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Original article

Therapeutic Apheresis Registry of the Spanish Society of Nephrology. Analysis of activity over the last five years



Registro de aféresis terapéutica de la sociedad española de nefrología. Análisis de la actividad en los últimos 5 años

E. Rodríguez^{a,*}, L. Sánchez-Cámara^b, E. Márquez^a, A. Herreros^c, S. Benito^c, M. Fernández-Lucas^d, M.V. Rubio^e, R. Franquelo^f, R. Escaño^f, N. Ramos^g, E. Tamarit^h, J.M. Benlliure^h, O. Siverioⁱ, M.I. Gallardo^j, M.P. Valenzuela^k, E. Davin^l, N. Martín-Aleman^m, L.M. Cuetoⁿ, M.T. Padrónⁿ, M.T. Rodrigo de Tomáso^o, A. Aymat^o, V.R. Mercado^p, R. García^q, S.M. Cruz^r, I. González^r, L. Medina^s, E. Sánchez^t, D. Barraca^b; en nombre del Grupo de Trabajo de Aféresis Terapéutica de la SEN

^a Servicio de Nefrología, Hospital del Mar-IMIM, Barcelona, Spain

^b Servicio de Nefrología, Hospital Universitario Gregorio Marañón, Madrid, Spain

^c Servicio de Nefrología, Fundación Puigvert, Barcelona, Spain

^d Servicio de Nefrología, Hospital Universitario Ramón y Cajal, Madrid, Spain

^e Servicio de Nefrología, Hospital Clínico Universitario Lozano Blesa, Zaragoza, Spain

^f Servicio de Nefrología, Hospital Vithas Xanit Internacional, Málaga, Spain

^g Servicio de Nefrología, Hospital Universitario Valle de Hebrón, Barcelona, Spain

^h Servicio de Nefrología, Hospital General Universitario de Valencia, Valencia, Spain

ⁱ Servicio de Nefrología, Hospital Universitario Nuestra Señora de Candelaria, Santa Cruz de Tenerife, Spain

^j Servicio de Nefrología, Hospital Universitario Galdakao-Usansolo, Galdakao, Spain

^k Servicio de Nefrología, Hospital Universitario Parc Taulí, Sabadell, Spain

^l Servicio de Nefrología, Hospital San Pedro de Alcántara, Cáceres, Spain

^m Servicio de Nefrología, Hospital Universitario Dr. Josep Trueta, Girona, Spain

ⁿ Servicio de Nefrología, Hospital General Universitario de Toledo, Toledo, Spain

^o Servicio de Nefrología, Hospital Universitario de Donostia, San Sebastián, Spain

^p Servicio de Nefrología, Hospital Universitario Infanta Sofía, San Sebastián de los Reyes, Madrid, Spain

^q Servicio de Nefrología, Hospital Juaneda Miramar, Palma Islas Baleares, Spain

^r Servicio de Nefrología, Hospital Universitario Juan Ramón Jiménez, Huelva, Spain

^s Servicio de Nefrología, Hospital Universitario Infanta Leonor, Madrid, Spain

^t Servicio de Nefrología, Hospital Universitario Central de Asturias, Oviedo, Asturias, Spain

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ABSTRACT

Introduction: Therapeutic apheresis (TA) is an extracorporeal technique used to treat various renal and non-renal pathologies, for which the ASFA guidelines provide recommendations. In Spain, nephrology services have progressively adopted various forms of TA, and since 2018, the Spanish Society of Nephrology (S.E.N.) has maintained a national TA registry to monitor its use.

Objective: To describe the activity of nephrology services participating in the TA registry of the S.E.N. (AFT-S.E.N.) between 2019 and 2023.

Material and methods: A descriptive observational study was conducted that included all treatments consecutively recorded in the AFT-S.E.N. registry between 2019 and 2023. A total of 4331 procedures performed on 525 patients across 19 nephrology services were analysed.

Results: The median age was 43.7 years, and 49.6% of patients were female. The main indications were neurological diseases (33%), renal diseases (22%), and metabolic diseases (19.6%). Sixty percent of the procedures were performed for acute episodes and 40% in chronic programmes. The most commonly used

* Corresponding author.

