Clinical Kidney Journal, 2023, vol. 16, no. 12, 2523–2529

https://doi.org/10.1093/ckj/sfad155
Advance Access Publication Date: 3 July 2023
Original Article

ORIGINAL ARTICLE

Impact of peritoneal dialysis strategy on technique and patient survival

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ABSTRACT

Background. The aim of this study was to evaluate the impact of peritoneal dialysis (PD) strategy on technique and patient survival.

Methods. This was a retrospective, single-center study conducted on consecutive patients with chronic kidney disease who underwent PD between January 2009 and December 2019. The study sample was stratified into four different groups according to PD technique [automated (APD) or manual (CAPD)] and icodextrin use (yes versus no). The primary endpoints were survival of both technique and patient.

Results. A total of 531 patients were included in the analysis. Mean ± standard deviation age was 60.6 ± 14.6 years, 68.4% (363) were men and 34.8% (185) had diabetes. The median technique survival time was 19 (15) months. A total of 185 (34.8%), 96 (18.1%), 99 (18.7%) and 151 (28.4%) patients were included in the CAPD/No-Icodextrin, CAPD/Icodextrin, APD/No-Icodextrin and APD/Icodextrin study groups, respectively. Throughout the study, 180 (33.9%) patients underwent renal transplant, 71 (13.4%) were changed to hemodialysis and 151 (28.4%) died. Age [hazard ratio (HR) 0.975, 95% confidence interval (CI) 0.960–0.990, $P = .001$] and incidence of early peritoneal infection (HR 2.440, 95% CI 1.453–4.098, $P = .001$) were associated with technique survival, while age (HR 1.029, 95% CI 1.013–1.045, $P < .001$), Charlson Index (HR 1.192, 95% CI 1.097–1.295, $P < 0.001$), use of icodextrin (HR 0.421, 95% CI 0.247–0.710, $P < .001$) and APD/Icodextrin (HR 0.499, 95% CI 0.322–0.803, $P = .005$) were associated with patient survival.

Conclusions. Icodextrin use and APD/Icodextrin had a positive impact on patient survival, while older age and higher Charlson Index had a negative one. Age and incidence of early peritoneal infection significantly impacted on technique survival.

LAY SUMMARY

Peritoneal dialysis (PD) can be performed either manually, as with continuous ambulatory PD (CAPD), or with the use of a cycler, best termed automated PD (APD). According to the osmotic agent, PD solutions can be broadly divided into those using glucose, at different concentrations, as the osmotic agent, and those using icodextrin, an iso-osmolar solution, which induces ultrafiltration through its oncotic effect. The purpose of the present study was to evaluate the impact of PD strategy on technique and patient survival. Study sample was stratified in four different groups according to PD technique (APD or CAPD) and icodextrin use (yes versus no). The primary endpoints were survival of

Received: 15.1.2023; Editorial decision: 22.5.2023

both technique and patient. This is a retrospective, single-center study conducted on consecutive patients with chronic kidney disease (CKD) who underwent PD between January 2009 and December 2019 which included 531 patients. The results of this study suggest that the use of APD with early icodextrin (before Day 90) was associated with better survival in CKD patients. Based on this finding, we consider that prescription of this strategy may be recommended for improving clinical outcomes.

Keywords: chronic renal insufficiency, icodextrin, peritoneal dialysis, peritonitis, survival analysis

INTRODUCTION

Peritoneal dialysis (PD) is a renal replacement therapy (RRT) strategy that provides significant advantages for treating patients with chronic kidney disease (CKD). There is evidence supporting that patients in PD have similar survival rates to those in hemodialysis [1, 2]. Moreover, it has been suggested that PD might grant a greater survival in the initial years of RRT [3].

In addition, other advantages have been associated with the use of PD, including greater patient satisfaction and better patient quality of life [4], positive impact on graft function in those patients who underwent renal transplant (RT) [5], lower incidence of anemia and lower need for erythropoiesis-stimulating agents [6], or better preservation of residual renal function, with its subsequent impact on mortality rates [7, 8].

According to data of the Spanish Renal Registry, the prevalence of CKD in RRT was 1367 patients/per million, with 5.5% undergoing PD [9]. The desired aims of PD include improving both patients' survival and their quality of life.

