ARTICOLI ORIGINALI

Quality of life of hemodialysis patients in Central and Southern Italy: cross-sectional comparison between Hemodiafiltration with endogenous reinfusion (HFR) and Bicarbonate Hemodialysis

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Abstract

Introduction: in hemodialysis (HD) patients, poor health-related quality of life (HR-QoL) is prevalent and associated with adverse outcomes. HR-QoL is strictly linked to nutritional status of HD patients. Hemodiafiltration with endogenous reinfusion (HFR) is an alternative dialysis technique that combines diffusion, convection and absorption. It reduces burden of inflammation and malnutrition and this effect may cause beneficial effect on HR-QoL. However no data on HR-QoL in HFR is currently available.

Methods: we designed a cross-sectional multicentre study in order to compare the HR-QoL in patients treated with HFR versus Bicarbonate HD (BHD). We enrolled adult patients HFR treated for at least 6 months, with life expectancy greater than six months and without overt cognitive deficit. The recruited patients in HFR were matched for age, gender, dialytic vintage and performance in activities of daily living (Barthel index) with BHD treated patients. SF-36 questionnaire for the assessment of HR-QoL was administered.

Results: one hundred fourteen patients (57 HFR vs 57 BHD) were enrolled (age 65.4±13.5 years; dialysis vintage 5.4 (3.3-10.3) years; 53% males) from 18 dialysis non-profit centres in central and southern Italy. As result of matching, no difference in age, gender, dialytic age and Barthel index was found between HFR and BHD patients. In HFR patients we observed better values of physical component score (PCS) of SF-36 than BHD patients (P=0.048), whereas no significant difference emerged in the mental component score (P=0.698). In particular HFR patients were associated with higher Physical Functioning (P=0.045) and Role Physical (P=0.027).

Conclusions: HFR is associated with better physical component of HR-QoL than BHD, independently of age, gender, dialysis vintage and invalidity score. Whether these findings translate into a survival benefit must be investigated by longitudinal studies.

Key words: hemodiafiltration, hemodialysis, quality of life

Introduction

Despite the improvement in the treatment of complications and symptoms of End Stage Renal Disease (ESRD) observed in these last decades, patients on maintenance hemodialysis (HD) experience poor quality of life [1] [2] (full text), associated with increased morbidity and mortality [3] (full text) [4] (full text) [5].

Health Related-Quality of Life (HR-QoL) is directly dependent on functional status of patients, that is the ability of individual to perform daily activities, such as walking, dressing, bathing, etc. In fact, the initiation of dialysis is associated with a substantial and sustained decline in functional status. In particular, a survey performed in 3702 nursing home residents in the United States starting HD treatment, showed that after 12 months from the initiation of HD, 58% had died and 29% had a substantial decline in functional status; therefore pre-dialysis functional status was maintained in only a remarkable minority (13%) of patients [6] (full text). This decline in functional status in HD patients has a complex and multi-factorial pathogenesis: CKD-related factors, such as malnutrition, chronic inflammation, acidosis, anemia, bone demineralization, muscle hypotrophy, increased burden of co-morbidities (CV diseases, diabetes) as well as the side effects of treatment [7] [8] (full text).

Hemodiafiltration (HDF), ameliorating the uremic symptoms, could potentially provide a beneficial effect on HR-QoL, however available data on the effect of different HD techniques on HR-QoL remain controversial [9] [10] (full text) [11] [12] (full text) [13] [14] (full text).

Haemodiafiltration with endogenous reinfusion (HFR) is a dialysis technique, that combines three mechanisms, diffusion, convection and absorption. Some studies showed an improvement of nutritional and inflammatory status in patients treated by HFR [15] (full text) [16] (full text) [17] [18] [19] [20], as well as an amelioration of hemodynamic instability [21]. The beneficial effect on the inflammatory status, on the oxidative stress and on the malnutrition in HD patients may be associated with an improvement of functional status and consequently of HR-QoL. However data on HR-QoL in HFR are not currently available.

Therefore, aim of this cross-sectional study is to evaluate HR-QoL in HFR patients as compared with those treated with standard Bicarbonate HD.

Methods

This is a cross-sectional study, which involved 18 centers in central and southern Italy (10 centers in Campania, 8 centers in Lazio).

All adult patients treated with HFR, from at least 6 months were included into the study and they were matched with patients in HD standard (1:1), by age, gender, dialysis age and disability score (Barthel index). Exclusion criteria were: treatment with other dialysis techniques, life expectancy lesser than six months, overt cognitive deficits.

In all selected patients,main demographic, clinical and therapy were collected and SF-36 questionnaire for the evaluation of HR-QoL were administered.

As shown in Table 1, the SF-36 questionnaire consists of 36 items that can be summarized in 8 scales, from which you get two summary scores: one for the component Physical (PCS, Physical Composite Score) and one for the mental component (MCS, Mental Composite Score) [REF?]. Each component consists of 4 domains, respectively Physical function (PF); Role-Physical (RP); Bodily Pain (BP) and General Health (GH) for PCS and Vitality (VT); Social Functioning (SF); Role Emotional (RE) and Mental Health (MH) for MCS.