E-mail address: erodriguez@hmar.cat (E. Rodríguez).

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technique was plasma exchange (72.2%), followed by double filtration (19.7%). Adverse effects occurred in 7% of sessions, primarily hypotension and vascular access issues.

Conclusions: The AFT-S.E.N. registry represents the first multicentre initiative in Spanish nephrology. The data demonstrate the expansion and diversification of TA techniques and the implementation of chronic programmes. They also show that TA is being integrated into clinical nephrology practice, with an acceptable safety profile.

RESUMEN

Palabras clave:

Registro
Aféresis terapéutica
Técnicas de aféresis
Indicaciones aféresis

Introducción: La aféresis terapéutica (AFT) es una técnica extracorpórea indicada en múltiples patologías renales y no renales, con recomendaciones establecidas en las guías ASFA. En España, los servicios de Nefrología han incorporado progresivamente diferentes modalidades de AFT y, desde 2018, la Sociedad Española de Nefrología (S.E.N.) mantiene un Registro Nacional de AFT para monitorizar su uso.

Objetivo: Describir la actividad de los servicios de Nefrología participantes en el Registro AFT-S.E.N. entre 2019 y 2023.

Material y métodos: Estudio observacional descriptivo que incluye todos los tratamientos registrados de forma consecutiva en el Registro AFT-S.E.N. durante 2019-2023. Se analizaron 4331 procedimientos en 525 pacientes tratados en 19 servicios de Nefrología.

Resultados: La edad mediana fue 43,7 años; 49,6% mujeres. Las principales indicaciones fueron enfermedades neurológicas (33%), renales (22%) y metabólicas (19,6%). El 60% de los procedimientos se realizaron en episodios agudos y el 40% en programas crónicos. La técnica más utilizada fue el recambio plasmático (72,2%), seguido de doble filtración (19,7%). Los efectos adversos ocurrieron en el 7% de las sesiones, principalmente hipotensión y problemas con el acceso vascular.

Conclusiones: El registro AFT-S.E.N. constituye la primera experiencia multicéntrica en Nefrología en España. Los datos muestran la expansión y diversificación de técnicas de AFT, la implementación de programas crónicos y un perfil de seguridad aceptable, evidenciando la integración de la AFT en la práctica clínica nefrológica.

Introduction

Therapeutic apheresis (TFA) is the treatment of choice for various pathologies; the relevant indications and guidelines are outlined in the *Guidelines on the Use of Therapeutic Apheresis in Clinical Practice* (ASFA).¹ Given that nephrologists are well-trained in TFA, many nephrology services have incorporated the different modalities of this technique into their service portfolios and have applied it to both renal and extrarenal pathologies. In recent years, AFT-based chronic treatment programs have been implemented in a growing number of centers.

In 2013, the Working Group of Therapeutic Apheresis of the Spanish Society of Nephrology (Aféresis Terapéutica de la Sociedad Española de Nefrología, AFT-SEN) administered a nationwide survey to identify which nephrology services offered AFT in Spain, and 30 services responded.² That same year, the project to create an apheresis registry was proposed at the XLII Congress of the SEN. In 2018, a new survey on the offering of AFT services was administered, to which 60 services responded, 12 of which reported that they had developed chronic treatment programs in the previous five years.

Several centers confirmed the incorporation of new modalities of TFA, such as rheoapheresis, photopheresis, and low-density lipoprotein (LDL) apheresis, among others. The results were presented at the 48th Congress of the SEN, after which the National AFT Registry was implemented.³

Initial data from the AFT-SEN registry were presented at the 50th Congress of the SEN in 2020.³ The main objectives of registry,⁴ as summarized in Table 1, were to record the number of patients treated in different nephrology departments, the AFT techniques implemented, the clinical protocols used, and the safety variables evaluated—all of which are needed to optimize clinical practice. To our knowledge, there are no published records of TFA use in nephrology services, and therefore no direct comparisons can be made. There are, however, data from international hematology registries as well as from the *World Apheresis Association* (WAA),⁵ which resulted from the 2002 merger of the Canadian, French and Swedish registries and the participation of Spanish hematology services.^{6–8} Currently, this latter registry has information from more than 140,000 patients from 19 countries.⁹ As these data come from hematology and blood bank

Table 1
Objectives of Apheresis records.

