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Original article

Health-Related Quality of Life and Associated Factors in Patients Undergoing Kidney Replacement Therapies

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ABSTRACT

Objective: Characterize the health-related quality of life among patients undergoing kidney replacement therapy and to explore associated factors.
Method: A descriptive observational study was conducted using the Kidney Disease Quality of Life Short Form questionnaire to assess health-related quality of life. The Dader Method was employed to evaluate negative outcomes associated with medications. Face-to-face interviews and clinical records were utilized to collect sociodemographic and clinical data from patients undergoing kidney replacement therapy at the Nephrology Department of Virgen de las Nieves University Hospital (Granada, Spain). We explored the association between independent variables (clinical and demographic factors) and dependent variables (Mental Component Score and Physical Component Score) using the linear regression method.
Results: Ninety-one participants were included, 47 (48.35%) were females. The mean age was 62 years, 52 patients (57.14%) were on hemodialysis, 13 patients (14.29%) on peritoneal dialysis, and 26 patients (28.57%) on other forms of kidney replacement therapy. The study revealed a mean Physical Component Score of 40.89 and a Mental Component Score of 47.19. Additionally, 98.90% of the patients experienced negative outcomes associated with medications. Influential factors include age, comorbid conditions, the number of medications, and clinical parameters such as vitamin D and calcium levels.
Conclusions: This study underscores significant findings in patients undergoing kidney replacement therapy, indicating low Mental Component Score and Physical Component Score, accompanied by negative outcomes associated with medications.

Calidad de Vida y factores asociados en pacientes con tratamiento renal sustitutivo

Palabras clave:
calidad de vida
tratamiento renal sustitutivo
enfermedad renal estadio 5

RESUMEN

Objetivo: Caracterizar la calidad de vida relacionada con la salud en tratamiento renal sustitutivo y explorar los factores asociados.
Método: Se llevó a cabo un estudio observacional descriptivo utilizando el cuestionario Kidney Disease Quality of Life Short Form para evaluar la calidad de vida relacionada con la salud. Se empleó el Método Dáder para evaluar los resultados negativos asociados con la medicación. Se realizaron entrevistas y se utilizaron historias clínicas para recopilar datos sociodemográficos y clínicos de pacientes sometidos a terapia de reemplazo renal en el servicio de nefrología del Hospital Universitario Virgen de las Nieves (Granada, España). Se exploró la asociación entre las variables independientes (factores clínicos y demográficos) y las variables dependientes (Puntuación del Componente Mental y Puntuación del Componente Físico) utilizando el método de regresión lineal.
Resultados: Se incluyeron 91 participantes, 47 (48,35%) eran mujeres. La edad media fue de 62 años, 52 pacientes (57,14%) estaban en hemodiálisis, 13 pacientes (14,29%) en diálisis peritoneal, y 26 pacientes (28,57%) en otras

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formas de tratamiento renal sustitutivo. El estudio reveló una puntuación media del componente físico de 40,89 y una puntuación del componente mental de 47,19. Además, el 98,90% de los pacientes presentaba resultados negativos asociados a la medicación. Entre los factores asociados se incluyen: la edad, el número de comorbilidades, el número de medicamentos prescritos y parámetros clínicos como los niveles de vitamina D y calcio.

Conclusiones: Este estudio subraya hallazgos significativos en pacientes con tratamiento renal sustitutivo, indicando bajas puntuaciones de los componentes mental y físico medidas por el cuestionario, acompañadas de resultados negativos asociados con la medicación.

Introduction

The concept of health-related quality of life (HRQoL) is complex and focuses on how patients' well-being is affected by their health. For individuals with end-stage renal disease (ESRD), a low HRQoL is associated with higher risks of mortality and hospitalization.[1–8] Assessing HRQoL is crucial for evaluating treatment outcomes in chronic kidney disease (CKD) patients undergoing kidney replacement therapies (KRT). Various tools are being tested to improve patient outcomes by measuring HRQoL, which is significantly impacted by lifestyle changes, emotional disturbances, and physical and psychosocial symptoms.[8–12]

