 clinics) were enrolled in the study. We evaluated the RestVol of 665,712 treatments during the study period of 12 months and converted the results into monthly averages resulting in 38,630 observations. The mean RestVol was 345 (*SD* 1.76) ml/treatment (ranging from ≥200–≤500 ml).

4 | RESULTS

The patients' baseline haemoglobin and ferritin levels were 11.07 (*SD* 1.17) g/dl and 564.05 (*SD* 315.09) ng/ml, respectively. Figure 1 summarizes the monthly development of the three variables: RestVol, Hb and ESA. Haemoglobin concentrations were between 10–13 g/dl in 80.89% and <10 g/dl in 13.59% of the patients. At baseline, treatment was performed with darbepoetin α and the route of administration remained constant for each patient throughout the whole follow-up period.

The mean ESA dose was 1.57 (*SD* 1.54) μg kg^{-1} $month^{-1}$ (EPO 86.11 *SD* 84.77 IU kg^{-1} $wk^{-1)}$, and all patients were treated with intravenous iron and the consumption assessed on a monthly basis; mean dose was 3.04 (*SD* 2.28) mg kg^{-1} $month^{-1}$ (0.57 *SD* 0.59 g kg^{-1} wk^{-1}).

4.1 | The effect of RestVol in Hb levels and effect moderator of ESA and iron

According to the presented data (Table 1), the RestVol explained only 0.6% (r^2 = 0.006) of the variation observed in Hb levels. This means that 99.4% can be attributed to other factors. Although these results seem to be low, this represents an increase of Hb 0.1318 g/dl per unit of RestVol (100 ml). However, RestVol and ESA administration as an independent variable (model 2) or as retarding (model 3) explained 22.9% (r^2 = 0.229) of the variation of Hb levels. Similarly, when evaluating the relationship to iron as independent or moderate variable, we found out that this variable explains only 0.7% of the variation of Hb. The variable RestVol is also significant in the