PD can be performed either manually, as with continuous ambulatory PD (CAPD), or with the use of a cycler, best termed automated PD (APD). According to the osmotic agent, PD solutions can be broadly divided into those using glucose, at different concentrations, as the osmotic agent, and those using icodextrin, an iso-osmolar solution, which induces ultrafiltration through its oncotic effect. When compared with glucose, icodextrin increases ultrafiltration and decreases the peritoneal load [10]. Each of the strategies has its advantages and disadvantages, and the selection of one of them depends mainly on patient characteristics and physician preferences [11].

Although it has been suggested that icodextrin may have clinical benefits for some patients undergoing PD [12], as far as we know, the influence of technique selection (CAPD vs APD) and the impact of PD solution on both technique and patient survival have not been fully elucidated. In order to address this issue, long-term observational studies, including a large cohort of patients followed over a long period of time, would be beneficial for providing such information in a clinical setting.

The purpose of the current study was to evaluate the impact of PD strategy (CAPD vs APD) and PD solution (icodextrin vs 1.36%, 2.26% or 3.86% glucose) on both patient and technique survival. Additionally, this study also investigated potential baseline factors associated with the failure of the procedure.

MATERIALS AND METHODS

Design

This was a retrospective, observational, single-center study conducted on consecutive incident patients with CKD, who underwent PD as RRT, between 1 January 2009 and 31 December 2018.

The study complied with the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Hospital Universitario Central de Asturias (Oviedo, Spain), which waived the need for informed consent for participating in the study. Written informed consent was obtained from the patient(s) for their anonymized information to be published in this article.

Participants

Subjects with CKD who underwent PD, either CAPD or APD, during the study period were eligible.

Patients with a survival in the technique of <90 days were excluded of the analysis. The decision to exclude these patients was mainly due to avoid the influence of previous RRT on clinical outcomes.

Demographic (age and sex) and clinical characteristics (presence of diabetes, Charlson Index without age and incidence of early peritoneal infection) were collected from patient charts. Early peritoneal infection was defined as one the onset of which occurred within the first 3 months of PD.

PD were performed using 2 l biocompatible PD solutions, either Bicavera® 1.5%, 2.3% and 4.25% (Fresenius Medical Care, Bad Homburg, Germany) or icodextrin 7.5% (Extraneal®) and Physioneal® 1.36%, 2.27% and 3.86% (Baxter Healthcare, Deerfield, IL, USA).

CAPD or APD selection was based on patients' characteristics, as well as on patient/physician choice, whereas PD solution selection was based on physician preference.

Study groups

According to PD strategy and PD solution, the study sample was stratified into four different groups: Group I, CAPD/No-Icodextrin; Group II, CAPD/Icodextrin; Group III, APD/No-Icodextrin; and Group IV, APD/Icodextrin.

Definitions

Technique survival was the time elapsed until being changed from PD to HD during the study follow-up; those patients who died or underwent renal transplant were censored. The reasons for changing modality are varied and range from peritoneum dysfunction as a dialysis membrane, infections, problems with the catheter, the need for (and absence of) a caregiver or by the patient's wishes.

Survival time was defined as the time elapse from onset of PD to death; those patients who underwent renal transplant, or were changed to HD were censored.

Statistical analysis

SPSS 20® (SPSS Inc., Chicago, IL, USA) was used to perform the statistical analysis.

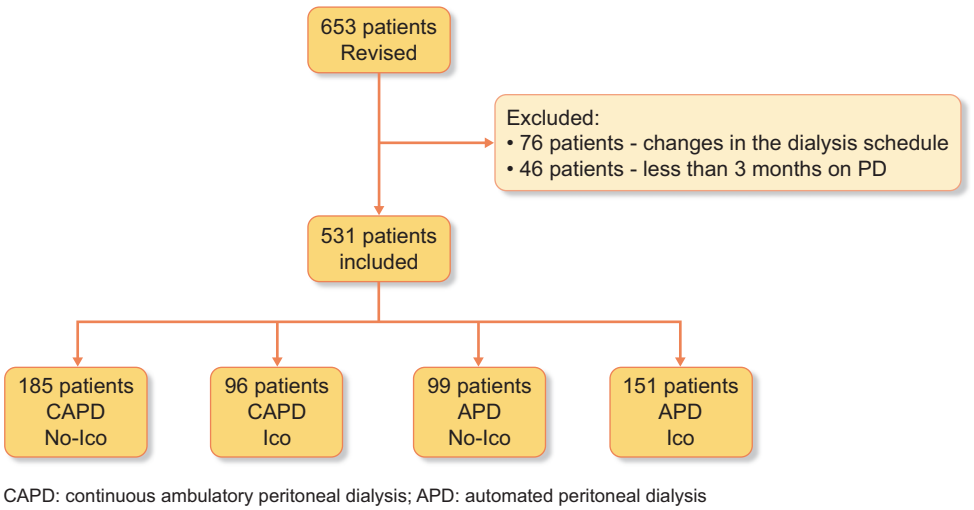

Figure 1: Flow of patients in the study.