Kidney transplantation (KT) greatly improves HRQoL,[9,13] with patients often achieving scores similar to those of healthy individuals.[9] However, dialysis patients typically experience a compromised HRQoL, facing challenges similar to those with other chronic conditions like cancer and heart failure.[2] While medications have improved health and HRQoL,[14] their extensive use has also led to a rise in adverse side effects, known as negative outcomes associated with medications (NOM).[15,16]

Several factors influence HRQoL in ESRD patients, including country, ethnicity, and demographic characteristics. Studies on HRQoL have included patients undergoing hemodialysis (HD)[3–5,12,17] or peritoneal dialysis (PD)[3,6] across various countries.[3,11] Understanding these factors can lead to better dietary, lifestyle, and educational recommendations, integrating HRQoL assessment into patient-centered care to enhance symptom relief, patient care, and rehabilitation.[10,11]

There is limited literature on HRQoL and NOM in KRT patients, with most studies focusing on the relationship between KRT modality and HRQoL.[3,5,6,8–11] The present study aims to characterize HRQoL among KRT patients and explore the associated factors to provide a comprehensive understanding that can inform healthcare practices and patient management.

Method

An observational study was conducted at the Nephrology Department of Virgen de las Nieves University Hospital in Granada, Spain. The research period extended from February 2, 2021, to July 31, 2023, spanning 29 months, and focused on patients with ESRD undergoing KRT.

All outpatient individuals who met the following criteria were included in the study: being over 18 years of age, undergoing KRT such as HD, PD, or KT at the nephrology department during the study period, and expressing a willingness to participate. Patients with cognitive impairments were excluded.

Eligible patients consulting the Nephrology Department at Virgen de las Nieves University Hospital were invited to participate. Informed consent was obtained from all participants, and variables were collected from medical records and through personal interviews. These interviews were used to gather information on HRQoL and symptoms not available in medical records. Patients meeting the inclusion criteria were recruited by nephrology experts.

HRQoL was assessed using the Kidney Disease Quality of Life Short Form (KDQOL-SF) Questionnaire, a 36-item tool specifically designed to evaluate quality of life in patients with chronic renal disease, including those undergoing dialysis. Although originally designed for dialysis patients, it has also been validated for use in transplant patients. The questionnaire includes domains such as the Physical Component Score (PCS), Mental Component Score (MCS), Symptoms and Problems of Kidney Disease (SPKD), Burden of Kidney Disease (BKD), and Effect of Kidney Disease (EKD). Scores were standardized on a scale from 0 to 100, with higher scores indicating better quality of life.[18] Medication adherence was assessed using the Simplified Medication Adherence Questionnaire (SMAQ), a brief and reliable tool for evaluating adherence to medication regimens.[19] Both questionnaires have been validated in the Spanish population.[19,20]

Data were collected using a combination of methods, including electronic medical record reviews, semi-structured interviews, and questionnaires administered through face-to-face interviews. The Dáder Method, developed by the Pharmaceutical Care Research Group at the University of Granada, was used to identify and classify DRP/NOM according to the Granada Consensus.[15] Pharmacists facilitated discussions with nephrology experts to ensure comprehensive data collection. The pharmacist conducted thorough reviews of electronic medical records and interviews to assess prescribed medications, baseline demographics, comorbidities, clinical laboratory data, allergies, and the number of NOM or DRP.

The stage of kidney disease was determined using the estimated glomerular filtration rate, calculated from serum creatinine levels using the Chronic Kidney Disease Epidemiology Collaboration equation, as documented in electronic medical records. Laboratory tests were recorded as part of routine clinical practice.

NOM were defined as health outcomes affecting the patients that are, or may be, associated with medication use. A DRP was defined as an event or circumstance involving drug therapy that interferes, or potentially interferes, with desired health outcomes.[15]

Statistical analyses were conducted at a 5% significance level using R software version 4.3.2 (©2023 The R Foundation for Statistical Computing, R Studio 2023.09.1 © 2009–2023 Posit Software, PBC). Microsoft Excel was used for data entry and preliminary editing before analysis. Descriptive statistics, including frequency distributions, percentages, means, standard deviations (SD), and medians, were calculated for continuous data.