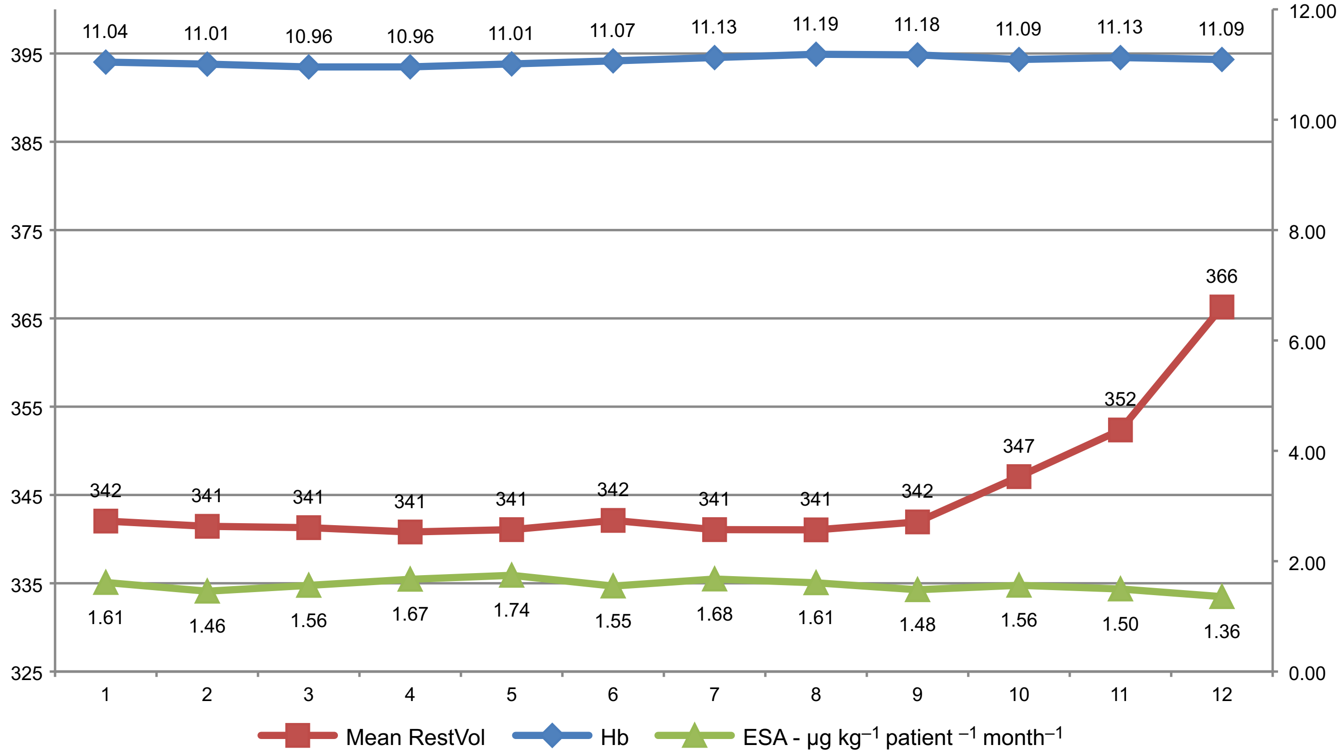

FIGURE 1 Trend of monthly averages for RestVol, Hb and ESA

three models (p < 0.0001; α < 0.05), that is the restitution volume has a significant effect on Hb levels independent of the ESA and iron administration dose. Table 1 summarizes the results of the multivariate analysis.

To evaluate the influence of RestVol and ESA therapy on the Hb levels, the ESA variable was found to have a higher explanatory weight (R^2=−0.398; p < 0.001) than the RestVol variable (R^2 = 0.077), however, with a negative influence (Table 2). Evaluating the influence of RestVol and iron on the Hb levels, we found out that the influence of the RestVol variable on Hb was higher ($R^{2\,=}$ 0.112) than the influence of iron variable (R^2 = −0.018). This relationship of iron with Hb had a negative influence on the Hb and ESA variable. However, this effect was not shown to be significant (Table 2) to determine the relationship between the restitution volume and haemoglobin by using ESA (p = 0.433) and iron (p = 0.440) as moderating variables.

TABLE 1 Multiple linear regression analysis of factors associated with Hb concentration

Variable	R^2	p value
RestVol (Model 1)	0.006	<0.0001
ESA (Model 2)	0.229	<0.0001
RestVol*ESA (Model 3)	0.229	<0.0001
Iron (Model 2)	0.007	<0.0001
RestVol*Iron (Model 3)	0.007	<0.0001

4.2 | Restitution volume and correlation with ESA and iron consumption

During the evaluation whether the clinics with higher RestVol would consume less ESA, we observed that the clinics which reinfused more volume spent on average 1.54 (SD 0.22) µg kg^{-1} $month^{-1}$, while the other clinics consumed 1.58 (SD 0.21) µg kg^{-1} $month^{-1}$ (Figure 2). However, these differences were not significant (p = 0.591).

During the study, we also assessed whether the clinics with more restitution RestVol would consume less iron. We found out that the clinics which reinfused more volume consumed on average

TABLE 2 Multiple linear regression analysis of factors associated with Hb concentration

Variable	Model 1 Regression coefficient	Model 2 Regression coefficient	Model 3 Regression coefficient	p value
Model to ESA				
RestVol (100 ml)	0.1318	0.07716	0.09691	0.001
ESA		−0.39761	−0.244	0.000
RestVol*ESA			−0.00012	0.433
Model to Iron				
RestVol (100 ml)	0.1318	0.112	0.07837	0.000
Iron		−0.01768	−0.053	0.007
RestVol*Iron			0.00010	0.440