Table 1: Overview of the main demographic and clinical characteristics of the study sample.

N/%	Overall 531/100	CAPD/No-Ico 185/35	CAPD/Ico 96/18	APD/No-Ico 99/19	APD/Ico 151/28	P
Age, years (mean ± SD)	61 ± 15	58 ± 14	67 ± 12	64 ± 14	54 ± 14	.001
Sex (% men)	68	71	58	78	66	.020
DM (% yes)	35	45	83	53	84	<.001
Charlson Index (mean ± SD)	4.2 ± 1.8	4.6 ± 1.9	4.2 ± 1.7	4.7 ± 1.8	3.6 ± 1.6	.001
Transport status (% high)	13	4	15	9	18	.002
Follow-up (months) (mean ± SD)	24 ± 23	29 ± 27	28 ± 26	20 ± 18	23 ± 22	.027

No-Ico: No Icodextrin users; Ico: Icodextrin users; SD: standard deviation; DM: diabetes mellitus.

For the analysis, only those subjects who did not modify their PD strategy were evaluated. However, different concentrations of glucose solutions in the No-Icodextrin groups were allowed.

Descriptive statistics number (percentage) and mean [standard deviation (SD)] were used, as appropriate.

Data were tested for normal distribution using a Kolmogorov–Smirnov test.

The one-way analysis of variance (ANOVA) test or the Kruskal–Wallis test were used to compare differences between groups. *Post hoc* analysis for pair wise comparisons were done with the Scheffé's method (ANOVA) or the Conover method (Kruskal–Wallis).

A conditional Cox hazard model was used to estimate and test factors for their association with survival (either technique or patient survival). A conditional hazard model was used for univariate and multivariate analysis. Those variables associated with survival in the univariate model were included in the multivariate analysis. A backward strategy was adopted, with a statistically significant cut-off for variable screening of 0.05.

RESULTS

Amongst the 653 patients revised, a total of 531 subjects met the inclusion and exclusion criteria and were included in the analysis (46 patients had not reached 3 months in PD and 76 patients did not maintain the same dialysis schedule during the follow-up period). Among them, 185 (34.8%), 96 (18.1%), 99 (18.7%), and 151 (28.4%) patients were included in the CAPD/No-Icodextrin, CAPD/Icodextrin, APD/No-Icodextrin and APD/Icodextrin study groups, respectively (Fig. 1).

Table 2: Main clinical and demographic variables of those patients who were withdrawn of peritoneal dialysis.

	RT	Death	HD	P
N (%)[a]	180 (44.7)	151 (37.6)	71 (17.7)	
Age, years (mean ± SD)	54 ± 13	68 ± 11	56 ± 17	.001
Sex (% men)	41	73	35	.003
DM (% yes)	23	52	38	<.001
Charlson Index >5 (%)	3.3	5.4	4.2	<.001
Transport status (% high)	9	7	9	.623

[a]Among 402 patients who were withdrawn from peritoneal dialysis.
RT: renal transplant; SD: standard deviation; DM: diabetes mellitus

Subjects included in the APD/Icodextrin study group were younger, had lower Charlson Index, and had a greater prevalence of diabetes and of high transport (Table 1). Baseline demographic and clinical characteristics are summarized in Table 1.

Over the course of the study follow-up, 402 (75.7%) were withdrawn from PD, 180 (44.8%) due to renal transplant, 151 (37.6%) died, and 71 (17.5%) were changed to HD. Table 2 shows their main baseline characteristics.

Patients included in Group IV (APD/Icodextrin) showed a lower proportion of deaths as compared with other groups (Table 3).

Table 3: Overview of withdrawn cause in the different study groups.