The association between independent variables (clinical and demographic factors) and dependent variables (PCS or MCS) was explored using linear regression. Additionally, relationships between independent variables (clinical, demographic, PCS, or MCS) and the dependent variable (medication adherence) were assessed using univariate and multivariate logistic regression methods.

Institutional Review Board approval was obtained from the Andalusian Biomedical Research Ethics Committee (FIS-IRB-2020-01) on July 28, 2020. Written informed consent was obtained from all study participants, ensuring adherence to ethical standards and respect for participant autonomy.

Table 1
Sociodemographic and clinical characteristics of patients.

1. Characteristics	$n=91$[a]
Age, mean (SD) years	62 (13)
Gender (female)	47 (48.35)
Current renal replacement therapy	
• Hemodialysis	52 (57.14)
• Deceased donor	25 (27.47)
• Peritoneal dialysis	13 (14.29)
• Living donor	1 (1.10)
Number of comorbid conditions per patient, mean (SD).	18.43 (4.46)
Number of medication per patient, mean (SD)	12.13 (3.28)
Number of medication administered in dialysis per patient, mean (SD)	1.67 (1.48)
Number of medication administered at home per patient, mean (SD)	10.45 (3.18)
Allergies to medications	24 (26.37)
Non-Adherence to medications	52 (57.14)
2. Serum clinical laboratory data	
Creatinine mg/dL, mean (SD)	6.82 (3.32)
Albumine g/L, mean (SD)	3.63 (0.44)
Sodium mEq/L, mean (SD)	138.64 (2.63)
Potassium mEq/L, mean (SD)	4.83 (0.56)
Calcium mg/dL, mean (SD)	8.84 (0.64)
Phosphorus mg/dL, mean (SD)	4.37 (1.12)
intact parathyrin pg/mL, mean (SD)	310.87 (205.39)
Vitamin D (25OH) ng/mL, mean (SD)	24.31 (9.52)
Haemoglobine g/dL, mean (SD)	11.68 (1.46)
3. Comorbidities[b]	
Mineral and bone disorder	80 (87.91)
Hyperphosphatemia	58(63.74)
secondary hyperparathyroidism	76 (83.52)
vitamin D deficiency/ insufficiency.	63 (69.23)
Anemia	81 (89.01)
Hyperkalemia	62 (68.13)
Diabetes	24 (47.06)
Hypertension	77 (84.62)
Dyslipidemia	65 (71.43)
Hyperuricemia	40 (43.96)
Personal history of COVID-19	24 (26.37)
Family history of kidney disease	23 (25.27)
Other cardiovascular diseases	55 (60.43)
Metabolic acidosis.	16 (17.58)
Mental and behavioral disorders	30 (32.97)
Diseases of the digestive system	74 (81.32)
Other diseases of the blood and blood-forming organs	34 (37.36)
Other Systemic infections (e.g., HIV, hepatitis B virus, hepatitis C virus)	42 (46.15)
4. Drug[c]**/ATC code**	
darbepoetin alfa/ B03XA02	72 (79.12)
sevelamer/ V03AE02	54 (59.34)
lanthanum carbonate/ V03AE03	12 (13.19)
calcium acetate/ V03AE07	1 (1.10)
calcium carbonate/ A02AC01	3 (3.30)
sucroferric oxyhydroxide/ V03AE05	14 (15.38)
polystyrene sulfonate/ V03AE01	28 (30.77)
sodium zirconium cyclosilicate/ V03AE10	11 (12.09)
drugs for acid related disorders/ A02	77 (84.62)
antiinfectives for systemic use/ J	26 (28.57)
cinacalcet/ H05BX01	31 (34.07)
paricalcitol/ H05BX02	55 (60.44)
etelcalcetide/ H05BX04	16 (17.58)
prednisone/ H02AB07	34 (37.36)
tacrolimus/ L04AD02	24 (26.37)
mycophenolic acid/ L04AA06	19 (20.88)
covid-19 vaccines/ J07BN	90 (98.90)
alopurinol/ M04AA01	38 (41.76)
atorvastatin/ C10AA05	27 (29.67)
simvastatin/ C10AA01	20 (21.98)
omega-3-triglycerides incl. Other esters and acids/ C10AX06	13 (14.29)
furosemide/ C03CA01	46 (50.55)
doxazosin/ C02CA04	33 (36.26)
manidipine/ C08CA11	34 (37.36)
atenolol/ C07AB03	22 (24.18)
bisoprolol/ C07AB07	19 (20.88)
repaglinide/ A10BX02	5 (5.49)
linagliptin/ A10BH05	12 (13.19)
insulins and analogues/ A10A	25 (27.47)
5. Types of NOM	
Number of patients with Untreated health problem (requiring additional drugs).	90 (98.9)
Untreated health problem, mean (SD)	12.01 (7.22)
Number of patients with Non-quantitative ineffectiveness.	5 (5.49)
Non-quantitative ineffectiveness, mean (SD)	0.11 (0.38)
Number of patients with Quantitative ineffectiveness (prescribed quantity or dosage of a medication is insufficient)	87 (95.6)
Quantitative ineffectiveness, mean (SD)	7.39 (5.19)
Number of patients with non-quantitative safety problem (adverse drug reactions)	46 (12.09)
Non-quantitative safety problem (adverse drug reactions), mean (SD)	1 (1.24)
6. Types of DRP	
Number of patients with risk of adverse effects	81 (89.01)
Risk of adverse effects (adverse drugs reactions), mean (SD)	4.66 (4.16)
Number of patients with wrong dose/ posology/ length	87 (95.60)
Wrong dose/ posology/ length, mean (SD)	9.49 (6.22)
Number of patients with not necessary drug	35 (38.46)
Not necessary drug, mean (SD)	1.02 (1.37)
Number of patients with non-adherence to medications	52 (57.14)
Non-adherence, mean (SD)	1.80 (2.79)
Number of patients with undertreated condition	88 (96.70)
Undertreated condition, mean (SD)	10.65 (6.24)