Clinical research and evidence-based practice	Data collection. Clinical trials.
Improvement of quality and standardization of processes.	Development of Clinical Guidelines. Practical improvements. Comparative evaluation (benchmarking).
Patient safety and outcome monitoring	Reduction of errors. Follow-up of adverse events. Evaluation of the reliability of the results.
Health policies and regulation	Development of health policies. Supervision of regulation.
Resource allocation	Cost analysis.
Cost management	Use of resources.
Education and Training	Education and improvement of the skills of health care professionals involved in TFA treatments. Improvement of clinical practice.
Patient protection	Registries provide clinical data that improve patient safety.
Scientific advances	The registries offer data that allow the development of new technologies and improvements in AFT treatments.

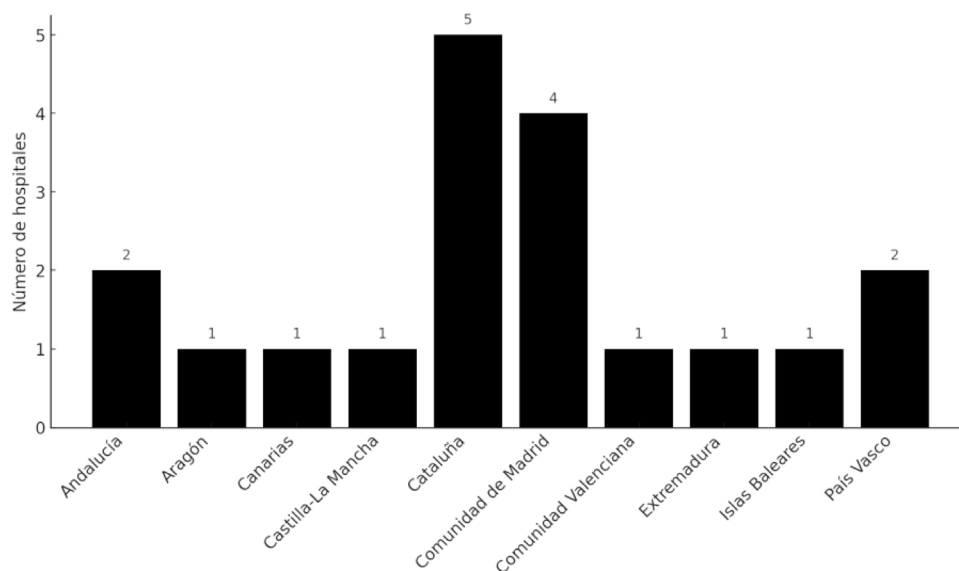


Figure 1. Geographic distribution of participating centers.

services, they involve different indications and modalities of TFA, limiting comparative extrapolation with our registry.

The objective of the present work is to describe the use of AFT in the nephrology services participating in the AFT-SEN registry.

Materials and methods

This descriptive observational study included all TFA procedures registered consecutively in the Therapeutic Apheresis Registry of the SEN between 2019 and 2023. Nineteen nephrology departments reported a total of 4331 procedures for 525 patients. Of the 19 nephrology departments, 17 (89.5%) are publicly owned centers, and 2 (10.5%) are privately owned. Furthermore, of the 19 nephrology centers, 18 are classified as adult nephrology centers, and one is a pediatric nephrology center.

The data are presented as absolute numbers, percentages, medians and interquartile ranges (IQRs). Descriptive analysis was performed with the statistical package SPSS V.21 (Chicago, IL).