	Overall	CAPD/No-Ico	CAPD/Ico	APD/No-Ico	APD/Ico	P
RT (%)	45	27	47	33	71	<.001
HD (%)	18	22	13	15	16	.351
Death	38	51	40	52	12	<.001

No-Ico: No Icodextrin users; Ico: Icodextrin users; RT: renal transplant.

Table 4: Univariate and multivariate Cox regression of risk factors for technique survival.

	Univariate analysis		Multivariate analysis	
	HR (95% CI)	P	HR (95% CI)	P
Age	0.985 (0.971–0.999)	.036	0.975 (0.960–0.990)	.001
EPI	2.247 (1.341–3.765)	.002	2.440 (1.453–4.098)	.001
DM	1.153 (0.710–1.872)	.564		
Ch-I (without age)	1.083 (0.814–1.169)	.316		
Icodextrin	0.714 (0.441–1.155)	.169		
APD	0.903 (0.791–1.054)	.184		
APD/Icodextrin	0.947 (0.562–1.595)	.837		
High transporter (PET)	1.115 (0.214–5.814)	.897		

EPI: early peritoneal infection; DM: diabetes mellitus; Ch-I: Charlson Index; PET: peritoneal equilibration test.

Table 5: Univariate and multivariate Cox regression of risk factors for all-cause mortality.

	Univariate analysis		Multivariate analysis	
	HR (95% CI)	P	HR (95% CI)	P
Age	1.043 (1.030–1.056)	<.001	1.029 (1.013–1.045)	<.001
DM	2.001 (1.445–2.771)	<.001	1.112 (0.763–1.620	.582
Ch-I (without age)	1.266 (1.173–1.366)	<.001	1.192 (1.097–1.295)	<.001
Icodextrin	0.307 (0.180–0.524)	<.001	0.421 (0.247–0.710)	<.001
APD	0.570 (0.365–0.891)	.014	0.655 (0.382–1.120)	.122
APD/Icodextrin	0.388 (0.270–0.557)	<.001	0.499 (0.322–0.803)	.005
High transporter (PET)	1.270 (0.897–1.799)	.177		
EPI	1.685 (0.970–3.069)	.112		

DM: diabetes mellitus; Ch-I: Charlson Index; EPI: early peritoneal infection; PET: peritoneal equilibration test.

Technique survival

Median survival time of the technique was 19 (15) months.

Factors that were significant predictors of technique survival in the univariate and multivariate analysis included age and incidence of early peritoneal infection (Table 4). Older age had a positive impact of survival, while incidence of early peritoneal infection had a negative one.

Patient survival

Over the course of the study follow-up, 151 (28.4%) patients died. They were older (68 ± 11 years; $P < .001$), had a greater prevalence of diabetes (52%; $P < .001$) and a higher Charlson Index (5.4, $P < .0001$) than those who remained alive. The median patient's survival time was 44 (19) months.

In the univariate model, older age, presence of diabetes and higher Charlson Index were associate with lower survival rates, while use of icodextrin and APD were associated with higher survival rates (Table 5). In the multivariate analysis, age, Charlson Index, icodextrin use and ADP/Icodextrin were significantly associated with patient survival (Table 5).

Kaplan–Meier survival analysis showed that the use of icodextrin (Fig. 2A) and ADP/Icodextrin strategy (Fig. 2B) had grater survival rates when compared with those patients with other modalities. No significant differences were found in terms of survival when analyzing the four groups separately (CAPD/No-Icodextrin, CAPD/Icodextrin, APD/No-Icodextrin, APD/Icodextrin).

DISCUSSION

The results of the current study, conducted on a large cohort of patients undergoing PD followed up during 10 years, showed that icodextrin solution, especially when used with APD, was associated with greater patient survival, although without modifying the survival of the technique.