Abbreviations: kidney replacement therapies (KRT); negative outcomes associated with medications (NOM), drug-related problems (DRP).
[a] Unless otherwise indicated values are expressed as n (%).
[b] The list of comorbidities is exhaustive for our cohort and was identified as documented in the medical records.
[c] The list of medications is exhaustive for our cohort and was identified as documented in the medical records.

Results

A cohort of 91 out of 117 patients undergoing KRT was included in the study. Throughout the study period, five patients from the cohort passed away due to causes related to kidney disease or complications of their health conditions. The sociodemographic and clinical characteristics of the study population are shown in Table 1.

The main causes of ESRD were as follows: glomerulonephritis (26 cases; 28.57%), unknown etiology (20 cases; 21.98%), polycystic kidney disease (12 cases; 13.19%), and diabetic nephropathy (11 cases; 12.09%).

The principal comorbidities among the group of patients undergoing KRT were mineral and bone disorder (80 cases; 87.91%), anemia (81 cases; 89.01%), and hypertension (77 cases; 84.62%).

Overall, the group of patients used 1093 medications: 951 medications at home and 152 at the dialysis unit. Table 1 displays the principal types of medications used in the treatment of patients.

Overall, we identified 1875 NOM and 2578 DRP during the study period, with a rate of 20.6 NOM per patient and 28.3 DRP per patient. The principal types of NOM and DRP are presented in Table 1.

Table 2 shows the distribution of scores for the five components of KDQOL-SF.

Moreover, we examined the relationship between independent variables and dependent variable (PCS or MCS) through the application of linear regression method.

The linear regression analysis (Table 3) showed that factors such as number of comorbid conditions, number of medication administered in dialysis, SPKD, BKD, or Vitamin D (25OH) are associated with PCS.

Table 3 shows that factors such as calcium, age, number of medication administered at home, EKD, or SPKD are associated with MCS.

We examined the relationship between independent variables and the dependent variable (adherence to medications) using univariate and multivariate logistic regression methods.

The univariate logistic regression analysis showed that the PCS, number of medications, number of medications administered at home, albumin, and creatinine were associated with adherence to medications.

Table 2
Comprehensive Assessment of Kidney Disease Quality of Life short form (KDQOL-SF): Breakdown of Domain Components and Results.