Results

Indications for therapeutic apheresis

Between 2019 and 2023, a total of 4331 procedures were reported for 525 patients in the Therapeutic Apheresis Registry of the SEN. The median (\pm interquartile range, IQR) age of 43.7 ± 6.7 years; moreover, 2150 (49.6%) of the patients were women and 2181 (50.4%) were men. An analysis of the geographical distribution revealed that the autonomous communities with the greatest number of centers participating in the registry are Catalonia (5) and Madrid (4) (Fig. 1). The most frequent indications for therapeutic apheresis in nephrology services were neurological diseases (1,425; 33%), followed by renal diseases (951; 22%) and metabolic diseases (849; 19.6%) (Table 2).

The renal pathology most frequently treated by TFA was glomerulonephritis associated with anti-neutrophil cytoplasmic antibodies (ANCA) (380 treatments), followed by Goodpasture syndrome (202 treatments), while the neurological disease most frequently treated by TFA was multiple sclerosis (331 treatments) (Table 3).

Sixty percent of the procedures (2608) were performed for acute episodes, whereas 39.8% (1723) were performed for chronic or

Table 2

Patient characteristics and indications for TFA.

	Baseline patient characteristics
Number of patients (n)	525
Number of treatments (n)	4.331
Age, years (median \pm IQR)	43.7 \pm 6.7
Sex, female (%)	49.6%
(n sessions, %)	TFA Indication
Neurological pathology	1.425, 33%
Renal pathology	951, 22%
Metabolic pathology	849, 19.6%
Hematological pathology	365, 8.4%
Digestive pathology	207, 4.7%
Dermatological pathology	91, 2.1%
Cardiac pathology	69, 1.5%
Systemic pathology	16, 0.3%
Other pathologies	358, 8.4%

Table 3

Apheresis treatments according to specialty and disease.

Renal diseases	ANCA-associated GNF 380 (8.7%)
	Goodpasture syndrome 202 (4.6%)
	GsFyS recurrence 126 (2.9%)
	Cryoglobulinemia renal involvement 43 (1%)
	Desensitization ABO TR 35 (0.8%)
Neurological diseases	HLA desensitization TR 31 (0.7%)
	Multiple sclerosis 331 (7.6%)
	Myasthenia Gravis 295 (6.8%)
	Optic neuromyelitis 133 (3.0%)
	Guillain-Barré syndrome 212 (4.9%)
Hematological diseases	Eaton-Lambert syndrome 12 (0.2%)
	Alzheimer's disease 119 (2.7%)
	SHU 33 (0.76%)
	PTT 235 (5.4%)
	MAT associated with drugs 41 (9.9%)
Metabolic diseases	Lipoprotein (a) 689 (15.9%)
	Hypertriglyceridemia 43 (0.99%)
	Familial Hypercholesterolemia 115 (2.6%)
Cardiac diseases	Heart transplant humoral rejection 55 (1.2%)
	Autoimmune dilated cardiomyopathy 14 (0.32%)
Digestive diseases	Inflammatory bowel disease 207 (4.8%)
	Cutaneous diseases
Inflammatory systemic diseases	Atopic dermatitis 12 (0.27%)
	LES (alveolar hemorrhage) 3 (0.06%)
Other	Catastrophic antiphospholipid syndrome 13 (0.3%)
	Calcifilaxia 15 (0.34%)
	Septic shock 19 (0.43%)

Table 4
Diseases of patients in the chronic TFA program.

Metabolic diseases	Familial hypercholesterolemia 103 (6.1%) Lipoprotein (a) 689 (41%)
Neurological diseases	Myasthenia Gravis 132 (7.9%) Multiple sclerosis 125 (7.4%)
Digestive diseases	Inflammatory bowel disease 169 (10.1%)

maintenance treatment; this included treatment for metabolic diseases (820; 50.2%), neurological diseases (567; 33.7%), and digestive diseases (169; 10%) (Table 4). These chronic treatment programs were implemented in nine nephrology departments in recent years.

All records in the registry reflect compliance with the ASFA Guidelines¹ in routine practice (Table 5); specifically, 25.5% of the indications for treatment with TFA met the criteria for Category I, 52.6% for Category II, 21.9% for Category III, and none for Category IV.