One of the responsibilities of specialists is to inform patients about the best treatment options. Despite clinical trials being the best way to obtain high-quality scientific evidence, in many cases they do not provide information about clinical outcomes in a real setting. In addition, randomized clinical trials do not allow

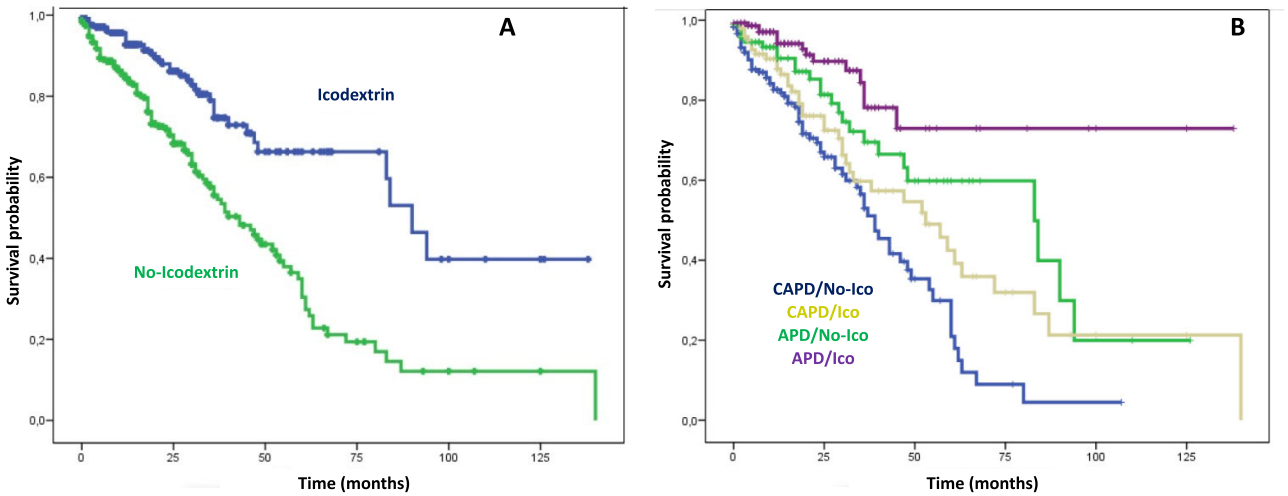

Figure 2: Kaplan–Meier survival curve. (**A**) Comparison between patients who underwent PD with or without icodextrin. Survival occurred in 204 (83.6%) Icodextrin patients and 171 (60.9%) No-Icodextrin patients (Log Rank 28.613; $P < .001$). (**B**) Comparison between patients who underwent CAPD or APD with or without icodextrin (Ico). Survival occurred in 134 (90.0%) APD/Icodextrin pateints and 240 (63.8%) No-APD/Icodextrin patients (Log Rank 21.311; $P < .001$).

patients a free choice of the dialysis technique, which conflicts with the principle of "patient autonomy."

Observational studies are therefore likely to be the most useful source of information about outcomes in PD. However, the characteristics of patients undergoing PD, including peritoneal transport status, residual renal function, comorbidities, etc., make it important to adjust between potential confounders when comparing outcomes between groups defined by any given exposure.

Over the last several years, numerous advantages to the use of icodextrin have been reported. Among them, Wang *et al.* [13] reported that the use of icodextrin was associated with an improvement in technique and patient survival in incident PD patients. Similarly, Han *et al.* [14], in a study that included 2163 patients from 54 centers in Korea, found that the use of icodextrin solution improved technique and patient survival in PD patients. Additionally, a retrospective study that included 4914 PD patients (2836 identified as icodextrin users) evaluated the impact of icodextrin on clinical outcomes of patients in PD [15]. According to the results of this study, icodextrin use was associated with better patient survival, especially among early users. However, the authors did not find differences in technique survival or incidence of peritonitis [16].

In addition to observational studies, some randomized clinical trials have also been published. In a Korean study, Chang *et al.* [16] reported better preservation of residual urine volume with icodextrin than with glucose solution, although there were no significant differences in fluid status and peritoneal transport between groups during follow-up. Htay *et al.* [17], in a meta-analysis that included 13 clinical trials and nearly 1300 patients, described how the use of icodextrin was associated with better clinical outcomes, including better peritoneal ultrafiltration rates and reduction of volume overload episodes, and was not associated with increased risk of adverse events. However, its use was not associated with an improvement of technique or patient survival. More recently another metanalysis of randomized clinical trials has been published, which aimed to compare once-daily long-dwell icodextrin versus glucose among patients with kidney disease undergoing PD [12]. This study concluded that, as compared with glucose solutions, icodextrin may be beneficial, especially for those patients who did not meet ultrafiltration targets and were at risk for fluid overload [12].

In our study, when considering only the use of icodextrin as a variable, we found better survival rates among icodextrin users. Moreover, it should be noted that baseline clinical characteristics were worse among icodextrin users, which stresses the benefits of icodextrin.