Domain components (number of items in scale)	Mean	Median	SD	*n*
SPKD (12)	76.52	77.08	39.58	91
EKD (8)	66.90	68.75	21.61	91
BKD (4)	47.32	50.00	30.28	91
PCS (12)	40.89	42.85	9.02	91
MCS (12)	47.19	50.36	11.37	91

Abbreviations: Kidney Disease Quality of Life short form questionnaire (KDQOL-SF), Physical Component Score (PCS), Mental Component Score (MCS), Symptoms and Problems of Kidney Disease (SPKD), Burden of Kidney Disease (BKD), and Effect of Kidney Disease (EKD).

Variables with a p-value <0.05 in bivariate analysis were subsequently included in the multiple logistic regression. Table 4 shows the results of the multivariate analysis.

Furthermore, we examined the relationship between the type of KRT (KT or dialysis) and BKD or EKD (univariate logistic regression analysis). The BKD (OR = 1.024; 95%CI = 1.003–1.051; $p < 0.05$) and EKD (OR = 1.038; 95%CI = 1.004–1.088; $p < 0.05$) were found to be associated with the type of KRT.

Discussion

The present study explores the HRQoL among individuals undergoing KRT and its associated factors, including NOM. HRQoL has emerged as a recommended clinical tool for evaluating patients on KRT, serving as a primary endpoint in various studies aimed at elucidating the effectiveness of comprehensive disease management.[20]

In the present study, low HRQoL was found within the sample, as evidenced by a mean PCS of 40.89 (SD: 9.02) and MCS of 47.19 (SD: 11.37). Our findings align with other studies that have reported low HRQoL among individuals with ESRD undergoing KRT.[3,9,11,12]

We found that the PCS and MCS exhibited the lowest scores, aligning with findings from a prior study[11] that used the KDQOL-SF questionnaire. Specifically, the previously identified most affected dimensions, namely the PCS and the BKD, has also demonstrated significant impacts in our study. Notably, the dimension of SPKD consistently yielded the lowest scores, indicating a substantial degree of impairment in this specific facet of health-related QoL.[11]

Table 3
Linear regression analysis of factors potentially associated with PCS and MCS.

Factor	Multiple R2	Adjusted R2	95%CI	p-value
Factors potentially associated with PCS				
Number of comorbid conditions	0.05	0.04	−0.04, −0.87	<0.05
Number of medication administered in dialysis	<0.01	0.11	−0.92, −3.32	<0.01
SPKD	0.18	0.17	0.37, 0.13	<0.01
BKD	0.06	0.05	0.14, 0.01	<0.05
Vitamin D (25OH) ng/mL	0.08	0.07	0.07, 0.46	<0.01
Factors potentially associated with MCS				
Calcium mg/dL	0.04	0.03	0.00, −7.33	0.05
Age	0.05	0.04	0.37, 0.02	<0.05
Number of medication administered at home	0.04	0.03	0.02, −1.46	0.05
EKD	0.88	0.08	0.26, 0.05	<0.01
SPKD	0.08	0.07	0.37, 0.06	<0.01

Abbreviations: Physical Component Score (PCS), Symptoms and Problems of Kidney Disease (SPKD), Burden of Kidney Disease (BKD), Mental Component Score (MCS), Effect of Kidney Disease (EKD).

Table 4
Influential Factors Affecting Medication Adherence.

Factor	Mean (SD)	OR [95% CI]	*p*-value
PCS	40.89 (9.02)	0.94 [0.89, 1.00]	0.05
Number of medication per patient	12.13 (3.28)	0.81 [0.56, 1.15]	0.25
Number of medication administered at home	10.45 (3.18)	1.41 [1.00, 2.05]	0.06
Albumine g/L	3.63 (0.44)	0.31 [0.08, 1.03]	0.07
Creatinine mg/dL	6.82 (3.32)	1.09 [0.93, 1.28]	0.29

Abbreviation: kidney replacement therapies (KRT); Physical Component Score (PCS).

Several factors were identified as contributors to these lower HRQoL scores. The PCS was associated with variables such as the number of comorbid conditions, the total number of medications administered during dialysis, the presence of SPKD, the BKD, and Vitamin D (25OH) levels.