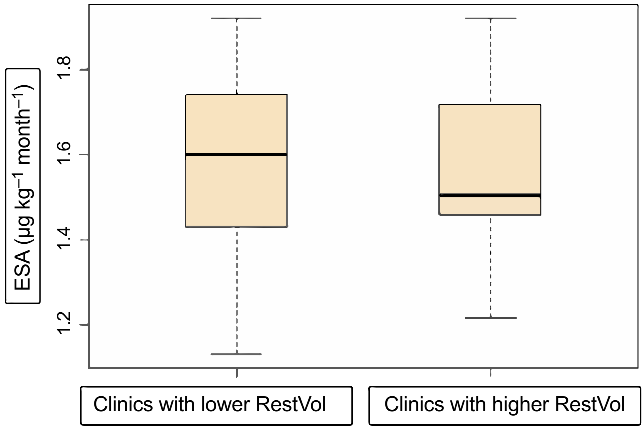

FIGURE 2 ESA consumption by clinics with different RestVol levels

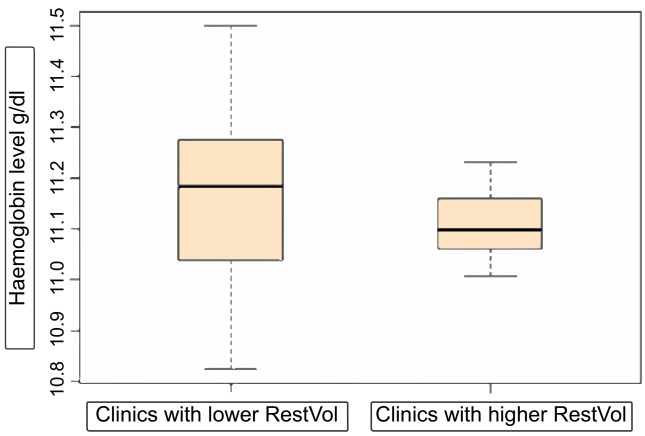

FIGURE 3 Restitution volume versus haemoglobin level

3.15 ± 0.624 mg kg^{-1} $month^{-1}$ of iron, while the other clinics consumed 3.15 ± 0.639 mg kg^{-1} $month^{-1}$. However, these differences were not significant (p = 0.701).

4.3 | Restitution volume and correlation with haemoglobin levels

The clinics with lower RestVol had better Hb levels, 11.17 ± 0.189 g/dl compared with the clinics with higher restitution volumes (11.12 ± 0.135 g/dl). Nevertheless, a higher concentration within Hb target (10–13 g/dl) was observed which is associated with a lower standard deviation (Figure 3). However, these differences are not significant (p = 0.714).

4.4 | Comparison of the mean RestVol between clinics groups

Table 3 shows the average of independent and dependent variables between the groups. The comparison of all the pair groups (1–2, 1–3 and 2–3, Table 3) demonstrated the following results: there was a statistical difference between G1 and G2 (average RestVol/ml G1 298.1 vs. G2 357.3 ml) (Pillai's trace = 0.002; F = 2.402, p = 0.048), with no differences between the G1 and G3 (Pillai's trace = 0.001; F = 1.468; p = 0.231) or between G2 and G3 (Pillai's trace = 0.002; F = 2.002; p = 0.135). Group 2 had less ESA and Fe consumption with similar results of average level of Hb. The quartile analysis of the same group (ranged from ≥320–<390 ml) showed that 380 ml was the ideal volume to clean the ECC and maintaining Hb levels with less consumption of ESA.

5 | DISCUSSION

At present, there are no studies identifying the impact of technical procedures and nursing care during dialysis with a loss of haemoglobin. These results showed that the RestVol played a significant role in the positive variation in Hb levels despite a low variation. With a baseline RestVol of 345 ml of online solution per patient/treatment, it represents an increase of Hb 0.4557 g dl^{-1} $patient^{-1}$ $month^{-1}$. This result is similar to the effect of ultrapure dialysate on anaemia parameters which also lead to a significant increase in the mean haemoglobin level of 0.40 g/dl (Susantitaphong et al., 2013), but less than polycystic kidney disease which was associated with higher Hb levels (0.82 g/dl) (Kalantar-Zadeh et al., 2009).