HFR, depicted in Figure 1, is provided by means of double chamber filter (2.2 m^2 of surface): first chamber consists of a high-flux membrane, which produces an ultrafiltrate (UF) that is "regenerated" through the passage in a styrenic cartridge, which adsorbs toxins and saves nutrients, such as amino-acids. Then, blood flows into the second chamber, consisting of low-flux polyphenylene membrane, where diffusion is performed.

BHD was performed by means of filters in polyphenylene, PMMA or polysulfone, blood flow at least 300 ml/min and dialysis flow at least 500 ml/min. The composition of the dialysate was the following: sodium: 140-143 mEq / L, potassium: 2-3 meq / L and calcium: 1.25-1.75 meq / L.

Statistical Analysis

Continuous variables were reported as either mean and standard deviation (SD) or median and interquartile ranges (IQR) according to their distribution. The differences were assessed intergroup were analyzed using T-test for parametric variables or by Kruskall-Wallis for non parametric variables. Categorical variables were reported as percentages, and analyzed by chi-squared test. A two-tailed p value <0.05 was considered significant. Data were analyzed using STATA 11.

Results

On the basis of the selection criteria 114 patients were enrolled (57 in HFR and 57 in BHD) from 18 participating centers.

In overall cohort, mean age was 65.4±13.5 years, 53% were males and dialytic vintage was in median 5.4 (IQR: 3.3-10.3) years. As result of matching, no difference emerged in terms of age, male gender, dialytic vintage and Barthel index in the two groups under study (Table 2)

As illustrated in Figure 2, in the group of patients treated by HFR, a better score of PCS was found (56±20) compared with BHD (48±23;P=0.048). In particular, in HFR we observed higher score in PF(61±26 versus 51±30, P=0.045) and in RP 66±47 versus 45±46, P=0.027), whereas in the remaining two items of PCS (BP nad GH) no significant difference was found in the two

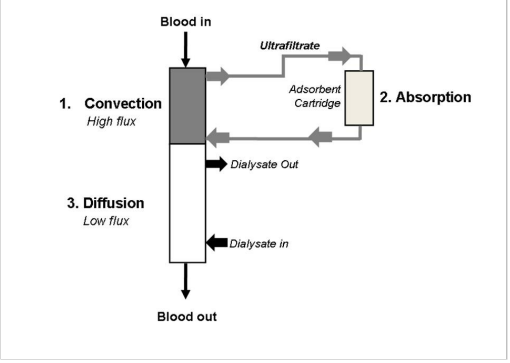

Figure 1.
Schematic representation of HFR

groups, respectively BP=63±25 and GH=40±17 in HFR and BP=58±31 (p=0.346) and GH 39±19 (p=0.676) in BHD.

As regard to the mental composite score of SF-36, no significant differences was found (57±21 in HFR vs 55±19 in BHD; P=0.698). In particular, in HFR we found VT=51±22, SF=64±25, RE=64±40 and MH=64±24. Similarly in BHD we registered the following scores: VT=48±21 (P=0.492 vs HFR), SF= 69±20 (P=0.290 vs HFR), RE: 60±43 (P=0.595 vs HFR) e MH: 60±22 (P=0.437 vs HFR).

Table 1. Scheme of Quality of Life questionnaire SF-36

	Items	Scales	Summary Measures
3a	Vigorous activities	Physical Functioning (PF)	Physical Composite Score (PCS)
3b	Moderate activities		
3c	Lift, Carry Groceries		
3d	Climb Several Flights		
3e	Climb One Flight		
3f	Bend, Kneel		
3g	Walk Mile		
3h	Walk several Blocks		
3i	WalkOne Block		
3j	Bathe, Dresss		
4a	Cut Down Time	Physical-Role (RP)	
4b	Accomplished Less		
4c	Limited in Kind		
4d	Had Difficulty		
7	Pain-Magnitude	Bodily Pain (BP)	
8	Pain-Interfere		
1	General evaluation of Health	General Health (GH)	
11a	Sick easier		
11b	As Healthy		
11c	Health to get worse		
11d	Health excellent		
9a	Pep/Life	Vitality (VT)	Mental Composite Score (MCS)
9e	Energy		
9g	Worn out		
9i	Tired		
6	Social-Extent	Social Functioning (SF)	
10	Social-Time		
5a	Cut down Time	Role-Emotional (RE)	
5b	Accomplished Less		
5c	Not Careful		
9b	Nervous	Mental Health (MH)	
9c	Down in Dumps		
9d	Peaceful		
9f	Blue/Sad		
9h	Happy		

Table 2. Main demographic and clinical features of patients treated by HFR and BHD

	HFR (N=57)	BHD (N=57)	p
Age (years)	66.3±13.1	66.3±14.3	0.99
Males (%)	54.3	45.7	0.27
Dialysis Vintage (months)	5.4(3.7-9.8)	5.9 (4.2-10.4)	0.44
Barthel Index	100(85-100)	100(80-100)	0.97

Discussion

In this study we report the findings of a cross-sectional analysis, comparing HR-QoL of ESRD patients treated by HFR as compared to those treated by BHD. Main result was that the patients treated by HFR showed higher score of physical component of SF-36 and particularly in the components of physical functioning and daily activities.