Similarly, the MCS exhibited associations with factors including calcium levels, age, the number of medications administered at home, the EKD, and the manifestation of SPKD. These insights underscore the multifaceted nature of HRQoL in individuals undergoing KRT for ESRD and emphasize the importance of considering various health-related factors in assessing their well-being.

Previous research has indicated that factors such as depression, sleep quality, and lower calcium levels are associated with a negative impact on mental well-being.[20]

Furthermore, within this cohort of patients, we identified NOM, notably characterized by the prevalence of untreated health problems (98.9%) and quantitative ineffectiveness (95.6%), where the prescribed quantity or dosage of a medication was deemed insufficient. These findings are consistent with the existing literature, which consistently reports low HRQoL in patients with NOM.[16]

Patients undergoing KRT often experience high rates of undertreated conditions due to the complexity of their comorbidities, the primary focus on managing their kidney disease, and the overlap of symptoms which can lead to misattribution. Frequent healthcare visits, medication management challenges, and specialized provider focus contribute to gaps in holistic care. Additionally, logistical barriers, limited patient education, and psychosocial factors like depression further complicate comprehensive treatment. Improving care for these patients requires a multidisciplinary approach, better coordination among healthcare providers, and enhanced patient education to address both their renal and non-renal health needs effectively.[11–13]

Identifying specific patterns of NOM sheds light on critical aspects of healthcare delivery, emphasizing the imperative to address gaps in treatment and optimize medication regimens to enhance overall patient well-being.

Understanding the risk factors associated with poor HRQoL is crucial for identifying vulnerable ESRD patients and developing targeted interventions to support them. Determinants of HRQoL in ESRD extend beyond clinical factors to include mental factors. Importantly, these mental factors are potentially modifiable, presenting an opportunity for interventions addressing the physical and mental aspects of well-being in this patient population. This comprehensive approach holds promise for improving the overall QoL for individuals with ESRD.[3]

Our study revealed a significant association between vitamin D levels and the PCS, and between calcium levels and the MCS. These findings align with prior research investigating the relationship between laboratory values—such as hematocrit, potassium, phosphorus, and calcium—and patient attributes in the context of HRQoL.[17,21]

Some limitations of the present study include the relatively small sample size, which may hinder our ability to detect significant differences in the type of KRT and PCS or MCS. Additionally, the study design only allows us to establish associations between variables and prevents the identification of causal relationships.

In conclusion, our study reveals that patients undergoing KRT exhibit a low percentage of MCS and PCS scores as measured by the KDQOL-SF questionnaire and demonstrate instances of NOM.

Various factors emerge as significant contributors to HRQoL, including age, the prevalence of comorbid conditions, the quantity of medications administered during dialysis or at home, the manifestation of kidney disease symptoms, the overall burden of kidney disease, and clinical parameters such as vitamin D (25OH) and calcium levels.

Identifying these influencing factors underscores the complexity of HRQoL in KRT patients.

Contribution to the scientific literature

This study contributes to the existing body of knowledge on health-related quality of life and negative outcomes associated with medications in nephrology.

Recognizing the health-related quality of life among patients undergoing kidney replacement therapies and identifying the predominant influencing factors could pave the way for recommending healthy dietary practices, lifestyle adjustments, and educational interventions. Additionally, evaluating health-related quality of Life in individuals with end-stage renal disease is a valuable tool for healthcare professionals, integrating seamlessly into patient-centered care.

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Data Access

For Data supporting reported results contact corresponding author.

CRediT authorship contribution statement

Alfonso Pereira-Céspedes: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Alberto Jiménez-Morales:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Aurora Polo-Moyano:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Elizabeth Spruce-Esparza:** Writing – review & editing, Writing – original draft, Investigation, Formal analysis. **Magdalena Palomares-Bayo:** Writing – review & editing, Writing – original draft, Validation, Supervision, Software, Project administration, Methodology, Formal analysis. **Fernando Martínez-Martínez:** Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Miguel Ángel Calleja-Hernández:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Conflict of interest statement

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analysis, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Ethical considerations

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board Andalusian Biomedical Research Ethics Committee (Protocol code FIS-IRB-2020-01 and date of approval July 28, 2020).Informed consent was obtained from all subjects involved in the study.

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