Therapeutic apheresis techniques

The most commonly used TFA technique in nephrology services was plasma exchange (PE), constituting 72.2% (3126) of procedures, followed by double filtration (19.7%, 855 procedures) and leukapheresis (4.6%, 201 procedures) (Fig. 2). The main technical characteristics of the different procedures are described in Table 6. The most commonly used plasma separation technique in PE was filtration, which was used in 3964 procedures (91.5%), while centrifugation was used in 97 procedures (2.3%). In PE with plasma separation via filtration, the most commonly used vascular access was the central line (2560 procedures, 59.1%), followed by an arteriovenous fistula (AVF) (1542 procedures, 35.6%), whereas in PE with plasma separation via centrifugation, the most commonly used vascular access was the medial route (84 procedures, 86.6%).

The most commonly used replacement fluid in PE was serum albumin (2946 procedures; 68.0%), followed by fresh frozen plasma (727 procedures, 16.8%) and, to a lesser extent, mixed replacement (5% serum albumin + fresh frozen plasma) (35 procedures, 0.8%).

The most commonly used anticoagulant was sodium heparin (1368, 31.5%), followed by low-molecular-weight heparin (822, 19%) and citrate (181, 4.2%). Notably, in 44% of procedures (1905), no type of anticoagulation was used.

Adverse effects were reported for 305 TFA procedures (7.04%), the most frequent of which was hypotension (93, 30.5%), followed by problems related to vascular access and the circulation (80, 27, 5%) (Fig. 3). These adverse effects were predominately associated with plasma exchange via filtration; however, vascular access issues were also reported in four (1.3%) centrifugation sessions.

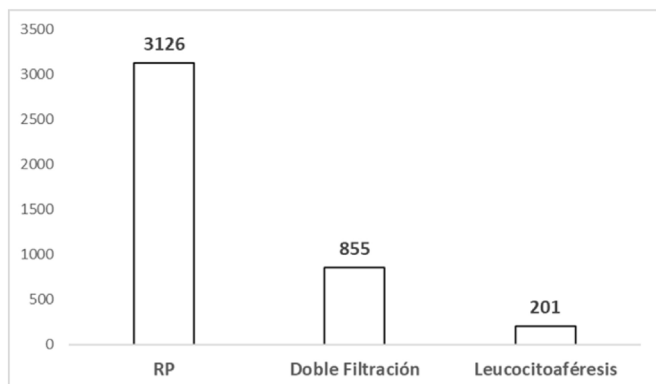


Figure 2. Most commonly used AFT techniques.
PR: plasma exchange.

Table 5
ASFA category definitions.

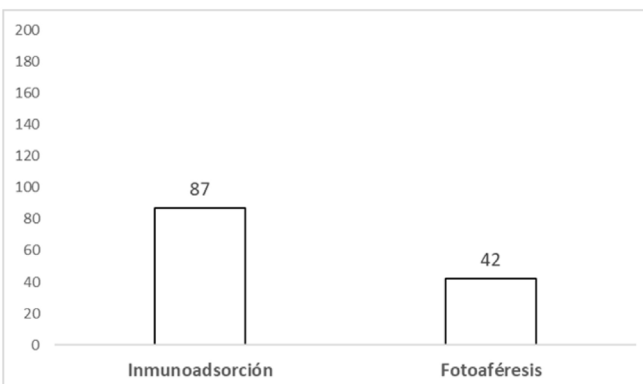
Category	Description
I	Diseases for which AFT is accepted as the first line of treatment, alone or in combination with other treatments.
II	Diseases for which AFT is accepted as a second line of treatment, alone or in combination with other treatments.
II	Diseases for which the role of AFT is not well established. Decisions must be individualized.
IV	Diseases for which treatment with AFT does not show any benefit.

Table 6
Technical characteristics of AFT.