It is well recognized that HD *per se* associates with decline of functional status, independent of type of treatment (HD or HDF) [6] (full text). Novel finding of this study is that in ESRD patients matched by age, dialysis vintage and invalidity score, those treated by HFR reported a better ability to exert daily activities. This observation may be effect of the reduction of main uremic complications, such s as inflammation malnutrition and anemia, as previously reported in HFR-treated patients [15] (full text) [16] (full text) [17] [18] [19] [20] [21];

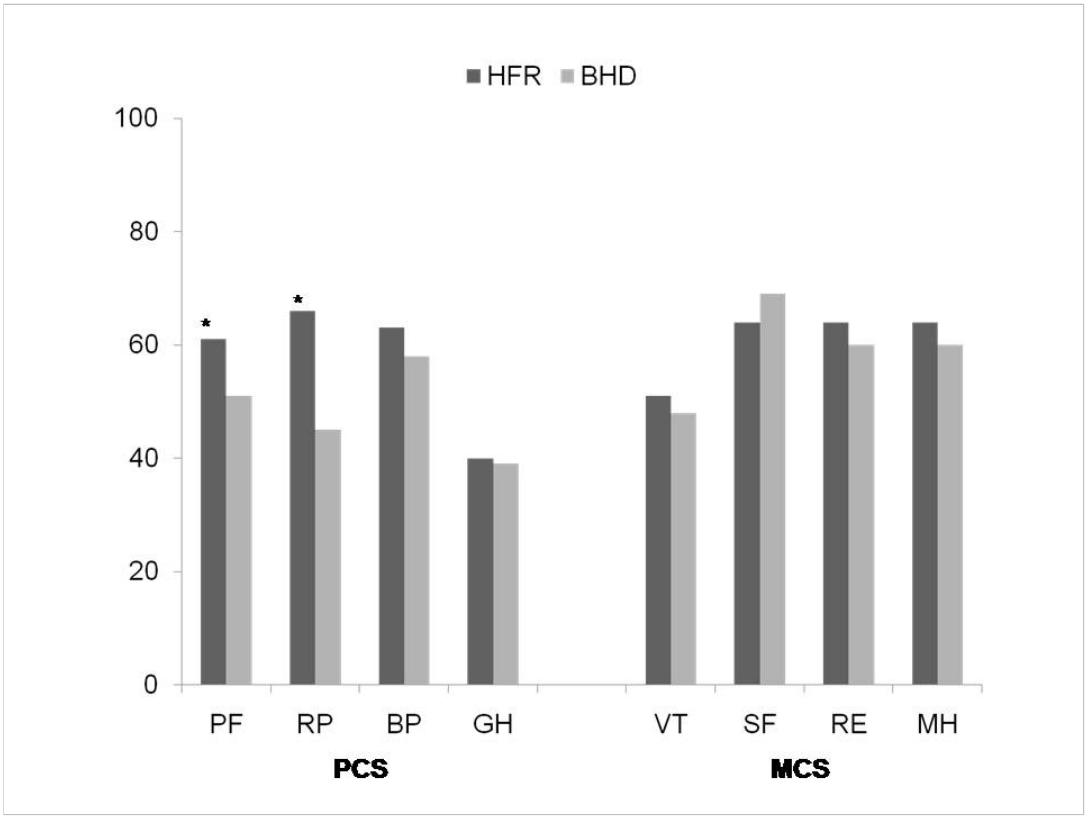

Figure 2.
Differences between HFR (gray) and BHD (light gray) of PCS (side a) and MCS (side b) in each of eight items of SF-36 questionnaire. Abbreviations: PF: Physical functioning; RP Role Physical; BP: Bodily Pain; GH: General Health; VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health; PCS: Physical Composite Score; MCS: Mental Composite Score

however, this association remains matter of speculation because it was not assessed in this cross-sectional analysis.

Early studies have reported an higher score of PCS in HDF versus BHD patients [9] [10] (full text) [11], but these findings were not confirmed in longitudinal studies. Indeed, the CONTRAST study, the longitudinal study evaluating HR-QoL after two years from initiation of dialysis, has not demonstrated an improvement of HR-QoL in HDF versus BHD [14] (full text).The cross-sectional design of our study does not allow to draw any causal conclusion on the observed findings. Therefore longitudinal studies designed ad hoc are needed to understand if these finding may turn into long term benefit on the HR-QoL as on the survival of these patients.

Conclusions

This cross-sectional analysis suggests that HFR is associated with higher score of SF-36 physical component, probably due to an improvement of oxidative stress and inflammatory status. This encouraging findings need to be validated by longitudinal studies in large cohorts.

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