Regarding the PD strategy, over the past several years the use of APD has increased due mainly to lesser incidence of complications and patient preference for the associated lifestyle benefits. Li *et al.* [18] compared, in an observational study, APD vs CAPD in a large cohort of Chinese people undergoing PD. According to the results of this study, survival in APD was found to be generally superior to that in CAPD during the first 4 years of follow-up; however, this advantage was not extended beyond that [18]. Conversely, Sanchez *et al.* [19] reported that such positive effect on patient survival was present only during the first year of treatment. In addition, the results of a prospective and matched cohort study comparing APD vs CAPD, which included 2890 patients, found better survival rates among APD patients [20]. Moreover, APD has shown some advantages among young patients [21] and among those with high peritoneal transport [22].

However, not all the studies have found better results with APD than with CAPD. Balasubramanian *et al.* [23] found that, as compared with CAPD, APD was not associated with better survival of the technique or better patient health status. Similarly, Badve *et al.* [24], after analyzing a cohort of more than 4000 incident PD patients over a period of 5 years, found no significant differences in patient survival between APD and CAPD.

In agreement with their results, the current study did not find significant advantage of APD over CAPD in either patient or technique survival.

From a clinical point of view, the main interest of the present study lies especially in the analysis of four different clinical situations, which were dependent on PD strategy (APD vs CAPD) and PD solution (icodextrin vs glucose). Regarding patient survival, the use of icodextrin, particularly when associated with APD, provided better patient survival rates. However, its effect on the survival of the technique was not demonstrated.

An important positive value of this study is that currently available scientific evidence evaluating technique and/or patient survival in patients undergoing APD with icodextrin is limited. There is only one published paper that refers to this aspect: the analysis of the Taiwan Health Insurance Database found that the use of APD and icodextrin appears to have significantly ameliorated mortality rates and was associated with a lower risk of technique failure [25]. In agreement with their results, we found better survival rates among subjects undergoing APD with icodextrin. However, we did not find differences in terms of survival of the technique. Supplementary data, Table S6 includes a summary of the characteristics and conclusions of the main studies published on this topic.

Other strengths of our study are the large sample (531 patients) and its long follow-up. It should be noted that most of the studies published in this field come from Asia and North America, so it is of great interest to study a European Caucasian population and the repercussions that this has on the final result.

Due mainly to differences in study protocols and disparity in both outcomes and definitions, it is difficult to obtain strong conclusions about the advantages of PD strategies or about the impact of icodextrin use according to the PD strategy.

In the current study, to include subjects with at least 90 days on technique minimized the effect of potential confounders due to previous RRT modalities. In addition, using a time-dependent covariate model took into consideration the influence of treatment changes over the course of the study on the final results.

This study has several limitations that should be taken into account when interpreting its results. The first one is its retrospective design. Potential bias and confounders are inherent to retrospective studies, and correlations do not prove causality. Nevertheless, the strict inclusion/exclusion criteria minimized such limitation. An additional limitation is its single-center design. Despite including a large number of patients, it was not possible to assess the effect of "center" on the results.

In our center, there is free choice of PD technique (CAPD vs APD) and this is the main argument for a patient to perform one modality or another. It is possible (rare) that some patients, due to the characteristics of their peritoneal membrane (for example, in the case of rapid transporters) have received the recommendation to opt for APD. This might result in an improbable selection bias. Finally, other factors, such as adequacy of dialysis, which might influence technique or patient survival, were not taken into consideration in this study.

Despite these limitations, the results of this study suggested that the use of APD with early icodextrin (before Day 90) was associated with better survival in CKD patients. Based on this finding, we consider that prescription of this strategy may be recommended for improving clinical outcomes.

SUPPLEMENTARY DATA

Supplementary data are available at *ckj* online.

ACKNOWLEDGEMENTS

Medical writing and Editorial assistant services have been provided by Ciencia y Deporte S.L.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author.

CONFLICT OF INTEREST STATEMENT

All the co-authors have no conflict of interest to declare.

AUTHORS' CONTRIBUTIONS

All authors met the ICMJE authorship criteria. All authors made substantial contributions to conception, design, analysis and interpretation of data, contributed to writing the article, provided critical revision of the manuscript and approved the final version.

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Received: 15.1.2023; Editorial decision: 22.5.2023