<i>AFT Technique (n sessions, %)</i>	
Plasma exchanges	3.126, 72.2%
Double filtration	855, 19.7%
Leukocytapheresis	201, 4.6%
Immunoadsorption	87, 2%
Photopheresis	42, 0.9%
Hemoadsorption with polymixin filter	19, 0.4%
Erythropheresis/Red blood cell replacement	1, 0.02%
<i>Plasma separation technique (n sessions, %)</i>	
Filtration	3.964, 91.5%
Centrifugation	97, 2.3%
Not registered	270, 6.2%
<i>Vascular access (filtration) (n sessions, %)</i>	
Central line	2.560, 59.1%
Arteriovenous fistula	1.542, 35.6%
Medial route	84, 1.9%
Others	145, 3.4%
<i>Replacement fluid (n sessions, %)</i>	
Serum albumin	2.946, 68%
Fresh frozen plasma	721, 16.8%
Serum albumin + Fresh frozen plasma	35, 0.8%
Not registered	623, 14.3%
<i>Anticoagulation (n sessions, %)</i>	
No anticoagulation	1.905, 44%
Sodium heparin	1.368, 35.1%
Low molecular weight heparin	822, 19%
Citrate	181, 4.2%
Not registered	55, 1.2%

Conclusions

The data from the AFT-SEN registry represents the first records of TFA use in the field of nephrology in Spain and reflect the widespread use of apheresis techniques by nephrologists. The number of



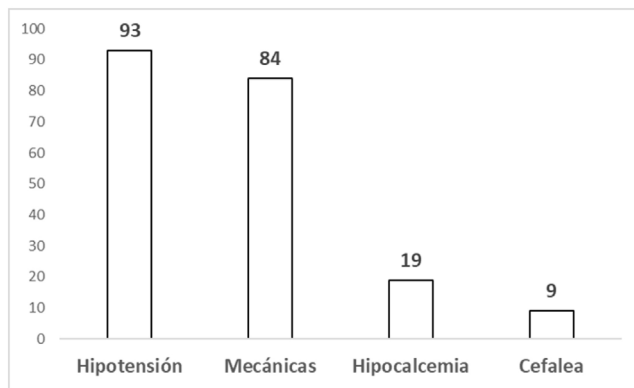


Figure 3. Most frequent adverse effects of TFA.

participating centers has increased significantly, from seven in 2018–2020 to 19 in 2023.^{2,3} Compared with the results presented in 2020, the results of this study revealed the progressive incorporation of new modalities of AFT beyond PE, including specific and nonspecific immunoadsorption, double filtration, leukocytapheresis and photopheresis. Similarly, new plasma separation techniques, such as centrifugation, have been introduced, and the forms of vascular access has expanded, with the aim of optimizing both the efficacy and safety of the procedure. The availability of these technologies has allowed the diversification of nephrology services and the extension of TFA to nonrenal patients. In fact, between 2018 and 2020, neurological patients constituted the most frequently treated group—more numerous than renal patients—with multiple sclerosis being the most common neurological indication.^{2,3} These results coincide with the data published by the WAA, in which neurological patients are the most commonly treated after hematological patients, particularly patients with myasthenia gravis.^{4,6,8} The needs derived from the management of nonrenal patients have aided in the creation of chronic treatment programs in nine nephrology services, three more than those registered in 2018.

It should be noted that, according to the ASFA guidelines, all the indications included in the registry could be classified as category I, II, or III, while none could be classified as category IV, indirectly suggesting the implementation of good clinical practices.¹ The safety analysis revealed a low incidence of adverse effects; hypotension appeared mainly in filtration-based PE procedures, while it has not been described in centrifugation-based PE. Mechanical complications, on the other hand, are recorded for both techniques and are mainly related to vascular access problems. Since the incidence of adverse effects depends on the technique, the type of vascular access, and the replacement fluid used, there is notable variability across centers, which limits the possibility of drawing more general conclusions. Together, these results reveal the progressive integration of TFA in nephrology clinical practice despite differences in its methodology across centers. While some centers are limited to only PE for renal patients, others have developed a broader portfolio of techniques and chronic treatment programs, thus expanding the scope of TFA to extrarenal pathologies.^{5,6,8}

A relevant observation from the data presented is the difficulty in establishing consistent comparisons with other series, both national and international. Unlike in hematology centers, where there is a longer tradition of multicenter cooperation in completing the records, in nephrology centers, data are often fragmented and heterogeneous, which limits extrapolation and precludes robust comparative analyses. The lack of standardized practices across centers similarly raises issues regarding interpretations of results and the evaluation of safety, particularly if differences in the techniques used and differences in vascular accesses are considered.