One can therefore assume that thorough cleaning of the ECC at the end of the treatment and return of whole blood to the patient can contribute to an improvement of Hb levels. Similarly, adjustment of inappropriate anticoagulation during treatment or monitoring of patients with changes in coagulation factors can improve blood losses in the ECC.

We also observed that the relationship between ESA doses and Hb was higher than the influence of RestVol, although it had a negative beta coefficient, thus confirming the finding of previous randomiszed trials that higher ESA doses are associated with lower Hb levels. This may be explained by the fact that prescription of ESA dose usually increases when Hb levels are low. This is also the reason why iron influenced the levels of Hb negatively.

The clinics with higher RestVol consuming less ESA had a similar iron consumption and 82.04% of patients were within the target 10–13 g/dl of Hb and 13.82% had <10 g/dl compared with the other clinics who obtained 80.51 and 15.42%, respectively. However, these findings are statistically not significant.

TABLE 3 Characterization of groups – average of RestVol, Hb, ESA and Fe

Group	RestVol/ml	Hb g^{-1} dl^{-1}	ESA μg^{-1} kg^{-1} $month^{-1}$	Fe mg^{-1} Kg^{-1} $month^{-1}$
1	298.1 (10.5)	11.142 (0.21)	1.633 (0.19)	3.401 (0.63)
2	357.3 (19.7)	11.128 (0.18)	1.495 (0.22)	3.118 (0.57)
3	404.4 (8.2)	11.139 (0.11)	1.580 (0.19)	3.140 (0.68)

Note: Standard deviations in parentesis.

6 | CONCLUSION

It can be concluded that the RestVol has an influence on haemoglobin levels, although this influence is low, independent of ESA and iron doses. It was also identified that the ESA dose influences haemoglobin levels and it was found to be much higher than the influence of the RestVol, although it is negative. Although with better results, reduced consumption of ESA in the clinics with higher RestVol was statistically not significant.

According to the results and quartile analysis of a RestVol of 380 ml (Group 2) seems to be the most efficient (ideal), since the clinics in this group managed to reduce ESA consumption with a negligible reduction in Hb levels (Table 3). The clinics in this group had more patients with values within Hb target (81.6%) compared with Group 1 (79.6%). Moreover, the 3rd quartile RestVol (over 387 ml) did not produce better Hb results.

6.1 | Relevance to clinical practice

One of the main roles of nurses is to prevent patient's blood loss with correct and efficient blood restitution until the bloodlines are completely rinsed and no residual blood remains in the extracorporeal circuit. In this study, 380 ml of the RestVol seems to be the most efficient result. An efficient and correct blood reinfusion at the end of the treatment helps to reduce anaemia risks and improves the quality of patient care.

6.2 | Limitations

This study has at least one limitation: As all observational studies, there is a residual possibility of confounding variables and it was not possible to isolate patients with infection status or who have received at least one blood transfusion.

CONFLICTS OF INTEREST

J. F. M., B. P., P. G., M. T. P, C. F., M. J. C., P. P. and R. P. are employees of Fresenius Medical Care and may hold shares in the company.

AUTHOR CONTRIBUTIONS

Fazendeiro Matos, J.; Peralta, R.: Design. Goncalves, P.; Peralta, R.: Data extraction. Rodrigues, R.; Carlos, V.; Peralta, R.; Fazendeiro Matos, J.: Data analysis. Peralta, R.; Félix C.; Pinto, B.: Writing. Carvalho, M J.; Fazendeiro Matos, J.; Parisotto, MT.: Revision. Fazendeiro Matos, J.; Ponce, P.: Responsible.

ORCID

Ricardo Peralta https://orcid.org/0000-0001-6962-1073
Ricardo Rodrigues https://orcid.org/0000-0001-6382-5147

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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