These findings reinforce the need to increase participation in the AFT-SEN Registry as a national standardization strategy to harmonize the collection of clinical, technical, and safety variables and to advance equity in access to all therapeutic apheresis techniques.

The use of international registries, such as the WAA Registry—the result of the merger of Canadian, French and Swedish registries—has led to the development of a common framework that can subsequently be used to improve the quality of care and facilitate research.^{2–4,9,10} Increasing participation in the AFT-SEN Registry would allow not only comparisons across centers but also the identification of areas of improvement, the design of multicenter studies and the development of specific clinical guidelines in nephrology. Similarly, it could improve the visibility of the discipline among specialty services, reinforce the role of nephrology in collaboration with other disciplines, and improve access to therapeutic apheresis at the national level.

Finally, it is essential to advance the development of common clinical protocols, promote multicenter studies and encourage the publication of results that consolidate and provide visibility to the growing role of TFA in nephrology services.

Limitations

This study has several limitations that should be considered. First, the voluntary participation of only 19 nephrology services may not fully reflect the use of TFA at the national level, as potential selection bias and underreporting may affect the results. The observational and descriptive design of the registry prevents the establishment of causal associations and the assessment of the comparative efficacy of the different techniques. Similarly, differences in the indications for TFA and the profiles of patients treated as well as differences in the resources available to the centers warrant careful interpretation of the results.

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Declaration of competing interest

The authors declare that they have no conflicts of interest.

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Appendix A. Participating centers

Dra. Sonia María Cruz Muñoz y Dra. Inés González Gómez. Hospital Universitario Juan Ramón Jiménez, Huelva

Dr. Rafael Franquelo y Dra. Rosa Escaño Marín. Hospital Vithas Xanit Internacional, Málaga

Dra. María Victoria Rubio Rubio. Hospital Clínico Universitario Lozano Blesa, Zaragoza

Dr. Orlando Siverio Morales. Hospital Universitario Nuestra Señora de Candelaria, Santa Cruz de Tenerife

Dra. Laura María Cueto Bravo y Dra. Maite Padrón Romero. Hospital General Universitario de Toledo, Toledo

Dra. María Alba Herreros García y Dra. Silvia Bento García. Fundación Puigvert, Barcelona

Dra. Eva Rodríguez García y Dra. Eva Márquez Mosquera. Hospital del Mar-IMIM, Barcelona

Dra. Natalia Ramos Terrades. Hospital Universitario Vall d'Hebron, Barcelona

Dra. María Pau Valenzuela Mújica. Hospital Universitario Parc Taulí, Sabadell

Dra. Nàdia Martín Alemany. Hospital Universitario Dr. Josep Trueta, Girona

Dr. Daniel Barraca Nuñez, Dr. Luis Alberto Sánchez Cámara. Hospital Universitario Gregorio Marañón, Madrid

Dra. Laura Medina Zahonero. Hospital Universitario Infanta Leonor, Madrid

Dra. Milagros Fernández de Lucas. Hospital Universitario Ramón y Cajal, Madrid

Dra. Verónica Ruth Mercado Valdivia. Hospital Universitario Infanta Sofía, San Sebastián de los Reyes (Madrid)

Dra. Esther Tamarit Antequera y Dr. Jorge María Benlliure Simón. Hospital General Universitario de Valencia, Valencia

Dra. Elena Davin. Hospital San Pedro de Alcántara, Cáceres

Dr. Raúl García Castro. Hospital Juaneda Miramar, Palma de Mallorca (Islas Baleares)

Dra. María Teresa Rodrigo de Tomás y Dra. Adriana Aymat Aguirre. Hospital Universitario de Donostia, San Sebastián

Dra. María Isabel Gallardo Ruiz. Hospital Universitario Galdakao-Usansolo, Galdakao

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